

freedom that Eastern and Central Europe gained in 1989 is permanent. And it will be an unmistakable safeguard against a reversal of democratic trends in Russia.

Poland, Hungary and the Czech Republic should be offered full NATO membership today. Many other nations from Slovenia to the Baltics rightly aspire to this goal. And Ukraine, despite the great pressures of its geography, remains a willing, dedicated, and welcome participant in cooperative activities with NATO. As I said, NATO enlargement is a process that should begin with Poland, Hungary, and the Czech Republic—but it should not end there.

When I am elected President, I will urge NATO to begin accession talks with Poland, Hungary, and the Czech Republic, and to set the goal of welcoming new NATO members at a summit in Prague in 1998—the 60th anniversary of the betrayal of Munich, the 50th anniversary of the communist takeover of Czechoslovakia, and the 30th anniversary of the Soviet invasion. There could be no more appropriate year or appropriate place to declare that Central Europe has become a permanent part of the Atlantic community.

I will actively promote cooperative efforts in NATO to develop and deploy Europe-wide missile defenses to protect against missile attack by rogue states poised on NATO's southern flank.

I will support the integration of Central and Eastern European militaries into the NATO defense structure, using the Defense Export Loan Guarantee program—ignored by President Clinton.

I fully recognize the importance of friendly relations with Russia. Lest we forget, in 1993 during a summit in Warsaw, President Boris Yeltsin and then-President Lech Walesa issued a joint declaration affirming that Poland's desire to join NATO did "not run counter to the interests of any state, including Russia." But, as Bill Clinton dragged his feet, extremist elements in Russia began to set the agenda in Moscow again. We should not be surprised that hesitation and vacillation fueled those who thought threats would deter us.

As President, I will not grant Russia a veto over NATO enlargement but I will offer Russia serious dialogue on long term relations with NATO. NATO is a defensive organization by its very nature, and its interests collide with Russia only where Russia intrudes upon sovereign nations. A non-expansionist Russia is not threatened by an enlarged NATO.

The hope of the world still rests, as it has throughout this century, on American leadership. There is no escaping the fact that only America can lead—others cannot, or will not, or should not. How firmly we grasp the remarkable opportunities before us in Europe will determine whether the next century repeats the violence and tragedy of the last or opens up a new era of peace, freedom, and security.

The promise of the future has never been greater. With strong, decisive American leadership, we can make that promise a reality for ourselves and the generations to come.

Thank you and God bless America.

Mr. COHEN. Mr. President, we need to make it clear, that we will not ignore continued Russian violations of biological, chemical and conventional arms control agreements.

In contrast to an approach based on romanticism, Senator Dole outlined:

An approach based on realism and a clear understanding of American interests.

A strategy that will reinforce the independence of the states of the former Soviet Union, that will support the new democracies of Europe, and

that will strengthen NATO and lead to its enlargement.

A policy that will deal with Russia as it exists today, so that we can effectively use what leverage we have to encourage Russia to become the country we hope it will be—free, prosperous, respectful of and cooperative with its neighbors.

But not a policy that is based on the illusion that Russia already has reached this stage of development.

Mr. President, there are many important elements to Senator Dole's speech, and I urge all Senators to take the time to read it.

Mr. President, I now yield my remaining 4 minutes to the Senator from Arizona.

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

Mr. MCCAIN. Mr. President, I want to join my friend and colleague from Maine in congratulating Senator Dole on his second very important foreign policy/national security speech, this time concerning our relations with Europe. I believe that he is establishing a conceptual framework with a clear vision and clear idea as to what we want the world to look like in the next century and a clearer definition of those threats as they are today and as we envision them in the future.

Although the speech was about Europe, I think it is important, although tragic, to note that an act of terror was committed just about the same time this speech was given, which is a compelling statement as to how fragile democracy is throughout the world and how easily acts of terror can be committed which take the lives of American citizens.

Mr. President, one of the major parts of the Dole speech given in Philadelphia was the subject of NATO. In it he says:

We must understand the linchpin of U.S. and European security is NATO. But as the world has changed, so, too, must NATO change. As former Prime Minister Margaret Thatcher recently said, "Our energies must be directed towards strengthening NATO, which is as important in the post-Cold War world as in the circumstances of its creation." And while our allies can and should take a greater share of the burden, we should not nurture the illusion that this is a substitute for American leadership.

American leadership is what the Dole speech was all about, Mr. President, American leadership in a world that is fraught with danger, that has become much less dangerous, but a much less predictable one. This speech that is articulated by Senator Dole is a clear vision and a clear call and challenge to the American people to again recognize that we cannot discard the mantle of leadership which was handed down to us early in this century.

Finally, Mr. President, Senator Dole said—I think it is worth repeating—

The hope of the world still rests, as it has throughout this century, on American leadership. There is no escaping the fact that only America can lead—others cannot, or will not, or should not. How firmly we grasp the remarkable opportunities before us in Europe will determine whether the next century repeats the violence and tragedy of the

last or opens up a new era of peace, freedom, and security.

Mr. President, I want to again congratulate Senator DOLE on an outstanding speech. I commend it to all of my colleagues and the American people. I yield the floor.

NATIONAL DEFENSE AUTHORIZATION ACT FOR FISCAL YEAR 1997

The Senate continued with consideration of the bill.

The PRESIDING OFFICER. The Senator from Arkansas is recognized.

AMENDMENT NO. 4365

(Purpose: To provide equitable relief for the generic drug industry)

Mr. PRYOR. Mr. President, I thank the Chair for recognizing me. For the benefit of our colleagues, Mr. President, let me state what has gone on today and what I think will go on for the next hour to hour and a half.

Mr. President, first, I am going to be sending an amendment to the desk in the first degree. Immediately following that introduction, the Senator from Utah will offer his amendment in the second degree to my first-degree amendment. We will debate these issues and vote on the Hatch amendment some 45 minutes later. After that vote, it will be very possible that I will offer the same amendment as my amendment in the first degree, which we will debate for 45 minutes and then vote.

I know this is somewhat of a Byzantine situation, Mr. President, but I have been attempting since December 7 to have an up-or-down vote in this Chamber on my amendment. It appears I am not going to get a clear up-or-down vote, but this is as near as possible.

Mr. President, with that explanation, hoping our colleagues understand the nature of this issue and the procedure that we will be following, I send my amendment in the first degree to the desk and ask for its immediate consideration.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Arkansas [Mr. PRYOR], for himself, Mr. CHAFEE, Mr. BROWN, Mr. BRYAN, Mr. DORGAN, Mr. LEAHY, and Mr. BYRD, proposes an amendment numbered 4365.

Mr. PRYOR. Mr. President, I ask unanimous consent that reading of the amendment be dispensed with.

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

The amendment is as follows:

At the end of subtitle F of title X add the following:

SEC. 1072. EQUITABLE TREATMENT FOR THE GENERIC DRUG INDUSTRY.

(a) SENSE OF THE SENATE.—It is the sense of the Senate that the generic drug industry should be provided equitable relief in the same manner as other industries are provided with such relief under the patent transitional provisions of section 154(c) of title

35, United States Code, as amended by section 532 of the Uruguay Round Agreements Act of 1994 (Public Law 103-465; 108 Stat. 4983).

(b) APPROVAL OF APPLICATIONS OF GENERIC DRUGS.—For purposes of acceptance and consideration by the Secretary of Health and Human Services of an application under subsections (b), (c), and (j) of section 505, and subsections (b), (c), and (n) of section 512, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (b), (c), and (j), and 360b (b), (c), and (n)), the expiration date of a patent that is the subject of a certification under section 505(b)(2)(A) (ii), (iii), or (iv), section 505(j)(2)(A)(vii) (II), (III), or (IV), or section 512(n)(1)(H) (ii), (iii), or (iv) of such Act, respectively, made in an application submitted prior to June 8, 1995, or in an application submitted on or after that date in which the applicant certifies that substantial investment was made prior to June 8, 1995, shall be deemed to be the date on which such patent would have expired under the law in effect on the day preceding December 8, 1994.

(c) MARKETING GENERIC DRUGS.—The remedies of section 271(e)(4) of title 35, United States Code, shall not apply to acts—

(1) that were commenced, or for which a substantial investment was made, prior to June 8, 1995; and

(2) that became infringing by reason of section 154(c)(1) of such title, as amended by section 532 of the Uruguay Round Agreements Act (Public Law 103-465; 108 Stat. 4983).

(d) EQUITABLE REMUNERATION.—For acts described in subsection (c), equitable remuneration of the type described in section 154(c)(3) of title 35, United States Code, as amended by section 532 of the Uruguay Round Agreements Act (Public Law 103-465; 108 Stat. 4983) shall be awarded to a patentee only if there has been—

(1) the commercial manufacture, use, offer to sell, or sale, within the United States of an approved drug that is the subject of an application described in subsection (b); or

(2) the importation by the applicant into the United States of an approved drug or of active ingredient used in an approved drug that is the subject of an application described in subsection (b).

(e) APPLICABILITY.—The provisions of this section shall govern—

(1) the approval or the effective date of approval of applications under section 505(b)(2), 505(j), 507, or 512(n), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (b)(2) and (j), 357, and 360b(n)) submitted on or after the date of enactment of this Act; and

(2) the approval or effective date of approval of all pending applications that have not received final approval as of the date of enactment of this Act.

Mr. PRYOR. Mr. President, it gives me great pleasure to announce I am submitting this amendment on behalf of myself and Senator CHAFEE, Senator BROWN, Senator BYRD, Senator DORGAN, Senator LEAHY, and Senator BRYAN.

With that, Mr. President, I see my friend from Utah is seeking recognition.

The PRESIDING OFFICER. The Senator from Utah.

Amendment No. 4366 to Amendment No. 4365 (Purpose: To provide equitable relief for the generic drug industry, and for other purposes)

Mr. HATCH. Mr. President, I send an amendment to the desk.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Utah [Mr. HATCH] proposes an amendment numbered 4366 to amendment No. 4365.

Mr. HATCH. Mr. President, I ask unanimous consent that reading of the amendment be dispensed with.

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

The amendment is as follows:

Strike all after the word "Sec." and insert the following:

SEC. ____ PHARMACEUTICAL INDUSTRY SPECIAL EQUITY.

(a) SHORT TITLE.—This section may be cited as the "Pharmaceutical Industry Special Equity Act of 1996".

(b) APPROVAL OF GENERIC DRUGS.—

(1) IN GENERAL.—With respect to any patent, the term of which is modified under section 154(c)(1) of title 35, United States Code, as amended by the Uruguay Round Agreements Act (Public Law 103-465; 108 Stat. 4983), the remedies of section 271(e)(4) of title 35, United States Code, shall not apply if—

(A) such patent is the subject of a certification described under—

(i) section 505 (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV)); or

(ii) section 512(n)(1)(H)(iv) of such Act (21 U.S.C. 360b(n)(1)(H)(iv));

(B) on or after the date of enactment of this section, such a certification is made in an application that was filed under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act and accepted for filing by the Food and Drug Administration prior to June 8, 1995; and

(C) a final order, from which no appeal is pending or may be made, has been entered in an action brought under chapter 28 or 29 of title 35, United States Code—

(i) finding that the person who submitted such certification made a substantial investment of the type described under section 154(c)(2) of title 35, United States Code, as amended by the Uruguay Round Agreements Act; and

(ii) establishing the amount of equitable remuneration of the type described under section 154(c)(3) of title 35, United States Code, as amended by the Uruguay Round Agreements Act, that is required to be paid by the person who submitted such certification to the patentee for the product that is the subject of the certification.

(2) DETERMINATION OF SUBSTANTIAL INVESTMENT.—In determining whether a substantial investment has been made in accordance with this section, the court shall find that—

(A) a complete application submitted under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act was found by the Secretary of Health and Human Services on or before June 8, 1995 to be sufficiently complete to permit substantive review; and

(B) the total sum of the investment made by the person submitting such an application—

(i) is specifically related to the research, development, manufacture, sale, marketing, or other activities undertaken in connection with, the product covered by such an application; and

(ii) does not solely consist of that person's expenditures related to the development and submission of the information contained in such an application.

(3) EFFECTIVE DATE OF APPROVAL OF APPLICATION.—In no event shall the Food and Drug Administration make the approval of an application under sections 505 or 512 of the Federal Food, Drug, and Cosmetic Act, which is subject to the provisions of this section, ef-

fective prior to the entry of the order described in paragraph (1)(C).

(4) APPLICABILITY.—The provisions of this subsection shall not apply to any patent the term of which, inclusive of any restoration period provided under section 156 of title 35, United States Code, would have expired on or after June 8, 1998, under the law in effect on the date before December 8, 1994.

(c) APPLICATION OF CERTAIN BENEFITS AND TERM EXTENSIONS TO ALL PATENTS IN FORCE ON A CERTAIN DATE.—For the purposes of this section and the provisions of title 35, United States Code, all patents in force on June 8, 1995, including those in force by reason of section 156 of title 35, United States Code, are entitled to the full benefit of the Uruguay Round Agreements Act of 1994 and any extension granted before such date under section 156 of title 35, United States Code.

(d) EXTENSION OF PATENTS RELATING TO NONSTEROIDAL ANTI-INFLAMMATORY DRUGS.—

(1) IN GENERAL.—Notwithstanding section 154 of title 35, United States Code, the term of patent shall be extended for any patent which encompasses within its scope of composition of matter known as a nonsteroidal anti-inflammatory drug if—

(A) during the regulatory review of the drug by the Food and Drug Administration the patentee—

(i) filed a new drug application in 1982 under section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355); and

(ii) awaited approval by the Food and Drug Administration for at least 96 months; and

(B) such new drug application was approved in 1991.

(2) TERM.—The term of any patent described in paragraph (1) shall be extended from its current expiration date for a period of 2 years.

(3) NOTIFICATION.—No later than 90 days after the date of enactment of this section, the patentee of any patent described in paragraph (1) shall notify the Commissioner of Patents and Trademarks of the number of any patent extended under such paragraph. On receipt of such notice, the Commissioner shall confirm such extension by placing a notice thereof in the official file of such patent and publishing an appropriate notice of such extension in the Official Gazette of the Patent and Trademark Office.

(e) EXPEDITED PROCEDURES FOR CIVIL ACTIONS.—

(1) APPLICATION.—(A) This subsection applies to any civil action in a court of the United States brought to determine the rights of the parties under this section, including any determination made under subsection (b).

(B) For purposes of this subsection the term "civil action" refers to a civil action described under subparagraph (A).

(2) SUPERSEDING PROVISIONS.—Procedures adopted under this subsection shall supersede any provision of title 28, United States Code, the Federal Rules of Civil Procedure, or the Federal Rules of Appellate Procedure to the extent of any inconsistency.

(3) PROCEDURES IN DISTRICT COURT.—No later than 60 days after the date of the enactment of this Act, each district court of the United States shall adopt procedures to—

(A) provide for priority in consideration of civil actions on an expedited basis, including consideration of determinations relating to substantial investment, equitable remuneration, and equitable compensation;

(B) provide that—

(i) no later than 10 days after a party files an answer to a complaint filed in a civil action the court shall order that all discovery (including a hearing on any discovery motions) shall be completed no later than 60 days after the date on which the court enters the order; and

(ii) the court may grant a single extension of the 60-day period referred to under clause (i) for an additional period of no more than 30 days upon a showing of good cause;

(C) require any dispositive motion in a civil action to be filed no later than 30 days after completion of discovery;

(D) require that—

(i) if a dispositive motion is filed in a civil action, the court shall rule on such a motion no later than 30 days after the date on which the motion is filed;

(ii) the court shall begin the trial of a civil action no later than 60 days after the later of—

(I) the date on which discovery is completed in accordance with subparagraph (B); or

(II) the last day of the 30-day period referred to under clause (i), if a dispositive motion is filed;

(E) require that if a person does not hold the patent which is the subject of a civil action and is the prevailing party in the civil action, the court shall order the nonprevailing party to pay damages to the prevailing party;

(F) the damages payable to such persons shall include—

(i) the costs resulting from the delay caused by the civil action; and

(ii) lost profits from such delay; and

(G) provide that the prevailing party in a civil action shall be entitled to recover reasonable attorney's fees and court costs.

(4) PROCEDURES IN FEDERAL CIRCUIT COURT.—No later than 60 days after the date of the enactment of this Act, the United States Court of Appeals for the Federal Circuit shall adopt procedures to provide for expedited considerations of civil actions brought under this Act.

Mr. PRYOR. Mr. President, I will speak only for a very few moments and then I will yield time to my friend from Rhode Island, Senator CHAFEE, and those others who want to enter into this debate.

I had lunch with my interns a few moments ago, Mr. President. One of the young men at the table said, "What is all of this GATT-Glaxo debate all about?" It is very hard to explain, and sometimes it is arcane. Mr. President, the bottom line was stated by our colleague from Illinois recently as eloquently as I know how to frame this debate. I quote Senator PAUL SIMON: "This is a classic case of the public interest versus the special interest." This is indeed a classic case of the public interest versus the special interest.

That is exactly what the issue is today on the floor. Let me anticipate, Mr. President, if I might, and I hope I am not being presumptuous, as to what is going to happen and what the arguments of the Senator from Utah might be.

First, Mr. President, the Pryor-Brown-Chafee amendment closes a loophole that every expert in this field, from our Patent Office and the Food and Drug Administration to our U.S. Trade Representative, says should be closed.

We are also seeking to have the prescription drug industry play by the very same rules as every other industry in our country.

The third thing our amendment does, Mr. President, is guarantee that Amer-

ican consumers have access to affordable generic drugs as was intended by the GATT treaty. We are simply saying that affordable generic drugs should be able to come to the marketplace without the obstacles presented by Senator HATCH will not be allowed.

The fourth thing we do, Mr. President, is not affect medical research in any way. It is not an issue, although we will debate that point later. Nor does our amendment affect intellectual property rights in any way. That has been absolutely nailed down in concrete. Since our amendment is consistent with the GATT agreement, that is a moot argument and is simply a scare tactic.

Finally, Mr. President, our amendment guarantees that the financial windfall created by our mistake in the GATT agreement does not go to the drug companies. Instead, it goes to the consumers, it goes to the elderly, it goes to the veterans, and it goes to those who are vulnerable and in need of assistance in buying life-sustaining pharmaceuticals. Today, in the absence of our amendment, you will find that these companies are gaining a multi-billion dollar windfall as a result of our error.

Let me briefly state what the so-called Hatch substitute does. It codifies and puts our original mistake into law. It guarantees that the American consumer never gets the affordable, generic drugs intended under the GATT agreement.

Here is the so-called Rube Goldberg chart, Mr. President, showing what the Hatch substitute actually does. This chart shows how the Hatch substitute guarantees that generic competition is locked out and leaves it up to the consumer to continue paying for the multibillion dollar windfall to a few drug companies as a result of a congressional mistake.

Let me emphasize that affordable generic drugs will be something that will not be within the grasp of our American consumer should the Hatch provision prevail. The Hatch substitute guarantees Glaxo and a few other drug companies that they get the entire \$2.5 billion windfall. It is an enormous Christmas gift, Mr. President, that we have no business doling out as a special favor to undeserving companies.

Finally, Mr. President, the Hatch substitute would also grant a 2-year patent extension for a drug called Lodine, manufactured in the State of Pennsylvania by Wyeth-Ayerst, a division of one of the major pharmaceutical companies in the country, American Home Products. This patent extension was added by the Judiciary Committee, Mr. President.

In addition, the Hatch substitute creates the Christmas tree of other gifts like additional patent protection to brand name companies like Zeneca and Merck. These provisions were, once again, added by the Judiciary Committee. Mr. President, this is what I think is going to be occurring during

the next several minutes. I am wondering now if my colleague from Utah would like to respond, or if my colleague from Rhode Island would like

Mr. CHAFEE addressed the Chair.

The PRESIDING OFFICER. The Senator from Rhode Island.

Mr. CHAFEE. Mr. President, first of all, I want to congratulate Senator PRYOR, the Senator from Arkansas, for his tenacity in connection with this really outrageous situation that exists as a result of a mistake that was made and the failure of the Congress to correct that mistake. Senator PRYOR, recognizing the cost that this is incurring upon the U.S. Government, our State governments, and upon our citizens—especially our citizens—has, with tremendous tenacity, tried to correct it. I think Senator PRYOR deserves all of our thanks for this.

Now, what are we doing here? What we are trying to do today, Mr. President, is to correct an inadvertent error made in the 1994 GATT, General Agreement on Tariffs and Trade, that we passed. This error, as I say, is costing consumers and our Government, not just thousands of dollars, but millions of extra dollars, and is giving an unintended windfall to the drug companies. It is well past time for the Senate to act. I do hope that the PRYOR amendment will be adopted.

Now, what is this amendment that we are working on this afternoon? It is very simple. As I say, it corrects an inadvertent error. It is a mistake that was made that kept qualified generic drugs from going to market. What is a generic? It is something anybody can manufacture. It keeps these generic drug manufacturers from going to market, as they plan to do when the patent expired on these drugs, particularly those that are manufactured, in certain instances, by Glaxo. Now, the result has been that a handful of brand name drug companies have received a staggering—and, as I say, this is not thousands, this is really billions—\$4.3 billion windfall at the expense of consumers, and neither the Congress nor U.S. trade officials, nor even the companies themselves, expected this to occur.

Now, the cost to consumers, as I mentioned, is enormous. The drugs covered by the windfall are widely prescribed. They are used for everyday ailments that affect millions of Americans, particularly the elderly. Keeping the generic version of these drugs off the shelf for up to three additional years means that Americans—especially older Americans—are paying far more than was ever intended for these medications.

Not only are consumers paying for this error, but so are the governments—State governments and the Federal Government—in the form of higher reimbursement for prescription drugs. The military, likewise, is paying, because the military, as we all know, pays not only for drugs for the active duty personnel, but for retirees, as well.

Now, we in Congress made a mistake. We all recognize that, and we ought to fix it. In this case, the solution is obvious: Enact the conforming amendment presented by Senators PRYOR, BROWN, myself, and others, who have been working likewise.

Enacting the conforming amendment has a positive side effect, an important one for our States. Back in December, we had a vote on this, and because of parliamentary maneuvering, we were told repeatedly that it was important to have a hearing on this. Ultimately, we lost by one vote. This was going to go to a hearing. Since that vote last December, what has happened? Well, finally a hearing took place, 3 months later, at the end of February. What did we find out at the hearing? Well, we found out exactly what we have been saying all along. There were no new discoveries at this hearing. The USTR, U.S. Trade Representative, at the time GATT was enacted, Mr. Kantor, testified: "We did not intend for this to happen, and we support the correction of this oversight through the appropriate amendment to the Food, Drug and Cosmetic Act, and the Patent Act."

That is what Mickey Kantor, our U.S. Trade Representative, said.

Three months went by, and then two more months went by, a markup being continuously postponed. We finally saw our bill be marked up in the committee. What the result was, was a bill that did not correct the loophole at all. Senator PRYOR has touched on that already. I thought it was very interesting. This is, as he showed on his chart—and perhaps the Senator could go back to that original chart that shows this Rube Goldberg setup—how the generic drug companies could straighten out the situation. Well, it is ridiculous. I must say, I praise the ingenuity of those who worked out this intricate process.

So the situation has become ludicrous. Unfortunately, it has been more than a year since the FDA first ruled that it did not have the power to permit these generics to go to market. A year ago, we found out there was a problem. Instead of fixing it right away, we have been stymied time and time again by procedural motions and talk of hearings. We all know the time is running out.

So, Mr. President, I want to conclude by reading a couple of quotes from newspapers who have commented on this.

This is what the New York Times had to say:

Congress finds it hard to remedy the simplest mistakes when powerful corporate interests are at stake.

The Washington Post said:

It is doubly difficult to understand why the Senate refuses to do anything about a windfall that, as far as the administration is concerned, is based on nothing more than an error of omission.

We made an error and ought to correct it.

The Des Moines Register said:

Unless the Senate gives the issue another look, hundreds of Iowans suffering from ulcers and heartburn will each have to fork over about \$1,600 more than necessary for their prescriptions over the next 18 months.

The NBC Nightly News said:

This is one area where Congress could help save millions of taxpayers dollars now.

So, Mr. President, it is my hope that we will prove to our constituents that there is not business as usual around here, that we can and we will correct a mistake that was made and do the right thing and fix this loophole now.

I urge my colleagues to vote against the Hatch amendment and for the Pryor-Chafee amendment, the only bill that will close the loophole. I thank the Chair.

Mr. SPECTER addressed the Chair.

The PRESIDING OFFICER. The Senator from Pennsylvania is recognized.

Mr. SPECTER. Mr. President, I believe that the problems presented in the pending amendment could be solved if the parties would get together and agree to a procedure which would provide for prompt judicial determination as to what is a substantial investment.

I agree with my distinguished colleague from Rhode Island that this matter ought to be cured and acted upon, because the more time that passes, the greater the potential damages on one side or another, depending upon whether there has been a substantial investment. That is the issue which is outstanding, and it is my view that the generic manufacturer should be compelled to show that it has complied with the provisions of law and that it has, in fact, made a substantial investment before it can enter the marketplace.

With all due respect, I do not believe that this is a matter for editorial comment, or for generalization. Instead, it requires a hard look at the facts and a careful analysis of the law. What we are dealing with here is public policy to encourage pharmaceutical companies to make very substantial investments to produce pharmaceutical products. The other public policy consideration is to make available generic products for the benefit of many parties, once the patent has had a reasonable life term.

Those who benefit from generics are many. They are the senior citizens. They are the veterans. They are the Government. Many interested parties ought to have access to generic products.

The critical key issue is whether the generic company has made a substantial investment or not, and it is my view that that has to be judicially determined.

We had a very extended discussion on the Record back on June 20, just 8 days ago. It is summarized really as follows: I offered a procedure, first in the Judiciary Committee and now incorporated into the amendment offered by the Senator from Utah, which would provide for expedited proceedings which could be completed within 70 days.

What is really happening when the Senator from Arkansas is offering this amendment is that nothing is going to happen for a lot longer than 70 days. This matter has been pending for months. If the parties had agreed to expedited judicial proceedings, which the Hatch amendment is prepared to accept, if Senator PRYOR would accept that, we could have a determination of any generic company which had made a substantial investment within a relatively short period of time. That generic company could then begin to market its product.

I do not believe this matter ought to be left undefined. I think really we ought to have a definition of what is a "substantial investment." We hear a great deal of talk about the undesirability of judicial legislation; that we ought to have Congress act on these matters.

My staff and I made a very concerted and extended effort to try to define "substantial investment" and "equitable remuneration," sitting down with parties on both sides at some substantial length.

I continue to believe that, if the parties really wanted to resolve this and have a determination as to which generics had made a "substantial investment" so that those generic products would be made available to the public at large, that could be done instead of this extended debate.

But in the absence of that kind of an agreement, it seems to me that what is fair is to have the generic with its burden of proof of showing that a substantial investment had been made. And, with the additions I have made to the pending amendment offered by the Senator from Utah, we would have those proceedings concluded within a few short months. If the Senator from Arkansas was willing to adopt that kind of a procedure, he could have set the judicial mechanism in place long ago so that we could have had a determination of this matter.

Mr. President, I reserve the remainder of my time.

Mr. PRYOR. Mr. President, I thought that Senator HATCH would be speaking now. I think he has stepped out of the Chamber. Therefore, I will make a few remarks in response to my friend from Pennsylvania.

First, we are not changing the GATT language. We are keeping the GATT language as it relates to the term "substantial investment." This is simply what we are trying to do with the Pryor-Brown-Chafee substitute amendment at this time. We are trying to basically reinforce what we already have built into the GATT treaty, adopt that language, and apply to the drug companies the exact same rules and definitional standards that we apply to every other industry in our country and in our world today who are signatories to the GATT.

I want to make a couple of more points. The Senator from Pennsylvania has mentioned that we needed 70 days

in order to resolve all of this. What the Senator from Pennsylvania must be aware of, and what the Senator from Arkansas is aware of, is that every day that goes by these companies are getting, in my opinion, egregious windfalls totaling \$5 million extra every day that we estimate could be used to purchase cheaper or less expensive generic drugs.

What this is about, Mr. President, really is about a few drug companies. For example, here is Zantac. If we had a generic substitute today for Zantac, we would be paying about 40 percent or 50 percent less than we are paying with the brand name Zantac today in our drugstores.

Mr. President, this is an absurd situation. It is time for us to correct this. We hope that the Senate will avail itself of this opportunity.

Mr. President, inadvertently a few moments ago when I sent the amendment to the desk I did not mention our original cosponsor from Vermont, Senator LEAHY.

I ask unanimous consent that his name be added as an original cosponsor.

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

Mr. SPECTER. Mr. President, how much time do I have remaining?

The PRESIDING OFFICER. Five minutes.

Mr. SPECTER. Mr. President, I inadvertently referred to a judicial time line of 70 days. I really meant 7 months.

My point is this. This controversy first arose on May 25, 1995. Had we had in effect a procedure, which I am suggesting, for a maximum 7-month determination regarding companies that the Senator from Arkansas refers to, we could have had a judicial determination made on or about January 1, 1996. It could have already been made.

This legislation is really not the best way to solve the problem. There is a question as to what will happen in conference on this Department of Defense authorization bill, and whether the amendment will be adopted in the first place. There is also a question of whether the President will veto this Department of Defense authorization bill because it has substantially more spending than he is prepared to accept. But, if the parties agree to a procedure where there was expedited judicial determination as to what is a substantial investment, we could have generic products on the market within 7 months.

If my colleague from Arkansas would engage in a brief discussion—it has to be brief because I do not have too much time left—what would the problem be with the generic companies that the Senator from Arkansas refers to to accept the procedure where there would be a court determination made within 7 months as to whether they had made a substantial investment. Then, if the court finds in their favor, they could sell the generic drug plus recover full

damages for the period from the time that they could not sell the generic drug until the time the court determined there was substantial investment and they could sell the generic drug?

Mr. PRYOR. Are we on the Senator's time?

Mr. SPECTER. We are.

Mr. PRYOR. I ask that the time be allocated to the Senator, if I might respectfully say so.

I have a letter from Donna Shalala, the Secretary of HHS, and I quote from the letter that has been distributed throughout the Senate this afternoon.

Secretary Shalala says:

It will be nearly impossible to meet the substantial investment requirement under the Hatch substitute.

She concludes saying:

It would be virtually impossible for a manufacturer to obtain FDA approval for a generic drug product during this transition period.

Mr. SPECTER. If the Senator from Arkansas will also focus, in the very limited time, just on the issue of substantial investment. What Secretary Shalala had to say, with all due respect, is totally irrelevant. I have a very crisp question. If your generic company has to have a determination of substantial investment within 7 months, would that not be a lot better than this elongated, uncertain legislative process?

Mr. PRYOR. Mr. President, I simply respond by saying the generic companies cannot get the market because they cannot meet the requirements and the obstacles set forth in the Hatch substitute. It is that simple.

Mr. SPECTER. Mr. President, I want to reclaim my time. I want to conclude my argument in the very brief time that I have left.

With all due respect for my very distinguished colleague from Arkansas—and I do agree with Senator CHAFEE in complimenting Senator PRYOR for his tenacity here—this is a matter which requires a determination of what is a substantial investment. This matter has been pending now for more than a year—since May 25, 1995. If the parties really wanted to resolve this, we could come to terms on expedited judicial proceedings which Senator HATCH is prepared to accept. That would take, of course, a maximum of 7 months. Then the generic company would have a determination of substantial investment, and they would be in the field. In addition, they would be entitled to collect their damages in the interim.

I believe, as a matter of fairness, that we ought to get the judicial determinations as promptly as possible. But we also need to have fair protection for the substantial investments made by the pharmaceutical pioneer companies. This expedited procedure would ensure justice for all parties, and I submit that we ought to proceed forward with it.

I yield the floor.

Mr. PRYOR. Mr. President, I will respond by saying that this expedited

procedure and the substantial investment, is basically what the GATT Treaty calls for and lays out the rules for every other industry in the world today with the exception of the pharmaceutical industry.

We left out, by mistake, a conforming amendment that would guarantee the application of the GATT Treaty to brand name drug companies and as a result a few companies are protected against any generic competition.

Now, who pays the bill for that? Who pays the ante? Well, we know who pays. The consumer pays—the elderly pay, the veterans pay, the Medicaid Program pays, the government pays. But across the board these windfall profit dollars are going to the major drug companies, and we are asking today for the Senate to support less expensive drugs. We are begging today for competition in the pharmaceutical marketplace.

Just recently—and I ask that this item be placed in the RECORD at the appropriate place—Glaxo cut the cost of Zantac to the German people by 30 percent. The concern they were responding to was that a generic was about to become available and be a competitor to Zantac in that country—a 30-percent decrease in the cost of that drug. I wish they would give us the same cost decrease in this country.

But what the Senator from Pennsylvania is talking about—simply wait another 7 months for these drugs to be available in generic form—is another \$1 billion in consumer losses and another \$1 billion windfall profits for three companies in this country.

Mr. President, I do not think the Senate supports extension of this type of benefit to a few drug companies.

I see my friend from Utah. I would like to ask how much time I have remaining, please.

The PRESIDING OFFICER. The Senator has 1 minute 20 seconds.

Mr. PRYOR. Mr. President, I will reserve the remainder of my time.

Mr. HATCH addressed the Chair.

The PRESIDING OFFICER. The Senator from Utah.

Mr. HATCH. Mr. President, I would feel much more confident in the distinguished Senator from Arkansas's comments if he were willing to turn back all of the GATT blessings that Arkansas received. I have a list here which gives some of the examples of extensions made under GATT and the number of days.

Here are 25 Arkansas companies which received extensions, one of which had its patent extended as by 713 days, another by 667 days, another by 665. The Jacuzzi Brothers had a patent extended by 218 days.

None of their competitors has come to us and complained that they are being cheated.

I might ask why we aren't suggesting that all those companies give back the extensions they received? Because there were winners and losers in the GATT. Unfortunately, the distinguished Senator from Arkansas does

not happen to agree with some of the winners.

Mr. President, what you have heard this afternoon from our colleague, Senator PRYOR, admittedly is a compelling populist argument that will have a great deal of surface appeal to some people.

Who among us would not want to lower the price of drugs used by the elderly?

Who would not want to correct a mistake?

Who would not want to level the playing field to promote fairness between two very important segments of a very important industry?

Unfortunately, none of these arguments are accurate. All of them are built on a foundation of sand.

With one strong wave of reality this dream castle will come crashing down and we will be left with the truth of the matter.

The truth is that:

There is no loophole;

There is no technical error; and

And there is no need for the overreaching Pryor/Brown/Chafee amendment.

Let me give you the facts.

It should be no secret to anyone in this body that GATT extended the terms of patents. The GATT Treaty—a very important treaty that took decades to get—was debated extensively in open session. It was negotiated for a period of years, extending through three Presidential Administrations. It was one of the most talked-about pieces of legislation we have considered.

As a consequence of the GATT, the terms of about 1 million patents were extended. I just mentioned 25 of those were in Arkansas. They came from virtually every type of industry in the United States, including pioneer pharmaceutical patents.

From this debate, you would think that only pharmaceutical patents were extended, but that is far from true.

In truth, only about 100 pharmaceutical patents were extended—100 out of 1 million—100 patents out of 1 million.

Today you will hear the argument that this issue is a simple case of Congress making an oversight in a piece of complex legislation. Again, that is not correct.

In fact, the Food and Drug Administration has said as much. In black and white.

Last May, the FDA's Deputy Commissioner for Policy said:

(T)his apparently is not an example of Congress having overlooked a statutory provision it might have changed had it been aware of its existence . . .

So, it is clear that both the executive and legislative branches acknowledge this was not an oversight, even though we hear that over and over again.

But, if the FDA statement were not enough of an argument for you, consider that the courts have also reviewed this issue and have concurred

that there is no evidence that this was an oversight.

The Court of Appeals for the Federal Circuit noted last November in the Royce case that it could not find any definitive evidence on the question of intent.

The court said:

The parties have not pointed to, and we have not discovered, any legislative history on the intent of Congress, at the time of passage of the URAA, regarding the interplay between the URAA and the Hatch-Waxman Act.

By the way, I coauthored the Hatch-Waxman Act, and I do understand it.

When Senator PRYOR's glitzy, diversionary charts are put aside, it seems to me that my opponents must concede that they have no hard evidence that this is simply a case of legislative mistake. It is not. And by the way, those charts, as much as they are curly-cued to death are misleading. Every generic patentee must go through the process on that chart, under the URAA. It is not just a process set up for generic drugs.

Do not let their attempts at a revisionist history fool you. As the Federal circuit correctly noted, the true test of legislative history is what was stated when the bill passed, not what some are trying to say now, after the fact.

You will also hear today that the Congress should adopt the Pryor amendment so that generic drug manufacturers have the same protections afforded to every other generic product manufacturer under the transition rules.

This is the so-called level-the-playing-field argument.

The truth of the matter is that there are no reported cases of any generic manufacturer, including those 25 in Arkansas, for any other industry reaching—or for that matter even seeking to reach—the marketplace through these transition rules.

It is important for all involved in this debate to understand that under these transition rules, generic drugs have not been treated differently than any other generic products.

Not one individual in this body can point to any other industry except generic drugs which has used, or even attempted to use the transition rules. In other words, out of the 1 million patents extended, not one other industry, or for that matter not one person from one other industry, has attempted to use the transition rules.

The playing field is level.

In fact, the generic drug industry is actually trying to tilt the playing field in its favor.

It may surprise some in this body to see what the generic drug industry has been arguing in court.

Let me just read to you for a few moments from a transcript of the oral argument at the Federal circuit last October in the Royce case:

Milton Bass, a lawyer for the generic drug industry, said:

I suggest to this court that this statute in one respect is written expressly for generic

drugs and in the other respect primarily for generic drugs.

Judge Bryson:

You think the URAA was written expressly for generic drugs?

Mr. Bass:

Absolutely, and I'll tell you why . . . I can't think of a single act that was not infringing before June 8 that became infringing after June 8 except for the generic drug industry. . .

With other patents, a company is limited in what they can spend their money for to invest before the patent expires. Because if they use the patent, that's an act of infringement.

So we have the generic drug industry lawyer actually arguing that the transition rule was specifically intended for just this one industry.

That hardly sounds like a level playing field argument to me. That sounds to me like an argument for special treatment.

And this apparently was not just one of those statements that inadvertently slip out during the pressure of the moment in oral argument.

The same argument was repeated by the generic company's lawyer in his petition for writ of certiorari to the Supreme Court.

The generic drug company attorney stated to the Supreme Court:

The most obvious intended beneficiary of the statutory licensing system was the generic drug industry . . . In fact, since the adoption of TRIPS and the URAA no industry other than the generic drug industry has emerged as being potentially affected by the equitable remuneration system.

So there you have it: plain evidence that contrary to what our colleague will allege, the generic drug industry wants to tilt the playing field toward itself.

Frankly, the Pryor amendment is nothing more than an attempt to see that one industry, the generic drug industry, gains a special, widespread, wholesale benefit that no other type of generic manufacturer will ever likely get under the transition rules.

And why is this so harmful?

As much as we all sympathize with the goal of getting lower priced generic drugs to the American consumer—particularly our elderly living on fixed incomes, we must not act in a fashion that undermines the incentives to invest in biomedical research.

We want both new breakthrough therapies and cheap generic equivalents.

The issue is how best to satisfy both ends.

Over the years I have enjoyed working with Dr. C. Everett Koop, former Surgeon General of the United States. I stood behind Dr. Koop when many in this body were anxious to prevent him from becoming Surgeon General. Time has proven that Dr. Koop is one of the world's leading public health authorities.

I respect and value his opinion. I believe that the American people know that Dr. Koop is a man of integrity and speaks his mind. Dr. Koop wrote me a

letter last week which shows just how important it is to retain incentives for biomedical research. He said:

Because of my long-standing concerns about the effect on biomedical research of weakened patent protection, I have been following the efforts in the Senate to roll back the advances in intellectual property protection established by the GATT amendment.

The right to claim ideas as property allows innovators in any discipline to invest time and money to bring those ideas to fruition. This is especially true in the pharmaceutical industry, where each new medicine requires an average investment of 12 years and \$350-500 million. Stronger patent protection bolsters the incentives for these high-risk investments, and thus represents a significant leap forward in our effort to preserve and improve the nation's health. It is for this reason that I submitted testimony to the Judiciary Committee opposing legislation to roll back the GATT intellectual property protections for pharmaceuticals.

I think that Dr. Koop is focusing attention on the right issue when he points out the importance that strong intellectual property laws have on biomedical research.

Frankly, a strong case can be made by those who argue that it is unnecessary to make any changes in our current statutory framework. But in the spirit of compromise the Judiciary Committee passed on a 10-7 bipartisan vote compromise legislation on this issue, to which Senator SPECTER is referring.

The Judiciary compromise is the text of the amendment I offer today, with small-but-important modification suggested by Senator SPECTER last week which will ensure that the process envisioned in the Judiciary bill is a speedy one.

The Judiciary compromise is a responsible, reasonable alternative. It allows generic drug products to reach the marketplace before the expiration of the GATT-extended patents.

The difference between my approach and that of Senator PRYOR is that the Judiciary bill protects intellectual property by precluding the generic's entry into the marketplace until a court has decided that a substantial investment has been made. As with the Pryor approach, the manufacturer must demonstrate that it has made a substantial investment.

Mr. President, I reserve the remainder of my time.

Mr. PRYOR. Mr. President, did the Senator from Utah conclude his statement?

The PRESIDING OFFICER. He reserved the remainder of his time.

Mr. PRYOR. Mr. President, as I have only a few moments, let me point out that the Hatch substitute was born out of a proposal by PhRMA. PhRMA is the group that represents the major brandname drug companies. Every element, according to a memo of April 30, 1996, of a draft PhRMA proposal which, as they wrote to their members, "benefits members of PhRMA" wound up in the so-called Hatch substitute. That, Mr. President, is what they are interested in. They are not interested in

benefiting the consumer, they are interested in benefiting their own—regardless of what happens to consumers and taxpayers. This is why we should really call this proposal the PhRMA-Glaxo substitute. I hate to call it the Hatch substitute because I have such respect for my friend from Utah. Certainly he would not want to have his name associated with what he knows is an enormous boon to special interests.

Finally, the Hatch substitute has become a Christmas tree, literally a Christmas tree, of patent extensions and special favors for a variety of drug companies like Wyeth-Ayerst, Merck and Zeneca. Once again, I will quote our friend, Paul SIMON from Illinois. Senator SIMON, who we will miss greatly in this body, said: "This is a classic case of the public interest versus the special interest."

Mr. President, that is precisely what this vote we are about to take is all about.

I yield the floor.

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

The PRESIDING OFFICER. The Senator has 5 minutes.

Mr. HATCH. I have heard the arguments of the distinguished Senator from Arkansas over and over.

I know he is sincere.

I know he means well.

But his arguments fixate on one or two companies.

If you were to look at this in the context of all of the companies, the thousands of companies, that benefited from the GATT Treaty, it reduces his arguments to nothing.

If you look at the companies from Arkansas that benefited from the GATT Treaty, you have to ask why they should receive a benefit that others did not? It is because they had to draw the line somewhere. The simple truth is that there were some who won and some who did not.

The thrust of my colleague's argument is that consumers are spending exorbitant amounts of money for Zantac because one company, Glaxo, has had its patent expanded under the GATT Treaty.

It does not matter if Glaxo or any other company benefited under this treaty.

The important thing is that treaty be preserved. It took decades to bring this treaty about. It is a treaty with important intellectual property provisions, provisions important for the whole world.

We have taken decades to get other nations to sign on to this treaty, many of which did not want to. Some of them would like nothing better than to undermine this treaty.

If the United States, pursuant to the Pryor amendment, were to adopt this language and undermine this treaty, right off the bat, I think it would send the wrong message to all the nations which would like an excuse to undermine the treaty anyway.

If we uphold the treaty, then, it seems to me in the long run we will

save trillions of dollars for the consumers, compared to the relatively few millions the Senator is complaining about.

In the short run, consumers are going to pay more for some products under the treaty, because thousands of patents for all sorts of products and technologies were extended.

Let us just be honest about it. There is a lot riding here.

The overall goal of keeping the URAA intact outweighs the concerns of any one of us that one company or another may benefit somewhat from this. The fact of the matter is, there are a number of companies that benefit from this.

It is also important to note that, under the Hatch-Waxman Act, the generic industry gets something that no other industry gets. They can infringe the pharmaceutical pioneer companies' patents like no other industry can. We included that provision in the best interests of bringing pioneer drugs off patent into the marketplace as quickly as we could.

I am proud of that Waxman-Hatch Act. I worked my guts out to have it come to fruition.

It was negotiated, every word of it, right in my office.

It saved consumers billions and billions of dollars.

If we turn around now, just because, as the Senator argues, one or two or even eight out of a million companies may have benefited, we will undermine the very GATT Treaty that we fought so hard to get. That will be a mistake.

This is not some insignificant battle between two good people here in the U.S. Senate. This is a very, very important set of legal principles, legislative principles, treaty principles, and intellectual property principles.

Frankly, the arguments are not as the distinguished Senator would portray.

At this point I would like insert in the RECORD some examples of patents which were extended in Arkansas. I would also like to insert a statement by former Senator and Trade Representative Brock, who rebuts the arguments that former Ambassador, now Secretary Kantor says. And, finally, I would like to insert the letter from Dr. C. Everett Koop, former Surgeon General of the United States. I ask unanimous consent to have those printed in the RECORD.

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

EXAMPLES OF ARKANSAS PATENTEES GRANTED EXTENSIONS UNDER GATT AND NUMBER OF DAYS

Abilities Unlimited, 640.
AGL Corporation, 324.
Arthur W. Reed Machine Co., 660.
BC Pausch, Inc., 471.
BEI Electronics, Inc., 535.
BEI Electronics, Inc., 240.
BEI Electronics, Inc., 419.
BEI Electronics, Inc., 466.
Carroll Herring, 713.
Citation Manufacturing Co., Inc., 454.

Cordell Tackle, Inc., 296.
 Darrell Boyd, Kathy Sue Boyd, Mark Stodola, James Hall, Stuart Vess, J. Russell Reinmiller, 667.
 Domination Incorporated, 663.
 DuraCraft Boats, Inc., 403.
 Gator Products, Inc., 527.
 Hustler Corporation, 189.
 Jacuzzi Bros., 218.
 Klipsch and Associates, Inc., 481.
 Malvern Minerals Company, 410.
 Norman Manufacturing Co., 611.
 Roland Clardy Rogers, Ray Green Rogers, 541.
 Shakespeare of Arkansas, Inc., 437.
 Shakespeare of Arkansas, Inc., 552.
 Sprayrite Manufacturing Company, 465.
 SunPower Systems Corp., 688.

BROCK GROUP, LTD.,

Washington, DC, September 20, 1995.

Senator WILLIAM V. ROTH, JR.,
 Hart Senate Office Building,
 Washington, DC.

DEAR SENATOR ROTH: When I first proposed international agreements to extend intellectual property protection worldwide under the GATT, no one believed it could be done. Yet it was the crowning achievement of the recently successful Uruguay Round—thanks almost solely to the persistent and active support of the U.S. business community and U.S. governmental leaders.

Now I hear that some pending proposals could imperil the implementation of that agreement. I refer specifically to legislation recently introduced by David Pryor, called the Consumer Access to Prescription Drugs Act (S. 1191). S. 1191 creates special rules so that the generic pharmaceutical manufacturers can take advantage of preferential treatment under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch/Waxman Act") without adhering to the 20 year patent term negotiated during the GATT Uruguay Round negotiations.

Proponents suggest that this legislation is only a "technical" correction to the Uruguay Round Agreements Act (URAA) and neither weakens patent protection under URAA nor diminishes the United States' ability to fight for stronger international patent protection. I disagree! This issue is far too important to risk on the basis of hoped-for "good intentions" in nations which have never favored intellectual property protection.

Countries around the world are still in the process of implementing the Uruguay Round Agreement. A number have withheld their own action to wait and see what we do. We all know those whose prior actions have cost American inventors and entrepreneurs billions. They will see this retreat on our part as a ready excuse to implement their own minimalist versions on intellectual property protection. It will be difficult, if not impossible for the United States to force other nations to adhere to the TRIPS agreement if we set this unfortunate precedent.

In sum, in exchange for the hope of short term savings, the Pryor proposal could cost all U.S. firms and workers the enormous long term gains we worked so hard to achieve in the Uruguay Round. That is penny wise and pound foolish. The United States must continue to be a leader on full implementation of every aspect of the agreement on intellectual property in both substance and in form.

One final additional point. Domestically, this legislation would upset the delicate balance provided for in the Hatch/Waxman Act, which already grants generic pharmaceutical firms special treatment in the area of patents not available to other industries. S. 1191 would further the bias against pioneer pharmaceutical firms.

Please give careful consideration to the negative impact this legislation would have. I would be delighted to give you additional specifics if it would be helpful.

Sincerely,

WILLIAM E. BROCK.

BETHESDA, MD, June 20, 1996.

Hon. ORRIN G. HATCH,
 Chairman, Judiciary Committee, U.S. Senate,
 Washington, DC.

DEAR MR. CHAIRMAN: Because of my long-standing concerns about the effect on biomedical research of weakened patent protection, I have been following the efforts in the Senate to roll back the advances in intellectual property protection established by the GATT agreement.

The right to claim ideas as property allows innovators in any discipline to invest time and money to bring those ideas to fruition. This is especially true in the pharmaceutical industry, where each new medicine requires an average investment of 12 years and \$350-500 million. Stronger patent protection bolsters the incentives for these high-risk investments, and thus represents a significant leap forward in our effort to preserve and improve the nation's health. It is for this reason that I submitted testimony to the Judiciary Committee opposing legislation to roll back the GATT intellectual property protections for pharmaceuticals.

While I am still concerned about the impact that any change in our intellectual property protections could have on the incentives for medical R&D, the bill reported by the Judiciary Committee on May 2 is a significant improvement over the other proposals on this issue. I commend you and your colleagues for finding a way to accommodate the varied political interests that have been actively involved in this debate.

By allowing for the issues of "substantial investment" and "equitable remuneration" to be resolved before generic medicine comes on the market, the proposal mirrors the system that has worked well since it was instituted by the Hatch-Waxman Act. It also adheres with the requirements of the GATT legislation itself, which requires a court to determine these issues.

Most importantly, by requiring a court to establish "equitable remuneration," the Judiciary Committee's proposal establishes a procedure for the value of intellectual property to be recognized. This is crucial if we are to sustain the research that will answer patient needs now and in the future. It is absolutely essential if we as a society genuinely care about the nation's long-term health.

Ideally, no change would be made in the relevant laws establishing stronger patent protections. But given the political reality, you have done a good job of developing a compromise that maintains some reasonable protection for the intellectual property concepts that have made the U.S. a leader in medical innovation.

Sincerely yours,

C. EVERETT KOOP, M.D., Sc.D.,
 Surgeon General, 1981-1989.

Mr. HATCH. With regard to my amendment, which is the text of the Judiciary Committee bill, the court would consider expenses related to the generic drug application and other activities, such as plant construction and equipment purchases, made specifically in connection with particular generic drugs.

Our compromise would prevent applicants from gaming the system by precluding approval of applications submitted for products that come off-patent beyond 1998.

Also, at the suggestion of Senator BIDEN, we have included language that would make clear that pioneer drug patents could receive both the restoration extension afforded by the Hatch-Waxman Act and any additional time received under the URAA.

This is only fair, because these extensions derive from separate statutory sources.

Mr. President, I have worked long and hard on this issue and have endeavored to find a reasonable middle ground which will accommodate the interest of all my colleagues. The Judiciary bill is a good compromise, and I urge my colleagues to support the amendment.

Mr. HELMS. Mr. President, there are a number of red herrings flying across the Senate in an effort to politicize this issue and scare senior citizens and others. But the bottom line of this issue is whether we will support the search for new medicines or undermine it.

Let me quote from an article that was written by Dr. C. Everett Koop and published in the March 28, 1996, issue of *The Washington Times*:

Generic drugs play an important role in helping lower the cost of medicines. But it is the pharmaceutical research industry that discovers and develops those medicines in the first place, investing billions of dollars in research and development that can span decades without any guarantee of success—an investment made possible by our system of patent protection.

Congress should stand firm in its decision to provide greater protection for American innovators. This protection is a leap forward in our ongoing battle to preserve our long-term national health.

Speaking of our long-term national health, a company that Senator PRYOR frequently criticizes, was recently awarded the highest honor that can be bestowed on a company by the American Diabetes Association.

On June 6, Glaxo Wellcome, Inc., which is headquartered in North Carolina, was awarded membership into the Banting Circle. According to the announcement, the award recognizes Glaxo Wellcome's effort to cure diabetes.

Dr. Bob Bell, vice president of research at Glaxo Wellcome, explained that "If we can find that gene or combination of genes that causes diabetes, and link them to specific functions of their proteins, then we can use this insight to develop better treatments."

Approximately, 15 million people suffer from type II diabetes. How much longer does the Senator from Arkansas think they should have to wait for a better treatment or even a cure for their disease?

Ms. MOSELEY-BRAUN. Mr. President, I would like to take this opportunity to express my support for the Hatch substitute amendment. The Senate voted in December to require the Judiciary Committee to hold hearings on the General Agreement on Tariffs and Trade [GATT] patent extension provisions. As promised, the hearings were held, and a May 2 markup resulted in a vote in favor of a bipartisan compromise proposal.

The Hatch amendment, which represents this bipartisan Judiciary Committee compromise, would allow the Food and Drug Administration to approve a generic drug marketing prior to expiration of the GATT patent extension if the manufacturer complies with the GATT implementation law and the 1984 Hatch-Waxman law. This special exemption from patent laws is permitted by no other sector.

The Pryor amendment on the other hand, would modify the current GATT as it applies to patent protections for pharmaceutical products. This amendment, which was voted down in the Finance Committee, has been portrayed as a technical correction to the GATT agreement. It is not. This amendment opens up an international agreement on trade to resolve a domestic intraindustry dispute. It is short-sighted, counterproductive, and will impede the availability of life-saving drugs and therapies for all of us.

This is not an argument about whether the American people should generally have access to generic drugs. I firmly believe that all persons who are sick should have access to affordable and comprehensive health care services. My views on the GATT patent extension issue are in no way inconsistent with my support for health reform. In fact, I believe present attempts to undo and reopen GATT could have an adverse impact on the development of state of the art medicines and treatments, which in turn deny all of us the benefit of advances in medical science.

This argument in support of changing the GATT patent extension for pharmaceutical products seems to rest primarily on the potential cost savings to consumers of accelerating the availability of a generic version of one anti-ulcer drug. Such an argument totally ignores the fact that the anti-ulcer marketplace is highly competitive with a wide range of choices, including generics, for patients and physicians. There are new medicines available and coming to the market that can cure peptic ulcer disease. The senior citizen on a fixed income will save far more from the availability of medicines that eradicate the cause of his/her ulcer after a few weeks of therapy than from a less expensive version of a medicine taken daily.

On average, it takes 12 years and \$360 million to bring a new drug to market. Research-based pharmaceutical firms spend nearly \$18 billion annually on research and development. This emphasis on R&D has produced treatments not only for common conditions and ailments but also for life threatening diseases. The United States invests more than any other nation on research. I have received numerous letters from patient groups that are very concerned that modifications to GATT will adversely impact research and development particularly on orphan diseases for which it is not feasible to develop generic equivalents. We must continue

to increase our investment if we are to discover cures and effective treatments for diseases that continue to plague millions of Americans like AIDS, Alzheimer, Parkinson's Disease, and cancer.

Increased patent protection ensures that research and development will continue in, not only the medical field but also in all areas of innovation. This country leads the world in research and innovation, it contributes to the public good both here and abroad and every American benefits from our leadership. Changes to the GATT agreement that seek to repeal patent extensions for only one class of innovations are, in my opinion, shortsighted. Such changes will decrease private sector revenues for research and development, compromise U.S. leadership on intellectual property, and adversely impact the competitiveness of U.S. companies in relation to their foreign counterparts. They do nothing to provide greater access to affordable health care for consumers.

I have given careful consideration to all of these issues. I am convinced that the measures included in the GATT and the Hatch amendment will continue to increase the ability of U.S. industries to compete while also allowing low-cost generic equivalents to reach the market. It is for these reasons that I support the Hatch amendment and oppose the Pryor amendment.

Mr. COATS. Mr. President, this is an enormously complicated issue with very board implications. I understand that the Judiciary Committee has held hearings on the issue and that as a result, voted 10 to 7 to report out a bipartisan compromise. The compromise reached would allow the FDA to approve a generic drug for marketing prior to expiration of the GATT patent extension, but only after a generic drug manufacturer demonstrated in court that they had made a substantial investment before June 8, 1995.

This requirement is contained in both the GATT implementing law and the generic drug approval process in the 1984 Hatch-Waxman law and applies to all generic manufacturers. The investment of a generic drug manufacturer would have to be more than merely the filing of an abbreviated new drug application [ANDA] for regulatory approval with the FDA, although the costs of an ANDA could be included.

There have been a lot of questions raised concerning how this transition would work and why, for example, certain industries have been singled out and required to meet special criteria before they can bring their product to the market. In reality, under both current law and the Judiciary Committee compromise, a generic company in any industry must go to court to prove substantial investment, in order to bring its product to market. There is a prevalent misconception that no other industry has to go to court to prove substantial investment. This is simply not true.

Others have asked why the Committee bill fails to permit expenses related to filing of an abbreviated new drug application [ANDA] to be counted toward the determination of a substantial investment. The expenses related to the filing on an ANDA are unique to the generic pharmaceutical industry. These activities would constitute patent infringement for any other industry. The intent of the GATT transition provisions is to allow those companies which had made capital expenditures—like building or expanding a plant, to market their imitator product during the patent extension period. A generic pharmaceutical company should only benefit from the same type of expenses available to all industries.

Finally, the opponents of the Judiciary Committee compromise argue that the Judiciary bill treats generic pharmaceutical companies unfairly. This could not be farther from the truth. In fact, the Hatch compromise offers the generic pharmaceutical industry special protections not available to any other industry. The Judiciary bill would permit a generic pharmaceutical company to collect damages from the innovator company if litigation between the innovator and generic companies caused an unwarranted delay an imitator drug to the market. No other industry is afforded a similar benefit.

Mr. President, it seems to me that the compromise reached by the Judiciary Committee is both thorough and fair. It answers the questions that have been raised and does so in a very well thought out manner. This is a difficult issue and I appreciate the enormity involved in reaching an agreement. While I would have preferred using the normal Committee route to bring this legislation to the floor, I intend to support it.

Mr. KENNEDY. Mr. President, I want the Senate to overwhelmingly support the Pryor-Brown-Chafee amendment, which is the text of the Prescription Drug Equity Act. It is difficult to understand why it has taken over 6 months for this bill to return to the floor for a vote. The legislation proposed by Senator PRYOR, Senator BROWN, and Senator CHAFEE achieves the result clearly intended by the GATT treaty, and gives patients access to expensive drugs they should have had before now. Senate delay has cost American consumers, many living on meager incomes, millions of dollars. We owe it to them to close the Glaxo loophole today.

GATT was intended to give longer patent terms to all patent holders. But, those drafting the legislation to implement GATT recognized that longer patent terms would be an injustice for firms in many different industries who had been acting in good faith and preparing to market products based on the patent expiration date under prior law.

The GATT implementing law dealt with this problem through a fair compromise, by permitting such firms to begin marketing their products on the

pre-GATT expiration date, if they had made a "substantial investment" or commenced product activity before June 8, 1995. The firm must, however, pay the patent holder a fair price.

Unfortunately, a mistake was made. Laws affecting all other industries were modified to reflect the compromise, but not the pharmaceutical industries. By an accidental oversight, Congress failed to amend the relevant FDA law. As a result, generic drug companies that had planned in good faith to market products in reliance on the old law have been prevented from taking their products to market as planned. The result is an unintended windfall worth vast sums to a handful of brand-name pharmaceutical manufacturers. One company in particular—Glaxo-Wellcome—has benefited immensely from this windfall. To date, out of a total windfall of an estimated \$700 million; Glaxo-Wellcome alone has received \$550 million.

What has happened since discovery of the loophole is a lesson in greed. First, Glaxo and the other brandname manufacturers began an intense lobbying campaign to prevent this inadvertent mistake from being corrected. They claimed that correcting it would undercut pharmaceutical research and development. But the windfall was completely unexpected. Correcting the mistake will not deprive pharmaceutical companies of any funds budgeted for research and development. In fact, corporate profits, not research and development, will be the prime beneficiary of the windfall.

Brand-name manufacturers also claimed that the correction would undermine the GATT Treaty and weaken the United States in world trade. That's nonsense. Every other industry in America is living successfully and trading successfully under the GATT compromise, and so can Glaxo-Wellcome and other firms that are reaping these windfall profits.

Once it became clear that the Senate would take action, brand-name manufacturers helped shape the so-called Hatch "compromise," which is no compromise at all. Secretary of HHS Shalala has said that the Hatch bill would be ineffective in giving generic drugs the same benefits available to other industries under GATT. The Hatch proposal will lead to years of litigation. It is a one-sided deal that benefits Glaxo and other brand-name drug companies at the expense of the American consumer. The Senate is awash in crocodile tears and campaign contributions. This scandal has to end.

The Pryor-Chafee-Brown proposal corrects the error and achieves fairness for generic drug companies and consumers. The generic drug companies relied upon the law and made substantial investments to bring their products to market in good faith reliance on the prior law. They should not be penalized because Congress made a mistake.

Consumers should not pay more for pharmaceuticals as they are now doing

because of this mistake. Let's not force American consumers to absorb the cost of Congress's mistake any longer. The Senate should stop this price-gouging, support the Pryor amendment, and close the Glaxo loophole.

Mr. PELL. I would like to clarify my understanding of some language contained in section 2(B) of the section of the pending amendment entitled Determination of Substantial Investment.

It is my understanding that this section of the legislation is meant to simply set a standard for a determination of "substantial investment" by a generic drug company at a level higher than the simple completion of paperwork and testing necessary for filing of an application submitted under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act, the so-called ANDA, to the FDA. Is that so?

Mr. HATCH. That is correct.

Mr. PELL. In that regard then, is it correct to say that under the language of the amendment, when a company includes information in its ANDA which pertains to the capital investments it has made in bringing a product to the market, such as the building of plants, buildings, or equipment or investments in developing manufacturing processes or personnel, that that information can be fully used in court proceedings to prove its claim of substantial investment.

Mr. HATCH. That is correct. Evidence of plant construction, equipment, and the like are exactly the type of qualifying activities that the Judiciary bill contemplates.

Mr. PELL. To be perfectly clear then, under the amendment, generic drug companies will be able to use all of the information contained in their ANDA, in addition to any other evidence they wish, to assist in proving their claim of "substantial investment" in court.

Mr. HATCH. That is correct.

Mr. PELL. I thank the Senator for that clarification.

Mr. BRYAN. Mr. President, last week I joined my colleagues Senators PRYOR, CHAFEE, and BROWN in supporting and debating this loophole closing important amendment. I am glad that today we will get a vote on this issue.

As I said last week, what we are talking about is money—big money—hundreds of millions of dollars—even billions of dollars.

When that kind of money is on the table, all kinds of special interests come forward and seek to protect themselves.

The fact is that the prescription drug industry, through inadvertence and omission, has been given separate treatment—separate, distinct, special treatment—that no other industry or product in America receives.

Our amendment to correct this inadvertence has the endorsement of the U.S. Trade Representative, the Patent Office, and the FDA plugs this loophole.

Since last December, as these windfall profits have continued to accumu-

late, seniors across this country have continued to pay more than they should for certain prescription drugs.

The loophole is still open today. We face the same issue—each and every day. American consumers are paying millions of dollars more than they ought to.

So let me suggest, as I view my responsibilities as a Member of this Chamber, it is highly appropriate that we seek to correct this inequity and to provide the relief to which American consumers are entitled—and to do so immediately.

When the loophole closing amendment came to the Senate floor last fall, a critical vote was taken—and by a margin of only 1 vote—48 to 49—the Senate defeated this important amendment.

A compromise was reached after that vote. The Judiciary Committee would review the GATT Treaty problem, and report back to the Senate with its recommendation. This was to be a good faith effort to analyze the issue.

It is fair to ask what the outcome of this review was?

The Judiciary Committee did report out a substitute bill to our GATT amendment—albeit 5 months after our amendment was voted upon.

This substitute is called the Pharmaceutical Industry Special Equity Act of 1996. It has a somewhat ironic ring to it.

Who does it benefit?

It benefits the prescription drug industry in a very special way that is inequitable to American consumers, and particularly those on fixed incomes.

What we really are being asked to support today is a bill that CODIFIES—in my view codifies—the very GATT Treaty mistake our amendment is trying to correct. A bill that continues the GATT treaty loophole for such drug manufacturers as Glaxo-Wellcome, Inc. and its ulcer-heartburn drug, Zantac—the world's best selling drug, which costs twice as much as it should because of the loophole.

More than 100 drugs are being protected from generic drug competition because of this loophole. These include the hypertension drug, Capoten, which costs 40 percent more due to the loophole—the cholesterol lowering drug Mevacor, the ulcer drug Prilosec, and the anti-fungal agent drug Diflucan.

A bill that ensures that seniors across this Nation will pay more than they should for prescriptions drugs they need and that are essential to their health.

A bill that ensures American taxpayers will pay more than they should to provide prescription drugs for those essential programs offered by the Department of Defense, the Department of Veterans Administration and other agencies of the Federal Government which purchase prescription drugs on behalf of the clientele they serve.

A bill that creates tremendous legal barriers—in my view, insurmountable barriers—to the generic drug manufacturing industry to ensure that these

manufacturers cannot bring to the marketplace lower priced prescription drugs.

A bill that ensures the prescription drug manufacturers keep their \$2.3 billion windfall, plus a bill that extends special patent extensions for two brand name drug companies—Zeneca and Wyeth Ayerst Laboratories which received a 2-year patent extension for Lodine, its anti-inflammatory medicine.

So what has occurred here?

In my view, we have a situation worse than before.

Not only do some prescription drug companies retain their windfall profits—they are protected from nearly any possibility that any generic manufacturer will be able to compete against them during the extended patent term.

Generic drug manufacturers will be required to prove a substantial investment before being allowed to compete against any brand name drug. The key change, however, is that this substantial investment requirement is being defined differently to ensure that generic manufacturers cannot—as a practical matter—compete against any brand-name drug benefiting from the extended patent period under the GATT Treaty.

Under the substitute bill, substantial investment is defined much differently. In addition, generic manufacturers are required to make a determination of equitable remuneration to the brand name manufacturer before any generic drug to be manufactured.

You do not have to be a rocket scientist to recognize those who are enjoying these windfall profits are not going to be eager to agree as to what equitable remuneration may be. In effect, we create a lawyers' field day to debate what is, in fact, equitable remuneration.

The effect of the change is, first, it will be virtually impossible for any generic manufacturer to meet the new substantial investment standard.

Second, it will mean generic manufacturers will be tied up in court proving substantial investment and what is equitable remuneration before they can bring any generic drug to be marketed.

Two obstacles, two hurdles, two barriers that, as a practical matter, are going to be virtually insurmountable.

Who is being forgotten? Who gets hurt by this change?

Those Americans particularly that are on a fixed income. That is primarily our senior community. They have been paying and will continue to pay more than they should—for lack of a prescription drug alternative.

I am puzzled as to why anyone believes it is equitable to force seniors—many on very limited incomes—to pay more for a drug than they should so prescription drug manufacturers can continue to reap the windfall profits that this loophole has created.

I must say I am astonished by the provisions of this Pharmaceutical In-

dustry Special Equity Act—a misnomer if there ever was one. Its a special interest provision.

My colleagues who talk the virtues of competition in the marketplace surely must find this substitute bill to be a bit beyond the pale.

I remind my colleagues that there is no reason to allow a limited number of prescription drug companies an unintended windfall profit to the detriment of all Americans who depend upon prescription drugs in order to sustain their health.

Seniors, veterans, and the most vulnerable in our country cannot fight the brand name pharmaceutical industry on their own. They deserve and need our protection from an industry that is trying to "codify" a mistake to ensure their windfall profit margin.

I hope my colleagues can see both this loophole for the mistake it is—and this substitute bill for the even larger mistake it is.

We have the ability to end this inequity now. The vote you cast today is very clear. You vote for the pharmaceutical industry windfall, or you vote for seniors and all consumers who need fair drug prices. Please join me in stopping this travesty by supporting this amendment.

Mr. BYRD. Mr. President, Senator PRYOR has offered an amendment, of which I am a cosponsor, that would correct an unintended loophole created in the legislation implementing the General Agreement on Tariffs and Trade [GATT]. It is estimated that the loophole will ultimately result in a windfall profit of approximately \$2.5 billion to certain drug companies. Congress must take the responsible course of action and correct its mistake by passing the Pryor amendment.

Time is running out to correct this matter. Each day of inaction results in increased costs to consumers. In addition, to those who argue that this is not the appropriate vehicle, this amendment will result in savings to the Department of Defense [DOD] via the cost of prescription drugs purchased through DOD health programs.

How did this loophole come about? When Congress enacted the Uruguay Round Agreements Act [URAA], the legislation implementing GATT, which I opposed, it extended all patent terms from 17 years from date of approval to 20 years from the filing date. In addition, the legislation allowed generic companies to market their products as of the 17-year expiration date if they had made a substantial investment and would pay a royalty to the patent holder. The carefully constructed transition rules were meant to apply to all industries. However, because conforming language to the Federal Food, Drug, and Cosmetic Act was inadvertently omitted, this provision does not apply to the generic pharmaceutical industry. The result is that the drug industry is the only industry that is shielded from generic competition under GATT during the extended patent term.

The U.S. negotiators indicated that it was not their intent to exclude the pharmaceutical industry from this provision, and that the omission of the conforming language was an oversight. According to former-U.S. Trade Representative Mickey Kantor in a letter to Senator CHAFEE,

This provision [the transition rules] was written neutrally because it was intended to apply to all types of patentable subject matter, including pharmaceutical products. Conforming amendments should have been made to the Federal Food, Drug and Cosmetic Act and Section 271 of the Patent Act, but were inadvertently overlooked.

This oversight means consumers are paying more for their drugs than would otherwise have been the case. If generic drug companies cannot bring their versions of drugs to market under the transition rules, consumers will be forced to continue to pay more for their prescriptions. As I stated previously, nationwide, it is estimated the total cost to consumers may be \$2.5 billion. It has already cost consumers a great deal. The loophole is taking money out of the pockets of consumers and adding additional costs to public health care programs that are currently putting a strain on Federal and State budgets. We should not delay passing this legislation any longer.

Senior citizens are especially impacted by this Congressional oversight. Although seniors comprise 12 percent of the population, they use one third of all prescription drugs. At the same time, seniors live on fixed incomes and oftentimes experience difficulty in affording their prescriptions. It is outrageous that Congress would worsen the situation of seniors, and others who depend on prescription drugs, by failing to enact legislation to correct this Congressional oversight.

Mr. President, this situation can easily be remedied by adopting the Pryor amendment. I urge my colleagues to support the Pryor amendment and to oppose the substitute bill reported by the Judiciary Committee. The Judiciary Committee version does not fix the loophole. It will not ease the burden this unintentional oversight by the Congress has placed on the elderly, veterans, consumers, and taxpayers. The Secretary of Health and Human Services, in a letter to Senator PRYOR on the effect of the Judiciary Committee bill, states,

In brief, despite the bill's declared intent to eliminate the unequal treatment of generic drugs created by the URAA, S. 1277 as ordered reported would be ineffective in affording generic drugs the same transitional period benefits given to other technologies, leaving the generic drug industry for all practical purposes at the same disadvantage as under current law.

The Judiciary Committee bill would result in lengthy litigation keeping generic drugs off the market and the costs of certain prescription drugs high for consumers. Whereas other industries may go to market first and then have the questions regarding substantial investment and equitable remuneration decided by the courts, the

substitute would require these issues to be determined before a generic drug could be marketed. In addition, although the legislation implementing GATT does not define substantial investment, the substitute includes a definition of substantial investment that is extremely onerous. The bottom line is that the substitute will not remedy the situation and consumers will be left to pay the price as they are now because of Congress' failure to adopt the Pryor amendment when it was brought up last December. Let us not squander this additional opportunity Senator PRYOR has given the Senate to do the right thing. I urge my colleagues to pass the Pryor amendment.

Mr. KEMPTHORNE. Mr. President, the issue of pharmaceutical patents under the General Agreement on Tariffs and Trade [GATT] has been under review by this body for some time. Well respected individuals—from the Senate, from the Administration, and from the private sector—weighed in on both sides of the issue. Last December, I joined my Senate colleagues in voting to send this matter to the Judiciary Committee for hearings because I felt many questions remained unanswered about how certain patents were treated under the GATT. With no clear legislative history to follow, I believed—and still believe—it was important for Congress to carefully review the issue and get to the heart of the matter.

I am pleased to note that my distinguished colleague from Utah, Senator HATCH, followed through on his commitment to hold hearings on pharmaceutical patents and the GATT, just as I knew he would. With his long history on addressing issues of concern to the generic drug industry, I had no question that he would do all he could to get to the bottom of this issue. The subsequent hearings were sorely needed so that the Senate could adequately consider the ramifications of the various courses of action proposed on this matter. Taking some time to adequately review an issue leads to better legislation and better results for Americans. This is a serious matter, and deserved serious and thoughtful review.

Since those hearings concluded I have carefully reviewed the record on this complex issue. Based on this information, I have concluded that the question at hand is indeed the result of a drafting oversight in the GATT implementing language, and, as a result, I will support the amendment offered by my colleague from Arkansas, Senator PRYOR.

I believe very valid concerns were raised when this amendment was first introduced. Because of this, it is not an easy task to choose between amendments offered by my two distinguished colleagues. In this case, however, I feel the right decision is the one which restores fairness to this matter. The generic drug manufacturers moved ahead with their plans on the good faith effort that they would be treated the same as other industries with similar

circumstances. They believed, in good faith, that under the GATT they would be able to proceed to market, with some new limitations, on the same timetable which existed prior to Senate passage of the GATT implementing legislation. Only the Pryor amendment allows us to bring about what I believe is the fairest possible solution.

This is the primary reason why I cannot support the amendment being offered by the Senator from Utah. I understand and respect his concerns on this issue. I, however, am concerned about whether under his amendment, the generic pharmaceuticals will be able to get to market in a timely fashion. While the Senator's amendment offers some relief to the generic drug makers if they are unnecessarily prevented from going to market, I do not believe it truly restores fairness. It also does not offer any protection to the consumers who will be saddled with higher drug prices during the interim.

Another issue which must be addressed is that of medical research. I have heard the concern expressed that if the Pryor amendment becomes law future research into new and improved pharmaceuticals will not occur or will be significantly reduced. I simply do not believe this is true. Even if the Pryor amendment is adopted, the research-based pharmaceutical manufacturers will benefit more than if the GATT had not been approved. The claim that only the granting of an exclusive patent extension will guarantee future advancements in pharmaceutical research is an argument I do not accept.

The Pryor-Brown-Chafee amendment will get certain generic medications into the hands of the people within the time frame all parties reasonably expected prior to the passage of the GATT implementing legislation, saving consumers and the Government millions of dollars in the process. For this reason, I believe the amendment is the correct course of action for the Senate to follow.

Mr. HATCH. Mr. President, how much time do I have left?

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

Mr. HATCH. I yield the floor.

Mr. THURMOND addressed the Chair.

The PRESIDING OFFICER. The Senator from South Carolina.

Mr. THURMOND. Mr. President, I ask unanimous consent for 4 minutes to make final remarks on this amendment.

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

Mr. THURMOND. Mr. President, I rise as a cosponsor and in support of the second degree amendment offered by Senator HATCH. The underlying PRYOR first degree amendment concerns the complex interrelationship among the GATT Treaty, the Federal Food, Drug and Cosmetic Act, and the Patent Code.

We considered this very issue last December on the Senate floor when Sen-

ator PRYOR attempted to have this matter attached to the bill to ban partial-birth abortions. The Senate voted at that time to have the Judiciary Committee—that is the Committee with proper jurisdiction—to consider this important issue. The Judiciary Committee held a comprehensive hearing on this matter on February 27 of this year and Senator PRYOR testified at that time.

Mr. President, following the hearing in the Judiciary Committee, of which I am a member, the committee amended a proposal similar to Senator PRYOR's amendment with a bipartisan compromise. The Judiciary Committee approved the compromise. This bill will be available for Senate floor consideration in due course. It would be most appropriate to consider Senator PRYOR's amendment at that time. The Department of Defense authorization bill is not the proper vehicle on which to debate the Pryor amendment. Unfortunately, we are now having to debate this contentious intellectual property issue and I am compelled to support the second degree amendment offered by the chairman of the Judiciary Committee, Senator HATCH.

The second-degree amendment reflects the bipartisan compromise agreed upon by the Judiciary Committee. Senator HATCH has spoken on the practical effect of this amendment which he drafted with others when this matter was before his Committee.

Mr. President, as I noted earlier, this is a very difficult and complex issue which addresses how certain transition rules contained in the Uruguay Round Agreements Act apply to the pioneer pharmaceutical patents which have been extended by the act. The overall approach to this issue is to find an appropriate balance to encourage research and development of breakthrough innovator drugs while making low cost generic equivalents available to the public. The Judiciary Committee approved one approach which many believe reaches the goal of encouraging research and development but also expediting their generic equivalents to the marketplace.

It would be my preference to debate the Pryor amendment when the full Senate turns to consideration of the bill recently approved by the Judiciary Committee. That would seem to me to be the appropriate time to consider the Pryor amendment. Yet, here we are on the Defense bill debating the Pryor amendment in a compressed manner that does not avail itself to full discussion. I urge my colleagues to support the second-degree amendment which is essentially the compromise language already approved by the Judiciary Committee.

Mr. President, I yield the floor.

The PRESIDING OFFICER (Mr. ABRAHAM). The question is on agreeing to the amendment of the Senator from Utah, amendment No. 4366.

Mr. HATCH. I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

The PRESIDING OFFICER. The question is on agreeing to amendment No. 4366 of the Senator from Utah. The yeas and nays have been ordered. The clerk will call the roll.

Mr. SIMPSON (when his name was called). Present.

Mr. NICKLES. I announce that the Senator from Oregon [Mr. HATFIELD] is necessarily absent.

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

The result was announced—yeas 53, nays 45, as follows:

[Rollcall Vote No. 179 Leg.]

YEAS—53

| | | |
|-----------|------------|---------------|
| Abraham | Gramm | McConnell |
| Ashcroft | Grams | Mikulski |
| Bennett | Grassley | Moseley-Braun |
| Biden | Gregg | Murkowski |
| Bond | Harkin | Nickles |
| Burns | Hatch | Nunn |
| Campbell | Heflin | Pell |
| Coats | Helms | Rockefeller |
| Cochran | Hollings | Roth |
| Coverdell | Hutchison | Santorum |
| D'Amato | Inhofe | Shelby |
| DeWine | Johnston | Specter |
| Dodd | Kassebaum | Stevens |
| Domenici | Kyl | Thomas |
| Faircloth | Lautenberg | Thompson |
| Frahm | Lieberman | Thurmond |
| Frist | Lott | Warner |
| Gorton | Mack | |

NAYS—45

| | | |
|----------|------------|-----------|
| Akaka | Dorgan | Levin |
| Baucus | Exon | Lugar |
| Bingaman | Feingold | McCain |
| Boxer | Feinstein | Moynihan |
| Bradley | Ford | Murray |
| Breaux | Glenn | Pressler |
| Brown | Graham | Pryor |
| Bryan | Inouye | Reid |
| Bumpers | Jeffords | Robb |
| Byrd | Kempthorne | Sarbanes |
| Chafee | Kennedy | Simon |
| Cohen | Kerrey | Smith |
| Conrad | Kerry | Snowe |
| Craig | Kohl | Wellstone |
| Daschle | Leahy | Wyden |

ANSWERED "PRESENT"—1

Simpson

NOT VOTING—1

Hatfield

The amendment (No. 4366) was agreed to.

Mr. THURMOND. Mr. President, I move to reconsider the vote.

Mr. HATCH. Mr. President, I move to lay it on the table.

The motion to lay on the table was agreed to.

The PRESIDING OFFICER. Under the previous order, the Senator from Arkansas is to be recognized.

Mr. PRYOR. Mr. President, earlier today the Senate agreed to a unanimous-consent request agreement whereby at this point I would be recognized to offer the Pryor-Chafee-Brown amendment. This last vote, of course, was an up or down vote on the amendment offered by the Senator from Utah.

Mr. President, I think the Senate has spoken. I am sorry the Senate spoke in this manner, as we lost some key Senators who had supported our position

before. But that is the prerogative of each Senator.

Mr. President, I see no real reason to put the Senate through this vote again because I think there would probably be no changes. Therefore, I congratulate the Senator from Utah in his real win today. I thought we were within about one or two votes difference, but evidently that was not the case. I do feel, Mr. President, and I would like to say that I think, ultimately, this correction needs to be made in the GATT treaty. I feel very, very strongly about this.

If there is another way to frame this issue, or another way on another day to have a debate on this matter so that we can have more competition in the drug market, then I am going to, once again, rise on this floor and try to present that case to my colleagues.

Once again, I congratulate the Senator from Utah. I think I know when I am defeated. I think today we were defeated. I am very sorry for the outcome. But the Senate, Mr. President, has spoken, and I bow to the will of this great body.

Mr. HATCH. Mr. President, I want to compliment my colleague. I have been debating with our fellow Senators here for 20 years, and I have to say that no one has worked me over with greater regularity, or in a nicer way and with greater decency, than my dear friend from Arkansas. I do not think anybody in this body is going to miss him any more than I.

This has been a very difficult debate. The Senator from Arkansas is very sincere. He believes in what he is doing. He made arguments that I know he believed. I want everybody to know that I am very sincere, too.

I really believe in this GATT treaty.

My Committee has jurisdiction over patent, copyright, and trademark issues and I have worked with these issues during my whole Senate career.

I believe this is a tremendously important issue.

Although my colleague and I differ here today—and I feel badly that my colleague feels badly—I know that nobody could have put up a more noble or hard fight than he did. I hope that this is now resolved.

There are two good sides to this issue.

Senator PRYOR is trying to help consumers. I am trying to help consumers. We have people on the outside trying to malign both of us, and both of us are trying to do our jobs in the Senate. We just happen to disagree on how it should be done.

I respect my colleague from Arkansas.

I also want to pay particular tribute to the distinguished Senator from Pennsylvania, Senator SPECTER, who has worked long and hard to try and make the agreement that came out of the Judiciary Committee one that would function and work.

I pay tribute to my distinguished ranking Democrat leader on the Judici-

ary Committee, Senator BIDEN, who, I think, made a real difference on this matter with the suggestions he made.

Last but not least, Senator HEFLIN played a significant role in this, as has Senator THURMOND, and others.

I will not take any more time of the Senate. I want everybody to know that I appreciate those who voted with us, and I respect those who voted against us—especially my dear friend from Arkansas.

Mr. PRYOR. Mr. President, if I might respond by thanking the Senator for his very kind and generous words. I am deeply grateful for that. I have enjoyed a splendid relationship with Senator HATCH through this fight and other issues. He has always been a gentleman in every respect. He is a very eloquent adversary, I might say.

Mr. President, I also want to say a special word of thanks to the Senator from Rhode Island, Senator CHAFEE, who has been our ally in this fight, not only in the Senate Committee on Finance, but on the floor of the Senate. He and his staff have been unflinching in their support. We are very grateful for the opportunity to work with him and by his side. Also, I thank the Senator from Colorado, Senator BROWN, and the other cosponsors of this particular amendment.

Once again, Mr. President, I see no need to put the Senate through this vote again. I guess I will ask the leadership if they would like to attempt to vitiate the unanimous-consent agreement.

Mr. President, I yield the floor.

VOTE ON AMENDMENT NO. 4365, AS AMENDED

The PRESIDING OFFICER. The question now is on agreeing to amendment No. 4365 by the Senator from Arkansas, as amended by the Senator from Utah.

The amendment (No. 4365), as amended, was agreed to.

Mr. HELMS. Mr. President, I move to reconsider the vote, and I move to lay that motion on the table.

The motion to lay on the table was agreed to.

Mr. BYRD. Mr. President, if no other Senator seeks recognition, I have a brief statement I will make. But I will be glad to yield the floor if another Senator wishes to proceed with an amendment.

Has the Pastore rule run its course for the day?

The PRESIDING OFFICER. We are calculating. The Pastore rule expired at 12:30.

Mr. BYRD. I thank the Chair.

Mr. President, I will yield the floor to the distinguished Senator from Georgia with the understanding that I do not lose my right to the floor.

AMENDMENT NO. 4367

(Purpose: To require the President to submit a report on NATO enlargement to Congress.)

Mr. NUNN. Mr. President, I send an amendment to the desk and ask for its immediate consideration.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Georgia [Mr. NUNN], for himself, Mrs. HUTCHISON, Mr. BRADLEY, Mrs. KASSEBAUM, and Mr. COHEN, proposes an amendment numbered 4367.

Mr. NUNN. Mr. President, I ask unanimous consent that reading of the amendment be dispensed with.

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

(The text of the amendment is printed in today's RECORD under "Amendments Submitted.")

Mr. NUNN. I thank the Senator from West Virginia.

I yield the floor.

LETTING GO OF THE ONES WE LOVE

Mr. BYRD. Mr. President, earlier today, Senator Leahy rose to pay tribute to his late mother, Alba LEAHY, who passed away last month. It was a beautiful tribute, filled with memories about the love that his mother radiated throughout her life and about the people which that love nourished. I was moved by reading Senator LEAHY's remarks. The memories he conveyed were so vivid because, some 14 years ago, I sustained a great loss. Upon two or three occasions, I attempted to make reference to that loss and give a tribute to my departed grandson.

I came to this same Senate floor and gave a eulogy for my grandson, and it was a very difficult thing to do. And I know that Senator LEAHY's remarks today were very hard for him to deliver.

Letting go of those whom we love is one of the most trying experiences, if not the most trying experience, in human existence. But looking back over a road of 78 years, it seems to me that much of life is about the seemingly simple process of letting go. It begins early in our human experience, as we let go of the security of our mother's arms, our mother's lap, of our favorite toys—if we were fortunate enough to have any toys—of childhood friends, of the house in which we grew up, our favorite teachers, and the blissful security of being still a child.

It continues throughout life, as we let go of our youth, as we watch our children grow up, as we watch them go away, as we say our final goodbyes to our parents and other loved ones, and at last we let go even of our own earthly existence to progress along the pathway to an unknown final destination.

Somehow, although we spend our lives letting go and moving on, it never becomes any easier. The practice never seems to make perfect; never seems to ease the pain of all of the goodbyes. The best that we poor humans can do is to handle the letting go with a modicum of dignity, to soothe the outward signs of pain with ceremony and nourish the lingering void inside with the sustenance of memories.

So, today Senator LEAHY shared some of his precious memories with all

of us here in the Senate. He had told his mother that he would deliver such a eulogy. At the time he talked about it with her, he thought that the time that eulogy would be expressed was perhaps some years away. But we have no way of knowing what another day will bring forth.

He bade his wonderful mother a beautiful farewell. But, as with all farewells, things will forever be changed. There are relationships and rituals in the Leahy family often, but nothing will ever be quite the same anymore.

As Senator LEAHY and his family traverse the familiar but ever difficult process of letting go, my heart goes out to them. But, as he already knows, and as is so evident in his beautiful tribute to his mother's life, as they always do, the memories will never cease to sustain us.

Let Fate do her worst, there are relics of joy,
Bright dreams of the past, which she cannot
destroy;

Which come, in the night-time of sorrow and
care,
And bring back the features that joy used to
wear.

Long, long, be my heart with such memories
filled,
Like the vase in which roses have once been
distilled,

You may break, you may shatter the vase, if
you will,

But the scent of the roses will hang round it
still.

Mr. LEAHY addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. LEAHY. Mr. President, I thank my dear friend from West Virginia. I have been privileged to serve with him for now 22 years, and I daresay that everything I have learned about the rules and protocol of this body I have learned from him. But I have learned far more than that.

I have learned from my good friend from West Virginia the special bond that Senators have. It really goes beyond party, or region, or anything else. And when my good friend from West Virginia, Senator BYRD, called me the weekend my mother died, when I was at my farmhouse in Vermont, his words touched me as a friend, as a Senator, as a colleague, and as one who knew my mother and knew my late father. His words were a great comfort to me and to my family at that time, as they are today.

He is right. There are times, of course, when we have to let go in our lives. I know the great tragedy that the Senator from West Virginia had in his own life more than a decade ago—almost a decade and a half ago now. I recall sitting in his office on a rainy evening once when we talked of that great tragedy. I could understand, not from a parental or grandparental feeling, but more through my own experiences as a prosecutor. I grieved for him, and I know how much he has grieved over the years since then. But I think he found during that time, and since, that it is his own friends and the words and thoughts of those friends

that helped him just as he helps me in this.

So I do thank him for doing that. I told my good friend from West Virginia that among my mother's possessions were letters that he had sent her on different occasions—birthdays, and whatnot. Among the things she had collected were speeches of his in the CONGRESSIONAL RECORD and poems that he had spoken.

He is the only person I have ever seen who is able to recite poetry of all types at great length with nary a note. She read those. And in the later years, when her eyes failed, I would read to her "The History of the Senate."

So, my friend, thank you.

I yield the floor.

Ms. MOSELEY-BRAUN. Mr. President, at the outset, I would like to add my sympathy and my condolences to my friend, Senator PAT LEAHY. I would not have known but for the eloquence of the Senator from West Virginia. Certainly, I know that all of us join in our thoughts and prayers at a very sad time.

(The remarks of Ms. MOSELEY-BRAUN pertaining to the introduction of S. 1911 are located in today's RECORD under "Statements on Introduced Bills and Joint Resolutions.")

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

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

CONDEMNATION OF TERROR ATTACKS IN SAUDI ARABIA

Mr. HELMS. Mr. President, I send a Senate resolution to the desk and I ask that it be stated.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows.

A resolution (S. Res. 273) condemning terrorist attacks in Saudi Arabia:

S. RES. 273

Whereas on June 25, 1996, a massive truck bomb exploded at the King Abdul Aziz Air Base near Dhahran, in the Kingdom of Saudi Arabia;

Whereas this horrific attack killed at least nineteen Americans and injured at least three hundred more;

Whereas the bombing also resulted in 147 Saudi casualties;

Whereas the apparent target of the attack was an apartment building housing United States service personnel;

Whereas on November 13, 1995, a terror attack in Saudi Arabia, also directed against U.S. personnel, killed five Americans, and two others;

Whereas individuals with ties to Islamic extremist organizations were tried, found guilty and executed for having participated in the November 13 attack;

Whereas United States Armed Forces personnel are deployed in Saudi Arabia to protect the peace and freedom secured in Operations Desert Shield and Desert Storm;