GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT OF 2001

The ACTING PRESIDENT pro tempore. Under the previous order, the Senate will now resume consideration of S. 812, which the clerk will report.

The legislative clerk read as follows:

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

Pending:

Reid (for Dorgan) amendment No. 4299, to permit commercial importation of prescription drugs from Canada.

Graham amendment No. 4345 (to amendment No. 4299), to amend title XVIII of the Social Security Act to provide protection for all Medicare beneficiaries against the cost of prescription drugs.

AMENDMENT NO. 4345

The ACTING PRESIDENT pro tempore. Under the previous order, there will now be 90 minutes for debate, equally divided, on the motion to waive the Budget Act with respect to the Graham amendment No. 4345.

The Senator from Massachusetts.

Mr. KENNEDY. Madam President, I yield myself 8 minutes.

The history of the American people is one of a never-ending journey toward the goal of a more perfect Union. Americans believe in the ideal of equal opportunity so that individuals can achieve their fullest potential. We also believe that we are members of a great national family which seeks to protect all of its members. We understand that if one of us is hurting, all of us are hurting.

In this quest for a more perfect Union, we have encountered and overcome obstacle after obstacle. At the turn of the last century, we passed antitrust laws to begin the long process of controlling corporate abuse and asserting that the public interest must take precedence over the selfish interests of wealthy corporations.

We passed minimum wage laws to assert that a worker's right to a living wage took precedence over business rights to maximize profits.

We passed the Social Security Act and the Medicare Act to guarantee a secure and dignified retirement to every American who works hard and pays into the system.

Just 2 weeks ago, we passed landmark legislation to curb the modern-day robber barons whose dishonesty and greed have done so much to damage our economy and to defraud so many workers and investors of their hard-earned savings.

Today, Americans face a crisis in health care. The miracle medicines that can save and prolong life more and more are beyond the reach of average Americans. The prescription drugs we need to stay healthy and alive are just too expensive, and their costs go up and up with each passing day.

For the last week, we have been grappling with two more obstacles to a more perfect Union and a better life for all of our people: The exploding costs of prescription drugs and the failure of Medicare to cover those costs. The rapid rise in the cost of drugs burdens families, businesses, and patients, and our economy.

For the last 6 years, prescription drug costs have been escalating at double-digit rates: 10 percent in 1996, 14 percent in 1997, 15 percent in 1998, 16 percent in 1999, 17 percent in 2000 and 2001.

It is unacceptable when older Americans struggle to afford their heart medicines and diabetes medicines. It is reprehensible when hard-working families are impoverished trying to pay for the drugs that keep their children in the classroom and out of the hospital, but it is intolerable when much of their burden has been created by the wealthiest corporations in America, the brand-name drug companies, deploying an army of lawyers, lobbyists, and campaign contributions to exploit and maintain loopholes in the law to block competition and unfairly boost prices.

Today, the Senate is on trial. We will vote on whether to end those abuses, and just as the Senate has voted resoundingly to close accounting loopholes abused by Enron and WorldCom, we must also close the loopholes in our drug patent laws that are exploited by big drug companies and are hurting patients each and every day.

Ending the abuses of the law that have contributed to escalating drug prices will help every family. But the most important step we can take in this Congress towards the goal of a more perfect Union is to act at long last to provide prescription drug coverage under Medicare.

Last week, the Senate failed to fulfill its responsibility to senior citizens and their families. This week, we have the opportunity and the obligation to do better and to provide a downpayment on our commitment to provide a prescription drug benefit in the Medicare Program.

Medicare is a solemn promise between our Government and our citizens. It says: Play by the rules, contribute to the system during your working years, and you will be guaranteed health security in your retirement years. Because of Medicare, the elderly have long had insurance for their hospital bills and doctor bills. But the promise of health security at the core of Medicare is broken every single day because Medicare does not cover the soaring price of prescription drugs. We can no longer ignore the sad fact that too many senior citizens are living in pain because they cannot afford prescription drugs.

Too many elderly citizens must choose between food on the table and the medicine their doctors prescribe. Too many elderly are taking half the drugs their doctors prescribe or none at all because they cannot afford them.

Senior citizens built our country. They fought in our wars. They created our economic growth and prosperity. They worked hard. They supported their families. They played by the rules. And they stood up for America. Now is the time for America to stand up for them.

Last week, a majority of the Senate voted for the Graham-Miller-Kennedy amendment, a comprehensive program to provide prescription drug coverage under Medicare and mend its broken promise. A minority stood against the seniors and with powerful special interests, but under the rules of the Senate that minority was able to block action. Just as the Republican Party opposed the creation of the Medicare Program in 1965, it opposed the enactment of a comprehensive Medicare prescription drug benefit today.

The Senate is once again confronted with a choice: Is our priority prescription drugs for the elderly or more tax breaks for the wealthy? Will we give senior citizens the same loyalty that they gave our country or will we continue to offer an open hand to the powerful special interests and the back of our hand to the elderly and their families?

Over the coming years, Americans will spend $1.8 trillion on prescription drugs. So far, our Republican colleagues have said no to amendments that would cover only a third of those costs. Yet under the Senate health plan, Senators have 75 percent of their prescription drugs covered. How many of us are willing to face our constituents when we go home in August knowing we have secure coverage for 75 percent of our drug coverage but we reject proposals that do even less for our fellow citizens?

The Graham-Smith amendment is a bipartisan compromise. It is not the comprehensive program that I want or that a majority of the Senate wants, but it is an important downpayment on the kind of program senior citizens need and deserve. Under this proposal, every senior citizen will receive assistance and those with the greatest need will receive the most help.

I ask that during the quorum call, the time be charged equally against both sides.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

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

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mr. KENNEDY. I yield 4 minutes to the Senator from Florida.

The ACTING PRESIDENT pro tempore. The Senator from Florida.

Mr. GRAHAM. Madam President, I have a somewhat longer statement I will deliver later, but at this point I

will indicate clearly to my colleagues what exactly we are going to be doing in approximately an hour and 15 minutes. We will be voting on waiving the point of order that we anticipate will be raised against this amendment based on noncompliance with the budget resolution.

Let's look at a few facts. In 2001, the Senate established, as the amount of money to be expended for a prescription drug benefit for 10 years, from 2001 to 2011, the number of $300 billion. That is the last budget resolution the Senate has enacted. The Senate Budget Committee, in 2002, reexamined what would be required for an adequate prescription drug benefit, and they recommended up to $500 billion, but that resolution has never been adopted.

So 18 months later, we are being constrained by a $300 billion number, which has been found to be inadequate by the Budget Committee. The irony is that both the Republican proposal, the proposal of Senator GRASSLEY and others, and the Graham-Smith proposal have a total expenditure of $400 billion minus. There is probably not a 2- or 3-percent difference in the amount of money the Grassley bill and the Graham-Smith bill have found to be necessary in order to provide our seniors an adequate prescription drug benefit.

The issue of whether we are going to need to waive the Budget Act in order to get to the substance of this issue is one upon which both sides have agreed. So why do we not say yes, we have agreed that it is going to take more than $300 billion to have an adequate prescription drug benefit? Let's vote today to waive the Budget Act, and then we can have the full debate with amendments and all of the means by which Members of the Senate can express their specific policy positions on a variety of issues on this complex subject. If we cannot get past the Budget Act, the whole effort to provide 40 million Americans with some better access to a key component of their life and health will be again, for the seventh straight year, denied.

I do not believe that is the record this Senate wants to go on. Let's have a vote to do what we have all agreed—that it will cost more than $300 billion to provide a benefit. Then let's move on to a discussion that justifies the title of this institution as being the world's greatest deliberative body. Let us deliberate. Let us not quibble over the issues of dollars for which there is no quibbling because we both agree as to what it is going to cost to provide this benefit.

This is the last opportunity we are likely to have in 2002 to provide America's seniors this benefit. A vote against waiving the Budget Act is a vote for another year of denial. It is also a vote that when we come back next year, we are not going to be talking about the $400 billion that both sides have now agreed is necessary, we are going to be talking about a substantially higher number because of another year of prescription drug inflation and another year of that baby boom surge of entrants into the Medicare Program.

If we think it is difficult today to vote to provide a prescription drug benefit, be assured it will be only more difficult every year into the future.

I urge my colleagues to look at the reality of what we are doing and at least vote to waive the Budget Act so we can get on to a full debate on this issue.

Mr. KENNEDY. Madam President, I yield 10 minutes to the Senator from Oregon.

The ACTING PRESIDENT pro tempore. The Senator from Oregon.

Mr. SMITH of Oregon. I thank Senator KENNEDY, the manager of this bill, and my cosponsor of this legislation, Senator GRAHAM, for the time.

I say to the American people, what few may be up this morning watching these proceedings, that this is probably our last best chance to pass prescription drugs in the 107th Congress, and I think it is critical we do so.

I am optimistic we are going to succeed, but if we do not, it will be because of that old maxim that the perfect is the enemy of the good. What Senator GRAHAM and I have is the best we can produce for the greatest number of people, particularly the neediest, but for everyone in terms of discount cards and in terms of a catastrophic coverage. We have the best we can do with the financial constraints faced by this Government.

We have produced a plan that is affordable for seniors and it is affordable for the U.S. Government. It is a plan at a minimum that we ought to pass.

I thought what I would do in my remarks today was to try to give a comparison between our bill and the competing bill. Both of these bills can work. I have, in fact, voted for a version of the Grassley-Breaux bill. However, I am now on this bill because I think this is more in the realm of what is possible and workable.

I will spend some time focusing on the health and financial security aspect, which is what is available to every American under our plan who is under Medicare, and then focus on the sickest and the poorest, the protection for the most vulnerable in our society. Let me start first with the most vulnerable in our society.

Let's compare the low-income benefit. Under Grassley-Breaux, the low-income folks are covered at 150 percent of poverty; under the Graham-Smith bill, people 200 percent of poverty are covered. Under Grassley-Breaux, it includes an assets test which will drop 40 percent of otherwise income-eligible elderly; under Graham-Smith, there is no asset test. Under their proposal, beneficiaries below 200 percent of poverty can pay up to $3,700 due to copays, deductibles, and premiums. Under ours, beneficiaries out of pocket are limited to drug copays of $2 for generic and $5 for brands. That is an enormous difference in terms of what they will have to pay and who will be included.

Under their plan, they provide more limited coverage than some elderly get in current employer programs or State pharmacy assistance programs. Under our plan, coverage for low-income elderly is as comprehensive as State pharmacy assistance programs. CBO estimates that no employer will drop coverage because of what we have.

As to the catastrophic limit, their proposal kicks in at $3,700. Our proposal kicks in at $3,300, a very big difference, a 12-percent difference. That matters a great deal at the low end of the economic scale in our country.

Some may say this does not cover enough people. Let me give a few examples of a few States and how much this plan helps. These are percentages of people in various States falling below 200 percent of poverty: In Vermont, 42 percent of their elderly fall below that; in the State of Mississippi, 46 percent; in the State of Maine, 37 percent; in the State of Ohio, 41 percent; in the State of Nevada, 41 percent; the State of Illinois, 41 percent also; the State of Nebraska, 43 percent; the State of Iowa, 38 percent; in the State of Louisiana, 52 percent; in the State of Indiana, 46 percent; in the State of Alabama, 56 percent; in the State of Pennsylvania, 43 percent; and the State of Rhode Island, 48 percent.

These are dramatic numbers. There is hardly a State in the Union that falls below 40 percent of people who will be covered 100 percent by the Graham-Smith proposal. That is significant. That is an incredible start on a prescription drug program.

Let me turn to the health and financial security aspects and compare both bills. The premiums and fees: Under Grassley-Breaux, the elderly will pay $288 per year or more. The premiums imposed are imposed monthly, despite periods when the beneficiary receives no benefit. Unknown premium amounts that can vary by area dramatically, year by year. Under ours, there is no monthly premium.

Now to the deductible. Under theirs there is a $250 per year deductible. Under Graham-Smith there is no deductible.

Universal coverage: Under Grassley-Breaux, only low-income and those choosing to pay monthly premiums are covered. Under ours, all seniors and covered disabled are covered after a $25 annual fee.

As to employer coverage and crowding out private plans, the CBO estimates a third of current employer benefits will be dropped if Grassley-Breaux goes through. They estimate that under the Graham-Smith proposal all seniors and disabled will be covered, and they estimate no loss of current employer coverage. I think that is terribly significant. Ours overlays the existing program much better than the Grassley-Breaux proposal.

Now as to guarantee of current coverage levels: Under Grassley-Breaux,

some low-income elderly would receive reduced coverage than under the current State pharmacy programs. But under ours, low-income elderly are guaranteed a comprehensive benefit with a nominal cost sharing. CBO estimates under Grassley-Breaux one-third loss of current employer coverage, and coverage could be far worse than the elderly currently receive. CBO estimates under ours, no loss of current employer coverage.

Now, the stability of the delivery system. Grassley-Breaux imposes an untried and untested insurance model on our Nation's elderly and disabled and results in employer crowd-out. I assume this insurance program in the private sector could be developed, but it does not exist right now. So we are betting that it can be developed and that people would like it.

In the State of Oregon, if you ask how they like their private insurance, it is not much; they do not like it much. While they complain about Medicare, they certainly want us to support it.

Then on this issue of a stable delivery system: Senator GRAHAM and I build upon current State and market-based delivery models, and we do not result in an employer crowd-out. What is the overall cost? The Grassley-Breaux approach is scored at somewhere between $375 and $400 billion over 10 years. Ours is scored at $390 billion over 10 years. So they are comparable in that regard.

I conclude my remarks by saying we will hear this morning about the ''cliff''—that after 200 percent of poverty the people do not get anything; if you make $24,000 as a couple, you fall off a cliff. I wish we had a more graduated program, I grant that. There are many things about what Senator GRAHAM and I have that I would change if I could, but I can't, and get something passed and into conference. So let's start here.

Let me simply say to those who would describe this as a cliff, that you get nothing if you make more than $24,000 a year, to me it is not nothing to say that for $25 a year you get a discount card that, at a minimum, gives you 5 percent off all your prescriptions, but probably, because you get the benefit of pricing discounts, you get as much as 30 percent off every prescription drug, and, moreover, you add to that the fact that you never have to worry again as a senior in America that when you lose your health, you have to lose your home—you do not have to choose between food and medicine. That is significant. Tell me where in the private sector you can find an insurance policy that, for $25 a year, will do all of that.

Have we done enough? No. Have we done a tremendous amount of good? Absolutely.

I plead with my colleagues to vote to waive this point of order. We should not fail today. We should get this to the floor. People have ideas. We can perhaps make it better. But we can get on with the business that the seniors and citizens of this country are expecting. Let us get beyond the war of words and get to a prescription of wellness for the seniors and provide them a benefit that is workable, tried and true, affordable for them and our Government.

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Tennessee.

Mr. FRIST. Madam President, I yield myself 10 minutes, to be followed by the Senator from Maine, 10 minutes.

Madam President, I rise in opposition of the Graham drug Medicare proposal. I will make four points regarding my opposition in the few minutes I will speak.

The first point is, the bills we are considering on the Senate floor have not gone through the committee process. That is important for the American people to understand. It makes it incredibly challenging to receive an amendment yesterday such as this and having the opportunity only to read it for the first time. This legislation is very complicated.

In looking at the this bill compared to the bill passed by the House of Representatives, the tripartisan proposal or the bi-partisan Hagel-Ensign bill, the major substantive objection I have is that the bill costs more and yet fewer people benefit.

We do have huge gaps of coverage. We have huge gaps in terms of being able to look seniors in the eye and say, yes, we understand your problem is affordable access to prescription drugs, and then walk away because they don't fall into the category. There are cliffs and gaps and chasms, and these vacuums exist for that individual who falls into one of these gaps or chasms because we do not cover everybody in the sense of addressing their problem; that is, health care security for prescription drugs.

Of all the bills we have considered, this is not really a compromise bill. It is a very different bill that costs more and covers fewer and fewer people.

The tripartisan comprehensive plan the Senator from Maine put on the table—and we will hear from her shortly, along with Senators GRASSLEY and BREAUX and JEFFORDS is a much more comprehensive bill that I argue gives more secure comprehensive coverage and helps a broader swathe of people. If you look at individuals with disabilities, it doesn't have these categories of exclusion. Where there are some areas that you do not get as complete coverage, it is gradual, and you do not have these cliffs, these drop-offs. If you make one dollar more, all of a sudden you do not get the coverage.

In terms of how many people are covered, it is hard to factor it out. We have about 38 million Medicare beneficiaries, seniors and individuals with disabilities around this country. Of the 38 million, there are an estimated 18 million who are above 200 percent of poverty. We heard yesterday and last night about this drop-off, this cliff. Once you get to 200 percent of the poverty level for an individual or for a couple, all of a sudden you do not get benefits. There is a huge hole, a huge chasm, a gap that is there, this drop-off. Above 200 percent you get a minimum benefit of 5 percent. That does not give me the security to look in somebody's eye and say we are really helping you. We need to make affordable access to prescription drugs, which is our goal, a reality.

Only about 2 million of those 18 million will ever qualify for the catastrophic benefit. So you have 18 million above the cutoff level of 200 percent of poverty with very minimal benefit. But people say: Yes, for catastrophic coverage they will be helped. At the end of the day, only 2 million out of the 18 million will fall into that catastrophic category, again leaving essentially no benefit for 16 million seniors today.

I think it is important for our seniors to understand. I do not want to leave this body 2 days from now saying we passed prescription drugs, we took care of your problem, you will have affordable access to prescription drugs—which seems to be the implication. It has been said that we cannot leave here on recess without passing a package. This package is a shell, and it does not give seniors affordable access to prescription drugs.

If we pass it, we are not being honest going home saying we passed a real prescription drug package. It costs more, covers fewer people than what we have had on the floor, what we have been discussing. If we go back to the Finance Committee, I think we can come up with a very good bill. Under this bill, at least 15 million to 16 million seniors are left behind. That is, they do not get a substantial benefit; they only get that 5-percent discount. Fifteen million to 16 million people we are leaving behind.

Second, I think from our standpoint it is irresponsible to pass a bill and pretend we are doing something that we are not really doing when we have alternatives. If we did not have alternatives, we could say this is our best shot, and we can build on it in the future. But, really, the two bills that came to the floor each had different approaches. The initial Graham bill was much more Government run. The tripartisan bill involved the public and private sector, but both of those bills had more comprehensive coverage. For the seniors who are listening, for the dollar value, they had more benefits than the bill before us today. Therefore, we should not, by default, end up passing a bill today just to say that we have passed something.

Politically, people might be able to claim a victory saying we passed prescription drugs, but this particular bill never addresses the ''affordable'' problem, affordable prescription drugs.

The response to that is we are taking a good first step, and we have to do something. If we do something, maybe

we can work on it later. If we knew what that ''later'' was, I would say yes, we should have a one-two punch and come back. I have a great deal of confidence if we pass this, we will not come back and visit this in September or October and put together a truly comprehensive plan. We are not addressing the fundamental problem of seniors not being able to afford lifesaving drugs.

The third point I want to make is this bill fails to recognize that prescription drugs are, and need to be, considered a part of the overall modernization of Medicare. Yes, I admit all the bills we have considered over the last 2 weeks have not fully addressed the fact that prescription drugs need to be a part of the full armamentarium of what a physician has to deal with, what a hospital has to deal with, that doctor-patient relationship and outpatient care.

We are treating prescription drugs sort of on the outside, as if it is an appendage to Medicare, without in any way addressing the fundamental problems of Medicare. In truth, the sustainability, long-term, of whatever we promise—whether it is acute or long-term or preventive care—has to be part of a more comprehensive approach which we addressed. I mention that because the tripartisan bill, of all the bills we mention on the floor, is the only one that is health care security for our seniors, like the surgeon's knife, like acute care, chronic care, or preventive medicine. Remember, the tripartisan bill costs $370 billion, and the more limited bill we are considering on the floor is even more than that because the tripartisan bill at least reached out and said we understand prescription drugs are a part of overall Medicare. This bill does not address that. It has no element of modernization at all.

Thus, I think the bill on the floor, of all the bills we have considered, is the least effective in accomplishing what seniors expect. It does not guarantee seniors comprehensive prescription drug coverage. It locks into place a limited stopgap proposal. Everybody says this is not the answer but this is sort of a stopgap, something to do now. But it locks it in place at a far higher cost than it needs to. The taxpayers are paying for this—the people who are listening to me now. It is, my colleagues, constituents. All over the country, people are paying into this as taxpayers. So we need to give them an effective product as we go forward. The product itself, I think, is insufficient.

As I mentioned, it leaves a gaping hole in coverage. This is my final point. We have talked about doughnuts earlier in the debate. All last week we talked about a doughnut, which is a gap of people who simply do not get the benefits that other people get. This has a much larger gap than, again, any other bills; than the tripartisan proposal or the proposal that passed the House of Representatives, for example, several months ago.

It fails to provide Medicare beneficiaries with either an effective drug prescription benefit or some of the other much needed improvements that are present in the tripartisan bill.

I will close by simply saying that I think at this juncture the most prudent thing to do is to table this bill because of the reasons I have outlined and to recognize we have made huge progress compared to even a year ago. It was 3 years ago that we had the Medicare Commission. It basically proposed a public-private approach. That approach has been built upon by a series of bills. We have made great progress over the last 2 weeks. The Medicare debate is on the floor. People have talked about it. We recognize deficiencies. We recognize some advantages in some of the bills. I think the best thing to do is to go back through regular order that is usually in this body, and that is to go through the Finance Committee.

Let that process, based on what we know and what we talked about today, work so we can have that particular debate, and move forward.

I will be voting against this bill. I will be voting, if there is a point of order, to table the bill. I will support that, and I encourage my colleagues to do so.

I yield 15 minutes to my colleague from Maine.

The PRESIDING OFFICER (Mr. EDWARDS). The Senator from Maine is recognized.

Ms. SNOWE. Mr. President, I thank the Senator for yielding me the time.

I concur with what has just been suggested by the Senator from Tennessee in terms of returning to the regular process so that we can go back and resume the negotiations and discussions that were well underway over the course of the weekend with Senators from across the aisle—Senators KENNEDY, BAUCUS, and WYDEN—even through Monday to reach an agreement that would provide for comprehensive coverage for Medicare beneficiaries.

There is no reason we cannot have that discussion to develop the kind of plan that seniors deserve in the Medicare Program.

As I said yesterday, we should not have this vote. Why entrench and polarize both sides on this issue? Why make it more intractable? Why not go back and begin the process of negotiations that were well underway using the tripartisan plan as a basis? It provides comprehensive coverage. There is no reason we can't begin that process. This doesn't have to be the last vote.

With the Medicare give-back in the fall, we have an opportunity during this interim to begin this process anew so that we can achieve and craft a comprehensive plan that seniors need and deserve.

Looking over this proposal, there are many troubling features. I think that we ought to deal with the facts.

First of all, the proposal before us today, if you had told me more than a year ago—as the tripartisan group with Senator BREAUX, Senator JEFFORDS, Senator GRASSLEY, Senator HATCH, and myself, as members of the Senate Finance Committee invited all members of the Finance Committee to participate in this process—if somebody told me when we embarked on this legislative odyssey that somehow we would be considering in a serious way today a proposal that abandoned the basic precepts that had been the underpinning of the Medicare Program since its creation 37 years ago yesterday when President Johnson signed into law the Medicare Program—we never contemplated or considered during the course of this last year when we developed that tripartisan plan that we would abandon universal coverage. We never contemplated abandoning the ability to pay and resorting to a means-test program that is now before the Senate—a means-test program that places the low-income benefit in the Medicaid Program—not Medicare, in the Medicaid Program.

These are huge departures from the principles that we have embraced here in Congress year after year. In fact, the vote last week, with 97 votes on both sides of the aisle, was for the original plan that we were embracing for universal coverage—the principles that AARP and the major organizations representing seniors in America have always and consistently embraced for the 37 years of Medicare existence. Now the proposal before us abandons all of those principles.

It most certainly doesn't advance or improve the prescription drug debate. In fact, the bill before us today has not had the advantage of scrutiny by the Congressional Budget Office because the language of this amendment specifically has not been reviewed by the Congressional Budget Office in order to prepare a cost estimate on the proposal. I think we should understand that from the outset.

There is no certainty because the language in this legislative initiative has not been reviewed by the Congressional Budget Office. Are we to have confidence in the process and the Congressional Budget Office when the analysts have not even had the text of the amendment? We are creating a new Federal program at a cost presumably of a minimum of $400 billion without knowing the true fiscal impact of this legislative proposal.

Here is my first chart. One of my first major concerns about this initiative before us, which I think all Members of the Senate should readily understand, is that most seniors do not get a basic drug coverage under this plan because it is not a universal benefit. I think that needs to be understood.

The Graham proposal does not offer a basic drug benefit for 70 percent of seniors who have incomes above $17,720 for an individual and $23,880 for a couple. This is according to the AARP data: The number of seniors who have incomes above 200 percent of the Federal

poverty level. Seventy percent of seniors above 70 percent would not get basic coverage. They will have to spend $3,300 before they get any basic coverage. That is an important point.

In fact, in the New York Times the other day there was an op-ed piece written by the Urban Institute—that is not a conservative think tank—discussing the fact that most individuals usually have drug expenses between $2,000 and $3,300; and that many people are spending in that middle range, particularly on chronic illnesses such as high cholesterol, high blood pressure, and arthritis. But with a low-income catastrophic approach, that will provide very little help for most Medicare recipients with chronic illnesses. The chronically ill cannot get enough help under this type of an approach.

Under our legislation, 80 percent would even exceed our benefit limit of $3,450, and we had a catastrophic coverage of $3,700.

But the point here is that it now is 70 percent. In all States across the country, seniors are left behind.

I heard this morning about how many seniors will be covered. But let us look at the other side of that equation and who won't be covered.

If you look at these statistics, it is staggering. It is 71 percent in Maryland. In Oregon, 51 percent of seniors will be left behind. In my State of Maine, they will not get a basic drug benefit under this proposal; neither will 50 percent in Virginia, 67 percent in Arizona, 51 percent in Arkansas, 66 percent in Missouri, 72 percent in Washington, 64 percent in Iowa, 70 percent in Colorado, and 52 percent in Montana. These seniors will not get a basic drug benefit under the Graham plan because they earn at least $1 over the strict income limit for the comprehensive coverage offered to low-income seniors.

Only those seniors with incomes below 200 percent of the Federal poverty level obtain real prescription drug coverage under the Graham plan.

Let us look at chart 3. It is not a comprehensive benefit because it guts the most important part of any drug benefit program; that is, basic coverage. There is a huge gap. We were criticized for our gap between $3,450 and $3,700. But this is a canyon in terms of gap in coverage. You have no coverage from basically zero to $3,300 in out-of-pocket drug expenses—zero.

Seniors above 200 percent will have to spend $3,300 before they receive any coverage at all. According to the Congressional Budget Office, two-thirds of seniors will not have prescription drug costs even has high as $3,000 or $2,500. That means that most of the 26 million Medicare beneficiaries with incomes above 200 percent of the Federal poverty level would never spend enough to receive any coverage—no coverage at all. It is not a comprehensive benefit.

What about the 125 percent of seniors who will spend $4,000 annually on prescription drugs? They will not have any coverage for their prescription drug costs until about Thanksgiving Day after 10½ months with no coverage at all—no coverage at all for 10½ months.

I am told that under this plan most seniors will only get a 35-percent discount off their drug costs through the Government-managed plan until they spend $3,300 a year.

Private drug coverage plans get significantly larger discounts, anywhere from 20 to 40 percent, compared to a benefit such as this. I know the author of this amendment, Senator GRAHAM, claims seniors will get up to a 30-percent discount, but I challenge him to show me where it says that in this legislative initiative we are considering in the Senate. It is not in this legislation. And study after study has shown that discount cards, such as the one offered for seniors in this coverage gap, do not offer discounts that high.

What the typical senior actually gets from this plan is about $6 a month in help with drug costs. So the total annual benefit will be $72. What about the senior, as we said earlier, who is spending $2,000 to $3,000? They will get no coverage other than maybe this average of 5 percent off on discounted drugs, which will average about $6 a month.

This does not offer a Medicare drug benefit, in all reality, in the Medicare Program. This program would, in reality, be administered by the State Medicaid Program. This means the States will experience a huge unfunded Federal mandate in the Graham plan because they are required to pick up a large share of the cost of this new program.

An analysis conducted by the Centers for Medicare and Medicaid Services of the costs passed on to the States by this Graham amendment shows that many States across this country will be required to shoulder a sizable new financial burden.

Let's just talk about a few of the States hardest hit. I have a list of them, but I will go through a few: Arizona, Arkansas, California, Colorado, Iowa, Louisiana, Montana, Oregon, South Dakota, Washington, West Virginia.

Do you know what the annual impact will be on States, just in 1 year alone, based on our up-to-date analysis of the impact of this legislation? It is $5 billion in 1 year—$5.189 billion in 1 year—as an unfunded mandate on the States, for a grand total of $70 billion over 10 years. That is $70 billion over 10 years in an unfunded mandate to the States as a result of this low-income benefit now being placed, for the first time, in the Medicaid Program, not Medicare.

States, that as we all know are struggling in a sea of red ink, will be forced to raise taxes to implement the drug benefit for low-income seniors. Ironically, this new unfunded mandate will create a new funding crisis for States that we just tried to correct with the Rockefeller-Collins amendment last week, which was designed to give emergency Medicaid funding to States so they are not forced to cut their existing health care programs. I might add, that was returning to the States $9 billion for a year and a half. We are talking about an unfunded mandate, in 1 year, of $5.1 billion, and $70 billion over 10 years, to the States.

I might also say, this plan penalizes low-income seniors who earn extra income because it could mean they could lose their drug coverage. Only those beneficiaries who earn up to $17,720 for an individual and $23,880 for a couple will get comprehensive coverage, as I mentioned earlier. Any individual beneficiary who earns $17,720, plus $1, or a couple who earns $23,880, plus $1, gets no coverage. They are left to spend 18 percent of their income for prescriptions.

Just 2 years ago—another irony here—we passed legislation, in March of 2000. The Senate voted 100 to 0 to repeal the Social Security earnings limit. Yet here we are today considering a plan that would effectively establish a new earnings limit almost identical to one we repealed. Here is another contradiction in legislative policy.

So now we are going to penalize low-income seniors if they want to earn more money. Now we are creating a penalty——

The PRESIDING OFFICER. The Senator has used 15 minutes.

Ms. SNOWE. We are now creating a penalty on prescription drug coverage.

May I ask unanimous consent for 2 more minutes.

Mr. FRIST. I yield an additional 2 minutes to the Senator from Maine.

The PRESIDING OFFICER. The Senator from Maine.

Ms. SNOWE. Thank you, Mr. President.

That is an important point, that we are now creating this type of penalty for low-income seniors, because if they earn $1 more, they lose their prescription drug coverage.

Finally, employer-sponsored plans, labor-union sponsored plans, will be penalized under this legislation. There will be a disincentive for employers and labor unions to continue their coverage. You might ask, why? I will answer that question. Because now, under this legislation before us, they have revamped the standard for how you calculate your out-of-pocket cost for the catastrophic level of $3,300.

These plans will not be counted toward the out-of-pocket costs. So employers will not have an incentive to continue these programs. And certainly employees would not want to because they would not want to lose their coverage. Labor unions will drop their plans. So that is another disincentive.

Now 23 percent of retirees have such coverage. We do not want to create a disincentive for the continuation of those programs. But that is exactly what this Graham proposal will do that is before this Senate today. That is

why I am urging my colleagues not to support this initiative. Allow us to go back to where we were on Friday, continuing the discussions we were holding across the aisle with our tripartisan group, with Senator BREAUX, Senator JEFFORDS, Senator GRASSLEY, Senator HATCH, Senator BAUCUS, Senator KENNEDY, Senator WYDEN, and others, so that we can have a comprehensive plan for all Medicare beneficiaries, with universal coverage that the AARP and all of us have embraced for the last 37 years with the existence of the Medicare Program.

This isn't the last vote. This can be the beginning. And I cannot imagine this Senate, in September, considering a Medicare give-back to providers and not considering a prescription drug program for our Nation's seniors. They deserve better. And we can do better.

Mr. President, I ask unanimous consent that the following material be printed in the RECORD.

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

[From the New York Times, July 29, 2002]

FINDING A FORMULA FOR MEDICARE DRUG BENEFITS

(By Marilyn Moon)

Washington.—The political debate over how to add a prescription drug benefit to Medicare has dragged on now for more than four years. Prescription drugs have become an integral part of health care delivery, but unlike insurance for most working families, the Medicare program for older and disabled people provides almost no drug coverage. Politicians from both parties know they have to do something, but the hurdles are big: money and control.

The debate in the Senate is still ongoing. But large differences along party lines remain, and the Republican House plan that was passed on a party line vote in June makes hopes for compromise remote given the desires of consumers for broad coverage and of drug companies for minimal government controls.

The sums needed are enormous; over the next 10 years, Medicare beneficiaries are expected to spend $1.8 trillion for drugs. Thus, while the Senate Republicans' top offer of $370 billion over eight years is a lot of money, it represents only a bit more than one-fifth of drug spending over that period. The Republican plans contain big gaps in coverage and allow restrictions on what drugs will be covered. Democrats offer more coverage, but at a cost of $500 billion or more.

Since all proposed plans would be voluntary, those who spend relatively little on prescriptions need to be wooed into participating with the promise of receiving some benefits. Otherwise, only high users will enroll and any program will become very expensive over time.

All the competing plans offer generous coverage above a certain level of spending for those with catastrophic expenses. The differences arise in how to treat people who spend below the catastrophic level but still spend several thousand dollars annually on drugs. The Senate Democratic proposal requires beneficiaries to pay a portion of the costs, up to $4,000 a year. Beyond that limit, all drug costs are covered. But under the House Republican plan individuals must pay 100 percent of their drug expenses between $2,000 and $5,300.

Increasingly, many people on Medicare are ending up in this middle spending range, particularly those who take one or more drugs every day for a chronic condition. Drugs for such common ailments as hypertension, high cholesterol and arthritis cost $1,200 to $1,500 a year, creating a substantial financial burden for the chronically ill.

A viable compromise is to offer comprehensive coverage for those with low incomes and catastrophic help for all other beneficiaries, an approach that seems to be gaining favor in the Senate. But this plan would still cost about $400 billion, while providing little help for most Medicare recipients with chronic illnesses.

Money accounts for only part of the differences between the two parties. A big disagreement is over how the benefit is structured—and the precedent it sets for Medicare's future. The Democratic approach basically would have Medicare pay for drugs the way it now pays for hospital and physician benefits. Republicans want instead to have the benefit offered by private insurers. Compromise on this ideological question is especially difficult.

The Democratic approach is simpler and relies on Medicare's well-tested structure. But drug manufacturers, fearing that Medicare would impose price controls on drugs, are strongly opposed to enlarging Medicare itself to cover drugs.

Supporters of a private insurance structure argue that only competition among plans can achieve substantial control over rising prescription drug costs. But this theory has not been proved in other contexts. The private managed-care option in Medicare, for example, has raised costs to the federal government. Meanwhile, many Medicare recipients have had to suffer with plans that cut benefits or, worse, are withdrawn altogether because the companies offering them have quit the Medicare program entirely for lack of profits.

A privately administered drug benefit would be particularly problematic. If private insurers carry the risk for drug costs, they will probably structure their plans in ways that put high users of drugs at a disadvantage. For example, they can establish a list of preferred drugs (a formulary) and either not cover certain drugs or charge more for drugs that are not on the list. There are, for example, many anti-cholesterol drugs, but a formulary may not include the drug that works best for a particular patient. Consumers who need many drugs are likely to find it hard to decipher which medications the plans will cover and at what cost.

Ultimately, lawmakers and the rest of us must decide whether we trust government to deliver a new drug benefit effectively. What we do know is that the need for drug coverage is too great to let this issue remain unresolved.

SENIORS LEFT BEHIND BY THE LATEST GRAHAM PLAN

	Percent
Alabama	57
Alaska	68
Arizona	67
Arkansas	51
California	66
Colorado	70
Connecticut	70
Delaware	69
District of Columbia	61
Florida	64
Georgia	69
Hawaii	73
Idaho	61
Illinois	67
Indiana	65
Iowa	64
Kansas	68
Kentucky	50
Louisiana	51
Maine	61
Maryland	71
Massachusetts	64
Michigan	66
Minnesota	66
Mississippi	47
Missouri	66
Montana	62
Nebraska	55
Nevada	64
New Hampshire	65
New Jersey	65
New Mexico	60
New York	57
North Carolina	57
North Dakota	52
Ohio	64
Oklahoma	56
Oregon	66
Pennsylvania	62
Rhode Island	54
South Carolina	58
South Dakota	59
Tennessee	56
Texas	56
Utah	72
Vermont	59
Virginia	62
Washington	72
West Virginia	58
Wisconsin	65
Wyoming	60

State	Current Medicaid drug coverage (% of Poverty)	State share of costs of expanding Medicaid drug coverage (Percent of benefit cost)		Mandated state expenditures to pay for expanding Medicaid drug coverage in 2005		Total cost of new Medicaid mandate to states in 2005
		From current level of drug coverage to 120% of poverty	From 120% to 150% of poverty	New state mandate to cover up to 120% FPL (state portion of costs)	New state mandate to cover 120–150% FPL (state portion of costs)	
All States				$3,464,769,443	$1,725,226,680	$5,189,996,123
Alabama	74	29.4	20.58	71.839,488	27,330,240	99,169,728
Alaska	74	41.73	29.21	3,992,726	1,518,920	5,511,646
Arizona	74	32,75	22.92	46,279,680	17,602,560	63,882,240
Arkansas	74	25.72	18	39,374,234	14,976,000	54,350,234
California	100	50	35	242,560,000	212,240,000	454,800,000
Colorado	74	50	35	47,472,000	18,060,000	65,532,000
District	100	30	21	3,168,000	2,772,000	5,940,000
Georgia	74	40.4	28.28	110,017,280	41,854,400	151,871,680

State	Current Medicaid drug coverage (% of Poverty)	State share of costs of expanding Medicaid drug coverage (Percent of benefit cost)		Mandated state expenditures to pay for expanding Medicaid drug coverage in 2005		Total cost of new Medicaid mandate to states in 2005
		From current level of drug coverage to 120% of poverty	From 120% to 150% of poverty	New state mandate to cover up to 120% FPL (state portion of costs)	New state mandate to cover 120–150% FPL (state portion of costs)	
Hawaii	100	41.23	28.86	7,388,416	6,464,640	13,853,056
Idaho	74	29.04	20.33	11,114,189	4,228,640	15,342,829
Iowa	74	36.5	25.55	40,027,360	15,227,800	55,255,160
Kentucky	74	30.11	21.08	59,169,763	22,513,440	81,683,203
Louisiana	74	28.73	20.1	61,109,859	23,235,600	84,345,459
Mississippi	100	23.38	16.37	17,132,864	14,994,920	32,127,784
Montana	74	27.04	18.93	8,358,605	3,180,240	11,538,845
Nebraska	100	40.42	28.34	11,640,960	10,202,400	21,843,360
New Hampshire	74	50	35	19,872,000	7,560,000	27,432,000
New Mexico	74	25.44	17.81	26,026,138	9,902,360	35,928,498
North Dakota	74	31.64	22.15	11,876,390	4,518,600	16,394,990
Ohio	64	41.17	28.82	200,672,461	62,712,320	263,384,781
Oklahoma	74	29.44	20.61	45,069,107	17,147,520	62,216,627
Oregon	74	39.84	27.89	41,930,803	15,953,080	57,883,883
South Dakota	74	34.71	24.3	9,707,693	3,693,600	13,401,293
Tennessee	74	35.41	24.79	84,961,338	32,326,160	117,287,498
Texas	74	40.01	28.01	315,086,752	119,882,800	434,969,552
Utah	100	28.76	20.13	4,877,696	4,267,560	9,145,256
Virginia	80	49.47	34.63	108,596,544	47,512,360	156,108,904
Washington	74	50	35	93,472,000	35,560,000	129,032,000
West Virginia	74	24.96	17.47	27,188,429	10.342,240	37,530,669

NEW GRAHAM BILL IMPOSES BILLIONS IN UNFUNDED STATE MANDATES THROUGH MASSIVE MANDATORY MEDICAID EXPANSION

Why does the bill increase Medicaid cost for many states?

The bill mandates a major expansion of a form of Medicaid to provide prescription drug coverage. It creates a new category of Medicare-Medicaid ''dual eligibles,'' who qualify for drug coverage if they meet the means test requirement in the bill. States, through their Medicaid programs, are required to determine low-income eligibility and to pay the enrollment fee and most of the drug costs for beneficiaries with incomes below 200% of poverty. Low-income beneficiaries are responsible for paying a $2 copay for generic drugs and $5 for brand name drugs; the new drug benefit picks up all the rest of the costs. This is a comprehensive drug benefit, estimated to cost around $3200 per beneficiary on average in 2005. The Federal government pays for the Medicare portion of the benefit. But most of the cost of this comprehensive benefit must be paid through Medicaid. This is because the Medicare benefit is a limited one: Medicare covers only 5 percent of the cost of drugs up to the catastrophic limit of $3300, then provides catastrophic coverage with a $10 copay. Thus, state Medicaid programs must pay at least two-thirds of the cost of the drug benefit, around $2000 per beneficiary in 2005. This is a conservative estimate of Medicaid benefit cost, and it will increase rapidly over time.

The Federal government pays only part of the cost of the Medicaid benefit, based on the state's Medicaid FMAP rate and enhanced FMAP rate:

Percent of Poverty Rate	Medicaid Category	Required State Contribution
0–74	Truly Dually	Normal Medicaid Match
75–100	QMB's	Normal Medicaid Match
100–120	SLMB's	Normal Medicaid Match
120–150	Drug QMB1	Enhanced (SCHIP) Match
150–200	Drug QMB2	100% Federal Match

While all states have comprehensive Medicaid drug coverage up to 74 percent of poverty, many states do not have coverage up to 150 percent of poverty. States that currently do not provide comprehensive drug coverage up to 150% of poverty through either Medicaid or a state drug assistance program up to 150% are thus required to pay for a significant portion of the cost of comprehensive drug coverage. The cost of the new mandate depends on how many beneficiaries in the state currently do not have comprehensive coverage. The costs also increase rapidly over time, because drug cost are rising rapidly.

How much must your State pay?

The overall cost of this mandate to states in 2005 will exceed $5 billion, and may be much more. Over the 10-year budget window, the cost of the Medicaid mandate to the affected states will exceed $70 billion—about 14 times the 2005 costs. The attached table shows states that definitely will pay hundreds of millions more because of this proposal. Additional states may also face higher costs, if they do not already provide comprehensive drug benefits up to 150 percent of poverty.

NO HELP FOR RETIREES WITH EMPLOYER OR UNION COVERAGE FROM GRAHAM

Retirees with decent coverage from a union or employer do not incur actual drug costs out of their own pockets above $3,300, as they would have to in order to benefit from the Graham amendment. So this benefit provides nothing for them.

The Graham bill supporters note that ''no employers drop'' coverage as a result of their bill. This is because the benefit is so paltry.

In contrast, the Tripartisan bill provides a real subsidy worth almost $1,600 per retiree to help union and employer plans continue coverage.

And those that decide to ''wrap around'' the strong basic benefit for all Medicare beneficiaries still provide comprehensive assistance to their workers. This is real help for employer and union coverage.

The Graham benefit does little to stem the trend toward dropping employer coverage. And when employers drop, Graham leaves retirees with nothing until they incur over $3,300 in costs out of their own pockets.

Graham would spend $390 billion yet provide virtually no benefit for anyone with retiree coverage. When retirees find out that they won't benefit from this, how will they react?

Ms. SNOWE. I yield the floor.

The PRESIDING OFFICER. The Senator from Tennessee.

Mr. FRIST. Mr. President, I yield 10 minutes to the Senator from Iowa.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. GRASSLEY. I thank the Senator from Tennessee.

Mr. President, obviously, as you might expect, I rise in opposition to the latest amendment by Senator GRAHAM—whether it is Graham 2, 3, or 4, I am not sure, but it is another Graham idea on drugs.

First of all, I would like to address an argument that some Senators have been making on behalf of this amendment. They have argued that this is the Senate's very last chance to deal with the drug issue this year. Even though this amendment is terribly flawed, they say that somehow Senators should be encouraged to vote for it anyway.

Mr. President, I am second to none in my frustration with the Senate's failure on this issue at this point. The Democratic leadership has abandoned any pretense of a fair process. And fair process is what the Senate is all about. Instead of leading, the Democratic leader has been content to cook up his own proposals or have members of his party cook up their own proposals and try to somehow just ram them through the Senate.

For those of us who believe things in this body must be done in a bipartisan way, and through the committee process, and, in the end, get things done, this process in which we have been involved has been extremely frustrating.

The good news is that this vote is not the last vote. Fortunately, the Senate still has time and the ability to act. Speaking for my colleagues in the tripartisan group, we are ready to move on and begin work in the Finance Committee on a truly bipartisan compromise. I wish Senator DASCHLE had the confidence in Senator BAUCUS I have to move a bipartisan bill on Medicare prescription drugs out of committee.

No one should vote for this amendment in the misguided belief that it is their last chance because it is not their last chance.

Now I would like to address the substance of the amendment before us. The sponsors chose to spring the text of this amendment on the Senate yesterday for the first time. Perhaps they thought they could slip in something

new that we would not catch. Well, we caught it, and you know we have caught it by the speeches of the Senator from Maine. We actually have had a chance, and we have studied the Graham amendment.

The Graham amendment imposes a massive new burden on States just when State treasuries are in terrible shape. What does it do? Well, it mandates—do you like mandates?—that State Medicaid Programs provide cost-sharing assistance to an entirely new universe of seniors who have incomes up to 150 percent of the Federal poverty level. If that is not bad enough, it also socks the States with administrative costs of enrolling seniors with incomes up to 200 percent of poverty. Even beyond those costs, this enrollment burden is going to be an administrative nightmare for the respective States because of all the different populations involved.

At a time—and we know this is true in at least 45 of the 50 States—when they are experiencing tremendous budget pressures, massive new burdens of this type are the last thing the States need to have imposed upon them by the Federal Government. In fact, last week we heard of the problems of the State budgets and the problems States are having with their Medicare Program, because we voted for additional fiscal relief just last week. How ironic it would be if now we were going to add yet another burden.

Let me point out another problem with the amendment before us, and that is the low-income benefit, focusing on the beneficiaries that it serves. If you earn $1 too much to qualify for coverage, you get nothing. That is a cliff, we call it. We try to avoid cliffs. If we do policy right, we do avoid cliffs. But this amendment isn't about policy that makes sense, this amendment is about a political statement.

So seniors can find themselves in a situation where, if they earn $17,720, they qualify. If they earn an extra $1, $17,721, they lose drug coverage. So the Graham amendment sets up disincentives for beneficiaries to work at the same time as Congress has been trying to remove the wrong incentives from the law, and here we are considering a new disincentive. Once again, the policy just doesn't make sense.

Everything I have said so far pertains to the benefit for the 30 percent or so of low-income beneficiaries who get solid coverage under the Graham amendment. Unfortunately, there are another 70 percent out there who get very little coverage at all. Those 70 percent, in fact, are the biggest losers of all under this alternative.

Just how bad is this benefit in the amendment before us? A senior above 200 percent of poverty with average drug spending will receive approximately $6 of assistance every month—only $6 towards their prescription drug expenses. For me, $6 a month is hardly a benefit at all. I would be embarrassed to go home to Iowans and tell them I voted for an amendment that provided only $6 a month to average beneficiaries.

Why is there so little benefit? Because for 70 percent of the seniors, there is no coverage from zero to $3,300 in out-of-pocket spending. A week ago, the author of this amendment complained about a proposal I put forward because we had a $250 deductible. Now we are seeing a $3,300 deductible. Benefits paid by private insurance don't even count towards that.

Another problem: Retirees with decent coverage from a union or an employer do not incur actual drug costs out of their own pocket above $3,300, so the Graham benefit provides almost nothing for them.

I have to sound a sobering note: You don't pull the wool over the eyes of Americans—and seniors in particular. They don't appreciate false promises. I fear Senators who vote for the Graham amendment will have a lot to answer for down the road. I won't be one of them. I urge my colleagues not to be one of them either.

We are facing another mostly partisan vote on a mostly partisan bill, another vote that will fail to get 60 votes and will fail to help our seniors. Had regular order been followed, had the Finance Committee been given the right to work its bipartisan will, we could be completing action on this issue. Instead, we are still at a beginning.

The sponsors of the tripartisan bill, the only bipartisan bill in all of Washington, DC, to provide comprehensive, universal coverage, have always been ready and willing to talk to anyone about compromises, and we are still in this mode. We are ready to meet people any place, any time, anywhere to discuss this, including members and leaders of the AARP, who somehow got sucked in today to supporting something that a week ago they said they abhorred.

This situation is going to continue to be the case for us in this group, even after this morning's vote. So this vote is an ongoing, evolving process to get us a successful product. I have promised my constituents I will not give up on this issue. Adding a drug benefit to Medicare is business that simply cannot wait another year to cost $100 billion. Just as the need for prescription drug coverage in Medicare is not going to go away, we in the tripartisan group are not going to go away.

Mrs MURRAY. Mr. President, I rise today to reluctantly support the Graham/Smith amendment. I am casting this vote to move the process forward so we can get closer to providing seniors and the disabled with the prescription drug coverage they need.

I have got to tell you that I am frustrated and disappointed that Congress hasn't made more progress on this critical issue. Our seniors deserve better than the procedural fights we have seen here in the Senate, and they deserve better than the Graham/Smith amendment. Today I am voting for this amendment because it offers best hope of moving the process forward after so many delays.

Part of my frustration goes back to the priorities that were set last year. Strengthening Medicare should have been a top priority in Congress. Instead, the Republican-controlled House and Senate moved forward with a $1.25 trillion tax cut. Now we are fighting to provide a minimal Medicare prescription drug benefit that will not cost more than $400 billion over ten years. While we have come a long away since the President's inadequate $190 billion proposal at the start of the year, we still are not where we need to be.

I do want to applaud the efforts of our leader Senator DASCHLE and Senator GRAHAM. I know that they share my goal of a universal, affordable benefit as part of Medicare. Senator GRAHAM has worked especially hard on behalf of our seniors and the disabled.

While this amendment provides some targeted relief, it falls far short of our original goal. I supported S. 2625, a universal, affordable benefit that treated all seniors the same. Like the Medicare program, it offered every senior access to affordable coverage. I was disappointed that we could not secure the necessary 60 votes on this package. I do want to point out that S. 2625 did receive 52 votes, meaning a majority of my colleagues supported this approach. Unfortunately, due to procedural battles and partisan bickering, 52 votes were not enough.

This amendment does provide immediate assistance to the most needy and vulnerable. Ensuring that seniors below 200 percent of poverty receive access to affordable coverage is critical and will offer coverage to a larger number of seniors and the disabled. In Washington State, this could mean that 290,000 Medicare beneficiaries would be eligible for full coverage with a nominal copayment and no monthly premiums. This is a big improvement. It would ease some of the pressures on our State Medicaid program, which has been trying to fill the Medicare gap for low income beneficiaries.

But, as we all know, income is sometimes not always the best measurement of need. What about those seniors who earn just $1 over the 200 percent of poverty threshold? They could have significantly higher drug costs yet receive no benefit, until they reach a catastrophic level of $3,300.

In Washington State, this could mean 428,000 beneficiaries would not be eligible for the low income assistance. Yet, these seniors paid the same taxes and contributed the same percentage of their income while they were working to support the Medicare program.

I am pleased this amendment will offer catastrophic protection to all seniors regardless of income. Targeted relief to those with expensive drug costs does provide some level of fairness to the program. Ensuring that seniors with more than $3,300 in out of pocket

costs receive relief is a positive improvement and will offer some piece of mind.

This amendment is a good starting point, but it cannot be the final product we offer our seniors. I fear that this proposal could get worse in conference. The House-passed bill is nothing but a false promise of benefits. It is based on a private insurance model that has all but failed in most parts of the country. It would require significant out of pocket costs for even the low income and could result in less coverage for many seniors. It has a huge hole in coverage and does not offer a seamless benefit as part of Medicare. It is a sham, and once it sees the light of day, seniors will not be fooled.

I am willing to support this amendment with the understanding that this is only the beginning. This is the foundation for building a real universal benefit as part of Medicare. This cannot be the high water mark. I do not want a final conference report to offer only targeted limited relief based on a private insurance model. We cannot just merge this amendment with the House-passed bill. Instead, we must build on both approaches and make significant improvements. We must insist that the final product result in a seamless benefit that is part of Medicare that offers universal, affordable coverage.

I want to make one other point about our attempts to improve Medicare. As my colleagues know, I am very concerned about Medicare reimbursement rates. These rates vary by region and don't reflect the true costs of providing care in many States. I am concerned that this amendment builds on that flawed, unfair formula.

In Washington State, the annual per beneficiary payment from Medicare is $3,921 while in Louisiana it is as high as $7,336. Seniors in Washington State are suffering from this inequity. They cannot find a doctor to accept new Medicare patients and are forced to seek care in overcrowded emergency rooms. This inequity also puts providers in Washington State at a distinct economic disadvantage. Doctors are leaving my State for other parts of the country that offer higher Medicare reimbursements. In some parts of the country, Medicare payments are so high they subsidize private insurance payments. I can tell you that this is not the case in Washington State.

Unfortunately, the Graham/Smith amendment would result in some States receiving much greater coverage than others. Because the benefits will be targeted to those below 200 percent of poverty, some States will again receive much more Medicare funding than other States. In Washington State, only 40.4 percent of seniors would be eligible. However, in Louisiana 66 percent would eligible for coverage. As we work to improve Medicare we should make the program more fair to all seniors.

I understand that we will not be adding a provider package to this bill. We all recognize the need to address the provider shortfalls. I understand that the Majority Leader is committed to taking up a provider package in September. This must be a priority. It does little good to offer a prescription drug benefit if seniors cannot find a doctor. I urge my colleagues to work to address the inequities in the Medicare reimbursement formula as part of a provider package. We cannot continue to increase payments without a fix, as those at the top continue to receive a large percentage of the increased dollars.

So I am willing to support the Graham/Smith amendment as a starting point for our work on crafting an affordable, universal drug benefit that's part of Medicare. It's clear that we still have a great deal of work to do. And regardless of the outcome of this vote, I'm committed to working on this issue until we have the coverage that seniors and the disabled need.

Mr. HATCH. Mr. President, my, what a difference a week makes! Who would ever think that the Senate would now be considering a piece-meal, minimalist Medicare prescription drug coverage amendment.

Is that what seniors want? I don't think so and that is why I want to express my vehement opposition to the Graham plan.

Over the past few weeks, we have heard just about everything under the sun regarding prescription drug coverage. Some fact, much fiction.

What we need to do now is to sort out the rumors and false statements and look just at the facts.

The one undeniable fact where we all agree is this: the need for Medicare drug coverage is too great to let it become buried in a political quagmire.

We have all been working hard on this issue and we must not fail our seniors now by passing a piece-meal Medicare prescription drug plan. Apparently, our Democratic Leadership does not agree. Let's look at the facts.

We know that the tripartisan bill will cost $370 billion over 10 years. We hear that the latest Graham bill will cost close to $400 billion over 10 years, but the plan keeps changing so we do not have a true CBO score. We just received the legislative language late yesterday afternoon and CBO has not had a change to carefully review the legislative language.

We know that the tripartisan bill will provide a comprehensive benefit package for all seniors. Every single senior receives comprehensive, guaranteed coverage for his or her prescriptions.

We know that the Graham bill does not provide comprehensive coverage for all seniors. Under the Graham bill seniors only receive coverage for drugs if their incomes are below 200 percent of the Federal Poverty Level or if they reach their catastrophic coverage limit. What happens to middle-income beneficiaries? My friends, these seniors are just out of luck.

We know that the tripartisan bill will work to push drug costs down through private sector competition.

We know that the graham bill is going to have a new, federally-funded, government-run drug program that has no cost-saving mechanisms. In my opinion, a government-run program will lead us down the dangerous path of prescription drug price-setting. Look what has happened to the reimbursement rates of other Medicare providers, like hospitals and physicians.

The tripartisan bill encourages competition based on quality and cost. The tripartisan proposal lowers prices for all drugs without compromising quality and innovation. The Graham plan does not.

The tripartisan plan offers choice—a choice of plans, a choice of medication and a choice of Medicare coverage through our enhanced fee-for-service option. The Graham plan has a one size fits some proposal.

Our tripartisan plan improves the Medicare program by taking a global approach to meet the changing needs of seniors. The tripartisan bill provides protection against high hospitalization costs and offers free preventions benefits. This is what modern health care demands.

On the other hand, the Graham plan only provides minimal drug coverage for a small number of Medicare beneficiaries.

Why should seniors settle for a piecemeal approach? It just doesn't make any sense.

For less than the cost of the Graham catastrophic plan—or, I think, the catastrophic Graham plan—which would benefit less than half of seniors, the tripartisan approach provides comprehensive coverage with quality drug coverage, choice and cost savings for all Medicare beneficiaries.

A piece-meal approach and last minute changes to keep the CBO score down to placate people is the approach my colleagues on the other side have taken in putting this bill together. And it is the wrong approach.

So it is no surprise that is what their plan has offered—a piecemeal, band-aid approach to providing drug coverage.

We need to provide Medicare beneficiaries with adequate prescription drug coverage, this year. We must put aside our differences and self interests.. Partisan arguments only stand in the way of Medicare drug legislation being passed by the Senate.

Let's start the process of improving health care for our seniors by passing quality prescription drug coverage.

Let's not fail them again by allowing the piece-meal Graham plan to pass the Senate. Our Medicare beneficiaries are depending on us to provide them the best Medicare prescription drug coverage possible.

My friends, a vote in favor of the Graham plan does not accomplish this important goal. Our Medicare beneficiaries deserve better.

I urge my colleagues to vote against the Graham amendment.

Mr. HOLLINGS. Mr. President, I rise today to reluctantly oppose the Graham-Smith amendment. First of all, let me commend the distinguished Senior Senator from Florida for the leadership he has shown throughout the years to bring a meaningful prescription drug benefit to Medicare. America's senior citizens have no stronger ally in this body than Senator BOB GRAHAM. He has worked tirelessly to provide real relief to Medicare beneficiaries from their prescription drug costs and I was proud to stand with him, Senator MILLER, and Senator KENNEDY last week to try to move ahead with a real drug benefit. However, I must oppose this amendment because it largely neglects the vast middle-class of senior citizens.

Just yesterday, Secretary Thompson granted South Carolina a Section 1115 waiver to bring our state's SilverxCard program under Medicaid, thereby allowing the program to expand coverage to seniors with incomes of up to 200 percent of the Federal poverty level. Thus, the very same seniors that would receive comprehensive coverage under the Graham-Smith Amendment can already receive coverage, albeit more limited, in South Carolina through Medicaid or SilverxCard. This amendment would not make one additional Medicare beneficiary in South Carolina eligible for prescription drug coverage. I also have found that affluent seniors in South Carolina can either afford supplemental prescription drug coverage on their own or have a plan from a former employer that contains prescription drug coverage.

Which seniors are left furthest behind in South Carolina? It is the middle-class, those individuals who spent their lives working in the textile mills, manning the assembly line, teaching in our schools, and tending to our farmland. They worked hard, paid taxes into Medicare, and deserve to receive the same benefits under Medicare as anyone else. I cannot in good conscience vote for an amendment that tells a senior citizen with an income of $17,720 that, yes, you receive a real prescription drug benefit and another senior citizens with an income of $17,721 that, no, you have to spend $3,300 out of your own pocket before you receive any assistance. We did this once already with Medicare. It failed and this Senator learned that we should not do it again.

I understand the desire of many of my colleagues to pass something, anything to help citizens afford their prescription drugs. I talk to the same people and receive the same heart-wrenching letters from constituents as they do. I know their commitment and desire to enact legislation this year is real and genuine, but I simply cannot support this approach. All of our seniors deserve comprehensive Medicare prescription drug coverage.

I still believe that we can reach agreement before the end of the year on a real, meaningful benefit for all our seniors and stand ready to work with my colleagues to make this possible.

Mr. BUNNING. Mr. President, I rise today to speak briefly about the Graham-Smith amendment.

The Senate has been debating a prescription drug benefit for Medicare for the past two and a half weeks. In fact, Congress has been working on the issue for years now. Now our colleagues in the House have passed a proposal. The Senate needs to do the same.

All along I have supported the efforts of the Tripartisan group and their efforts to write a common sense Medicare prescription drug proposal. I voted for their bill because I think it targets relief in a fiscally responsible manner to those seniors who need it the most.

Unfortunately, I cannot support the Graham-Smith amendment.

While we all agree that seniors need help with their prescription drug costs, this amendment falls short for several reasons.

First of all, this amendment creates an ''all or nothing'' program for many seniors. Seniors below 200 percent of poverty, which is $17,720 for singles and $23,880 for married couples, will basically have all of their prescription drug costs paid for, with only a $2 or $5 copay for drugs.

However, folks who make over 200 percent of poverty, even if it is only by a small fraction, basically don't get a real benefit until catastrophic coverage kicks in at $3,300. Writing this steep of an income cliff into the law isn't fair. We can do better.

The difference between having an income of $17,720 and $17,721 shouldn't costs seniors $3,300 in prescription drug costs. In Kentucky, there are almost 240,000 seniors who have incomes above this threshold. Under Graham-Smith, they basically get nothing.

Second, this amendment doesn't give us enough bang for our buck. The Congressional Budget Office estimates that this amendment will cost $390 billion, which is a heck of a lot of money. However, even if we pass it, we still aren't offering a real benefit to all seniors, like we did with the Tripartisan amendment.

The Tripartisan proposal would have cost $370 billion, and all seniors could have had catastrophic coverage starting at $3,700, along with substantial help with their prescription drug costs below that. Even the Hagel Amendment, with a price tag of $295 billion, limited out of pocket expenses for folks below 200 percent of poverty at $1,500.

I just don't understand why we would want to pay an additional $20 billion or $95 billion more for a Medicare prescription drug plan that offers fewer benefits. This means that the Graham-Smith proposal shortchanges not only seniors, but the American taxpayer as well.

America's seniors need our help, and the Senate needs to pass a prescription drug bill. But because the Senate Democrat leadership insisted on bypassing the usual committee process and proceeding straight to the Senate floor with the debate, we have been struggling with a legislative free-for-all that, in the end, could lead to nothing passing at all.

When I made my first floor statement on this issue, I warned against this sort of procedural gimmickry and its possible consequences. So far we have voted on three prescription drug proposals, and only two have earned more than 50 votes, let alone the 60 that are needed under the budget rules. If the committee process had been allowed to work its will, I think there is a much better chance that we could pass a serious proposal to provide meaningful relief to seniors.

I can't support Graham-Smith. It's a day late, more than a few dollars too short and fails to provide real help to seniors who need it most. I think there is still a chance, a small one, to pass a real bill. But the door is about to close on our seniors yet again. I hope we don't let them down.

Mr. CORZINE. Mr. President, I rise today in strong support of the Graham-Smith amendment. I believe that this compromise represents an important victory for all our Nation's seniors, and particularly for seniors in my State of New Jersey.

Let me be frank: this is not the proposal I would have preferred and is not the proposal I have talked about with my constituents for the last few years. I have gone around New Jersey and have heard from my constituents about how they struggle to deal with rising drug prices, how they fear being bankrupted in their last years, and how they worry about burdening their families. That is why I strongly support a comprehensive Medicare benefit, and that is why I supported the Graham-Miller-Kennedy-Corzine amendment last week.

But, I am also a pragmatist, and I know that the Graham-Smith amendment is a good and necessary start, upon which we can build. It will provide critical relief to the neediest of seniors, and provides comfort to all seniors that castatrophic drug costs will not ruin them. And I know that if we can get this enacted, next year I will be back here fighting to expand its reach.

The Graham-Smith amendment will ensure that no senior spends more than $3,300 to buy their prescription drugs. It also provides comprehensive coverage to our Nation's neediest seniors, those with incomes up to 200 percent of the federal poverty level. In addition, it provides a thirty to forty percent discount on prescription drugs for all seniors. At a cost of $390 billion over ten years, the Graham-Smith amendment will guarantee all seniors much-needed prescription drug coverage at a reasonable price.

My State of New Jersey and many other States around the Nation have responded to the glaring need for prescription drug coverage for our Nation's seniors by creating state pharmacy benefit programs. In New Jersey,

we have the PAAD and Senior Gold programs. The PAAD program currently provides comprehensive drug coverage to seniors up to 220 percent of the Federal poverty line, and the Senior Gold program provides more limited coverage to certain higher income seniors.

I am pleased that the Graham-Smith amendment preserves and reinforces State pharmacy benefit plans like New Jersey's. I worked with Senators GRAHAM and SMITH to ensure that the amendment enables States with prescription drug programs to wrap their programs around the Medicare prescription drug benefit, to create more generous and more extensive benefits for all seniors. This is a crucial provision that will enable New Jersey, Pennsylvania, New York, Minnesota and the other 20 States that have State-funded prescription drug programs to expand and supplement their existing programs.

I also worked with Senators GRAHAM and SMITH to ensure that state pharmacy program spending counts toward a beneficiary's out of pocket limit. This will ensure that New Jersey seniors reach catastrophic coverage as quickly as possible. I want to thank Senators GRAHAM and SMITH for their assistance with these provisions.

Let me outline how the Graham-Smith amendment would benefit New Jersey seniors: 1,189,000 New Jersey senior citizens and disabled Medicare beneficiaries would be eligible for coverage under the Graham-Smith plan; 568,000 Medicare beneficiaries, 48 percent, would be eligible for low-income assistance and will receive all needed drugs in return for nominal copayments; 621,000 senior citizens and disabled Medicare beneficiaries, 52 percent, who are not eligible for special low-income assistance would benefit from discounts of 25–30 percent on each prescription.

I know many of my colleagues have raised concerns that this amendment does not provide comprehensive coverage for all seniors. But the basic fact is that this amendment provides prescription drug insurance for all our nation's seniors and disabled. It provides a thirty to forty percent discount on prescription drugs for all Medicare beneficiaries and would provide full prescription drug coverage to every Medicare beneficiary who spends at least $3,300 per year for their prescription drugs.

The Congressional Budget Office has estimated that by 2005, the year that this amendment would take effect, at least half of all Medicare beneficiaries will have annual prescription drug expenditures that exceed $4,000.

And, don't forget that the eighteen million Medicare beneficiaries with incomes below 200 percent of poverty would receive all the prescription drugs they need, for a small copayment of $2 for generics and $5 for brand name drugs.

At a time in which this Congress has voted to give billions of dollars in tax breaks to the wealthiest people in our country, it is wrong and hypocritical to tell seniors that we simply don't have the funds or the will to pass an amendment that will provide them access to affordable, essential medicines.

Mrs. FEINSTEIN. Mr. President, I rise today in support of the amendment offered by Senators GRAHAM and SMITH to add a prescription drug benefit to the Medicare program for low-income beneficiaries and those with high drug costs.

The amendment offered today is built on consensus and compromise, and is the product of weeks of extensive discussion. I believe in its final form, this amendment strikes a balance between the Senate's proper exercise of fiscal responsibility and the need to expand and update the Medicare program to include some help with the high costs of prescription drugs for today's 40 million Medicare beneficiaries.

I want to thank my good friend, Senator LINCOLN CHAFEE, for his commitment to getting prescription drugs to those in our society who are the sickest and the poorest. I have been working with him since the end of June in developing a cost effective alternative that would get prescription drugs to the lowest income and the sickest in our society immediately.

I believe that the Graham-Smith amendment we are debating today addresses my major concern which is to provide low-income individuals in our society with access to a full, prescription drug benefit at low cost.

I am pleased that others in the Senate agree with me that at a minium we should provide a comprehensive benefit to those individuals in our communities who are making daily decisions about eating or paying rent and buying their necessary, life-saving prescription drugs.

The prescription drug benefit created by this amendment includes three important components.

First, this amendment creates a voluntary, low-income benefit so that seniors would no longer be forced to continue making decisions between food or medicine. Under this plan, beneficiaries would pay no premium, no annual fee, and no deductible. Their only cost would be a nominal copay of $2 for a generic drug and $5 for a brand name drug.

I believe the assurance that over 18 million Medicare beneficiaries, 47 percent of all Medicare beneficiaries, with incomes below $17,720, 200 percent of the Federal poverty level, would have access to needed prescription drugs at a nominal cost is the most important component of this proposal.

For California, this means that 1.8 million senior citizens and disabled Medicare beneficiaries, 49 percent, with incomes below $17,720 for an individual and $23,880 for a couple would have immediate access to all needed drugs.

Second, this amendment would provide all 40 million Medicare beneficiaries with access to catastrophic coverage. For a simple cost of $25 a year for those with incomes above $17,720, every beneficiary would have the assurance that once out-of-pocket spending for prescription drugs exceeds $3,300, a copayment of $10 would provide them with access to full coverage at no additional cost to them.

Beneficiaries with incomes below $17,720 would not be responsible for the $10 copay. Low-income individuals would receive this benefit at no cost.

Third, this amendment provides the 14 million Medicare beneficiaries, 35 percent, making over $17,720 with access to discounts of about 25 percent on each prescription. For an annual fee of $25, these beneficiaries would have access to the federal negotiated rate and would receive a 5 percent government subsidy in addition on each prescription they purchase.

In California, this means an additional 1.9 million senior citizens and disabled Medicare beneficiaries, 51 percent, who are not eligible for low-income assistance would benefit from discounts of 25–30 percent on each prescription.

By providing coverage to low-income individuals and those with high drug bills, this proposal meets the most fundamental needs of our nation's senior citizens and disabled.

Passing this amendment is timely. On a daily basis, my office hears from California's seniors about the financial constraints they face which often prohibits them from buying necessary medication.

I recently heard from Helen Cecil, a senior citizen from Paramount, CA on this issue. She lives on a fixed monthly income of $1,000. Her rent is $421 a month, and she spends $150 a month on her prescriptions to treat high cholesterol, hypertension and arthritis. In total, Helen spends $1,800 annually on medication. She admits to having only one option: She must cut down on food in order to buy her medications.

Under the Graham-Smith amendment, Helen would pay no monthly premium and no deductible. She would only pay $2 per prescription for generic drugs. Assuming she purchases generic drugs, her monthly bill of $150 for three medications to treat her chronic health conditions would drop to approximately $6. Helen saves about $142 monthly. This is money she can use to buy groceries.

For the millions of Medicare beneficiaries that face the same predicament as Helen Cecil, I believe the government has a responsibility to see that they are not forced to choose between buying food and buying medications. Quite frankly, it is hard to think that in the richest nation on earth, we have allowed a situation to evolve where so many of our elderly must make such a choice.

I am hopeful that the Senate won't fail our Nation's sickest, poorest and most frail.

In the hopes of breaking the gridlock of this debate, and with the need to

pass legislation that meets both the budgetary restrictions of these uncertain times and the needs of our nation's low-income seniors, I urge my colleagues to support the Graham-Smith amendment.

Mr. LEVIN. Mr. President, I will support the Graham-Smith amendment. However, I would have preferred a prescription drug benefit added to Medicare, like the Medicare Outpatient Prescription Drug Act of 2002, commonly referred to as the Graham-Miller proposal. The Graham-Miller amendment would have provided a comprehensive, voluntary, affordable and reliable prescription drug benefit to Medicare beneficiaries. I voted for the Graham-Miller amendment, which was supported by a majority of the U.S. Senate in a vote last week. Unfortunately, the proposal required 60 votes and subsequently failed.

On balance, I will support the Graham-Smith compromise, even though I have some reservations. The bill has three major points. First, the Graham-Smith amendment provides all Medicare beneficiaries access to a prescription drug card which allows Medicare beneficiaries to pool their purchasing power and receive drug discounts of up to 35 percent. The Federal Government would add an additional 5 percent subsidy to any negotiated price. Second, low-income beneficiaries would receive full drug coverage—paying only a nominal copayment for their drugs. Third, ''catastrophic coverage'' would be available to Medicare beneficiaries so that someone doesn't have to spend more than $3,300 in out-of-pocket expenses on prescription drugs. After that, a beneficiary would only pay a $10 copayment for each prescription drug.

However, I do have a number of reservations about the Graham-Smith proposal. First, a prescription drug card is no substitute for adding a prescription drug benefit to the Medicare Program. I am a strong advocate of making prescriptions drugs an entitlement for every Medicare beneficiary who wants it. A prescription drug card can be uncertain, relying on a possible negotiated benefit that might not materialize and is no substitute for a guaranteed prescription drug benefit. I am also opposed to a means test for Medicare. Medicare's beneficiaries receive services because they have paid into the system their entire working lives. It is unfair for Medicare beneficiaries to receive different benefits based on their respective incomes. This sends the wrong message to our Nation's 40 million Medicare beneficiaries who rely on its stability and its application to all eligible seniors.

So, with reservation, I will be supporting the Graham-Smith proposal as the Senate's best chance to pass a Medicare prescription drug benefit this year, and I urge my colleagues to do the same.

Mr. REED. Mr. President, I would like to take a few minutes to share with my colleagues my thoughts about the Graham-Smith amendment that the Senate will be voting on shortly. I have to say that the proposal currently before us is a far cry from what I have previously supported and certainly no where near what I had hoped for in terms of a Medicare prescription drug benefit.

Indeed, this is not the benefit we ultimately should enact and, more importantly, this is not the benefit our seniors deserve. At best, the Graham-Smith proposal provides a universal catastrophic benefit to those seniors with the highest prescription drug costs and it will aid those States that do not already have a State-based prescription drug benefit. These concessions, offered in a spirit of compromise and bipartisanship, limit the effect and reach of this bill. Chief among these concessions has been cost. That constraint on resources is driven predominately by the passage of the President's tax plan, which leaves us with resources that are only sufficient to meet the needs of low-income seniors and those who spend over $3,300 out of their own pocket.

Nevertheless, the proposal does start us on the road to a universal, voluntary benefit for our Nation's elderly and disabled population by offering a comprehensive benefit for those living below 200 percent of the Federal poverty level. According to estimates, nearly half of the Medicare beneficiaries in Rhode Island would be eligible for the fully subsidized Federal prescription drug benefit. In addition, the amendment provides catastrophic coverage for drug costs above $3,300. And, contrary to other proposals, these benefits would be provided in the same manner that seniors receive all other health care benefits: through Medicare.

There are however several areas where I feel this amendment falls short.

First, seniors above 200 percent of poverty would receive, for a nominal annual enrollement fee, a discount card that would provide an automatic 5 percent Federal subsidy for all drug costs and additional savings that are expected to be captured through the negotiation of lower drug prices from the manufacturers. However, questions have been raised recently as to the effectiveness of prescription benefit managers, or PBMs, to achieve the best price for their subscribers. I believe that the potential benefits and drawbacks of PBMs on such a large scale have not been thoroughly explored, nor has the question of whether PBMs are a reliable mechanism to achieve lower drug prices been answered. I am also concerned about having a discount card as the sole source of coverage for beneficiaries above a certain income level because I believe it deviates from the basic tenents of the Medicare program and may not provide the kind of assistance seniors and disabled persons with substantial drug costs might need.

Second, there is no requirement that States with existing pharmaceutical assistance programs for low-income seniors, like my home State of Rhode Island, maintain their commitment to this particularly vulnerable population. I believe that the Graham-Smith amendment would have a much greater impact if it acknowledged and rewarded the ongoing efforts in many States and encouraged them to work as partners with the Federal Government to build a far-reaching prescription drug benefit that would offer more robust assistance to many more of our elderly and disabled than the Federal Government can currently achieve on its own.

While I understand that many of our States are facing dire budgetary situations, I believe our commitment to providing struggling States the temporary support they need has been demonstrated through the Rockefeller-Collins-Nelson amendment which passed the Senate by an overwhelming margin last week. I am disappointed that the Graham-Smith amendment does not take the role of the States into more serious consideration. If the proposal is enacted, I hope to work with my colleagues to strengthen the State's role in this program.

The plan that I cosponsored and supported, the Graham-Miller-Kennedy amendment, was the only true Medicare prescription drug proposal to be presented to the Senate. It is the only one that would have created a guaranteed, univeral benefit for all Medicare beneficiaries, regardless of income. In terms of the benefit structure, it required a modest monthly premium and reasonable co-payment for prescriptions. However, this benefit was deemed to be too costly by many of our Republican colleagues given the current Federal budget deficits. I would argue that we might be in a different position if we had not enacted a major tax cut bill last year.

Nevertheless, my colleague, Senator GRAHAM, has tirelessly worked to craft a scaled-back benefit proposal that is modeled after the Ensign-Hagel amendment and would seem to meet the chief concern of my Republican colleagues and should garner their support. I commend Senator GRAHAM and others for their efforts on this critical issue and I intend to support his amendment in the spirit of compromise and moving this debate forward. The Graham-Smith amendment is certainly not the end of the road in terms of the prescription drug issue, it is only the beginning. If Congress is going to have a serious chance of getting a Medicare prescription drug bill to the President's desk this year, we must take action now. I hope my colleagues will follow the lead of our colleagues, Senators GRAHAM and SMITH, and work towards the enactment of a Medicare prescription drug benefit.

Mr. LEVIN. Mr. President, I will support the Graham-Smith amendment. However, I would have preferred a prescription drug benefit added to Medicare, like the Medicare Outpatient Prescription Drug Act of 2002, commonly

referred to as the ''Graham-Miller proposal.'' The Graham-Miller amendment would have provided a comprehensive, voluntary, affordable and reliable prescription drug benefit to Medicare beneficiaries. I voted for the Graham-Miller amendment, which was supported by a majority of the United States Senate in a vote last week. Unfortunately, the proposal required sixty votes and subsequently failed.

On balance, I will support the Graham-Smith compromise, even though I have some reservations. The bill has three major points. First, the Graham-Smith amendment provides all Medicare beneficiaries access to a prescription drug card which allows Medicare beneficiaries to pool their purchasing power and receive drug discounts of up to 35 percent. The Federal Government would add an additional 5 percent subsidy to any negotiated price. Second, low-income beneficiaries would receive full drug coverage—paying only a nominal copayment for their drugs. Third, ''catastrophic coverage'' would be available to Medicare beneficiaries so that someone doesn't have to spend more than $3,300 in out-of-pocket expenses on prescription drugs. After that, a beneficiary would only pay a $10 copayment for each prescription drug.

However, I do have a number of reservations about the Graham-Smith proposal. First, a prescription drug card is no substitute for adding a prescription drug benefit to the Medicare Program. I am a strong advocate of making prescriptions drugs an entitlement for every Medicare beneficiary who wants it. A prescription drug card can be uncertain, relying on a possible negotiated benefit that might not materialize and is no substitute for a guaranteed prescription drug benefit. I am also opposed to a means test for Medicare. Medicare's beneficiaries receive services because they have paid into the system their entire working lives. It is unfair for Medicare beneficiaries to receive different benefits based on their respective incomes. This sends the wrong message to our Nation's 40 million Medicare beneficiaries who rely on its stability and its application to all eligible seniors.

So, with reservation, I will be supporting the Graham-Smith proposal as the Senate's best chance to pass a Medicare prescription drug benefit this year and I urge my colleagues to do the same.

The PRESIDING OFFICER. Who yields time?

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

The PRESIDING OFFICER. The Senator from Massachusetts has 22½ minutes. The Senator from Tennessee has 5 minutes.

Mr. KENNEDY. Mr. President, I yield 18 minutes to the Senator from Florida.

The PRESIDING OFFICER. The Senator from Florida is recognized.

Mr. GRAHAM. Mr. President, we have a very simple message this morning. America's seniors now, for 37 years and 1 day—since 37 years ago yesterday was the day Lyndon Johnson signed the Medicare legislation into law—have been waiting for prescription drug coverage. It was a minor amount of their expenditures in 1965. On average, it was $65 a year. It is a staggering amount for seniors today—over $2,100 a year, on average.

Today is the day that there are no more excuses for delay. There is no credible reason to vote against the motion to waive the Budget Act so that the Senate can then consider an affordable, bipartisan prescription drug proposal, and all of the modifications, amendments, and other alternatives that others might wish to propose.

There have been a number of objections raised to our proposal—some of them last week—being contradictory to the same provisions or modifications that are in our current bill, and some new issues were raised this morning. Let me briefly comment.

Last week, we heard that the prescription drug bill we had offered was too expensive, at an estimated cost of $594 billion for 10 years. We were told: we cannot support anything that is above $400 billion. So we went to work. We rolled up our sleeves, and we made a number of changes, and we have gotten the cost under $400 billion. In fact, the Congressional Budget Office states that in conjunction with the generic drug bill—on which our Presiding Officer has provided such leadership—the cost of our bill now will be $382 billion. So we have met the desire to have a less costly proposal.

Now we are getting the other argument, that because it is less costly, it is not sufficiently comprehensive. Let me explain what this bill will provide, first, for all senior Americans. In my opinion, the most important thing it will provide is peace of mind. If you are a relatively well American in the early seventies, you have prescription drug costs you can manage. The problem is that you never know whether a day from now you might not suffer from some catastrophic event, such as a heart attack, or be found to have a chronic disease such as diabetes, which will suddenly escalate your prescription drug cost, potentially threatening the economic security of your retirement.

This legislation will provide the peace of mind that will give you the assurance that, once having spent $3,300, you will get full coverage, but for a $10 per prescription copayment. That is a benefit of real value, which is available to all American seniors. The cost is $25 a year as an enrollment fee. There could be no greater bargain in the insurance market than to be able to buy the peace of mind of this catastrophic coverage for $25 a year.

That is not all of the benefits that will be available to all senior Americans. Because we are going to have 40 million Americans with a champion, called a pharmacy benefit manager, negotiating with the pharmaceutical companies to get the best discounted prices, Families U.S.A., the Chain Drugstore Association, and the U.S. Department of Health and Human Services have all stated that, under our legislation, they estimate that these organizations would be able to negotiate discounted prices in the range of 15 to 25 percent. That will be available to all seniors.

In addition to that, we are going to provide that there will be a 5-percent Federal supplement on top of whatever the discounted amount is. So there will be real benefits for all Americans.

But we did have to make some difficult choices when we reduced the size of this program by over $200 billion. One of those decisions was that we would focus our effort on those who had the largest prescription drug bills through a catastrophic program that would be available to all, and we would focus on those who were the neediest Americans and, therefore, had the greatest difficulty paying their prescription drug costs.

This business of life is a business of making choices, and we decided that those were the two groups that should get the most attention under the beginnings of a Medicare effort to provide prescription drug benefits.

I might say that this is very consistent with what President George Bush said as ''candidate'' George Bush when he emphasized that he thought a prescription drug benefit was a priority for the Nation and that the priority within the priority was providing prescription drug coverage for those who were most in need. That is what we have done.

For those persons who are under 200 percent of poverty—which today is 38 percent of America's 40 million Medicare eligibles—this will provide a very significant benefit; and with no premiums, with no deductibles, they will have access to prescription drugs for a copayment of $2 for generic drugs and $5 for brand name drugs. This will provide for the millions of senior Americans who are the most likely not to have any other source of assistance—they didn't work for an employer who provided retiree prescription drug benefits or they cannot afford a Medigap policy. This is the group of Americans who are at greatest need, and they will get the greatest assistance.

There have been some other arguments raised today about the plan we are proposing. It has been suggested that there will be massive costs to the States as a result of this plan. Let me read you a statement we have just received from the Congressional Budget Office. It states:

This plan will have almost no effect—

I would like my colleagues on the other side of the aisle to listen to this Congressional Budget Office release.

This plan will have almost no effect on State spending and will have savings to States when combined with the underlying generic bill. There will also be savings for

States that have their own State-funded drug programs. State savings come from the Federal Government paying all of the catastrophic benefits which are now paid by the State, as well as 5 percent of each beneficiary's drug cost, which is not subject to a match.

This is not a new idea. We have a program that has been in place for several years called the QMBs and SLMBs program. Don't ask me what the acronyms fully stand for, other than that they provide Medicare assistance to pay premiums, deductibles, and coinsurance for low-income Americans who are still above the Medicaid level. That has not proven to be an unmanageable program for State-Federal cooperation, and neither will this.

It has also been stated that previous employers will drop the insurance coverage of their retirees if we adopt this legislation. Quite to the contrary. The Congressional Budget Office, again, has stated that with our plan there would be no employer dropping of coverage, whereas with the plan that has been proposed by our colleagues on the Republican side, the same CBO estimates that up to one-third of the employers would drop prescription drug coverage.

The issue today, frankly, is not any of the questions that have been raised in opposition to the thoughtful proposal that is the result of real compromise between Democrats and Republicans, a true bipartisan outreach. On many provisions of this bill, we have adopted language verbatim from legislation that was introduced last week by, for instance, Senators HAGEL and ENSIGN. Senator GORDON SMITH has worked in the highest standards of cooperation and collaboration to give this Senate an opportunity to vote on a solid, significant prescription drug benefit.

What we are going to vote on in a few minutes is a motion to waive the Budget Act. How ironic. We have a Budget Act, which is 18 months old, that says the maximum amount we can spend on prescription drugs is $300 billion over 10 years.

Both the Republican plan and the Democratic plan are above $300 billion, a clear recognition that people who have looked at what will be required to provide a prescription drug benefit have come to the same conclusion: we cannot provide a meaningful, responsible benefit to senior Americans for $300 billion.

We are going to have an opportunity to vote to waive the Budget Act so we can then consider what would be a responsible prescription drug benefit, but unless we get 60 votes to waive the Budget Act, we will never get to the substance of this issue.

I urge my colleagues to focus on the question that is before us: Should we maintain a slavish commitment to an 18-month-old number that both Republicans and Democrats have clearly indicated is inappropriate or should we waive the Budget Act and have an opportunity to have a full, substantive debate on prescription drugs?

There have been some who said this is not the last time; that we can come back maybe in September or October, or some time in 2002, and act upon this. I admire their optimism, but as a pragmatist, I question the practical reality. In addition to the difficulty of passing legislation through the Senate, we know that we have to go to conference with the House, and the House is likely to have significantly different provisions, including different priorities in terms of where to place emphasis in a senior prescription drug plan for Medicare than the Senate will have.

If we waste the month of August, which would be an opportunity for serious consultation between the House and the Senate, in hopes that in September we can arrive at a compromise that can be voted by the Congress and then signed into law by the President, we will have missed our greatest opportunity to achieve this long-sought goal of senior Americans.

The real issue today is, we have a choice of saying, yes, we want to continue, we want to have the opportunity to develop a prescription drug benefit or we want to say no, that we are prepared to accept the status quo—another year in which senior Americans will be denied Medicare assistance in purchasing their prescription drugs, the fastest rising cost element in the typical health care budget of senior Americans.

Mr. President, I urge my colleagues today to vote yes to waive the Budget Act and then vote yes to continue a serious, substantive debate on the issues involved in providing our senior citizens access to a meaningful prescription drug benefit.

I would not like this debate to end in the ashes of a vote that says we are going to put a greater value on the homage to an archaic budget number, which nobody today is advocating as being adequate to meet the needs of senior Americans.

That is the issue: Do we say yes to the opportunity or do we say no to further gridlock and denial of this critical element of a modern health care program?

I thank the Chair.

The PRESIDING OFFICER. Who yields time?

Mr. KENNEDY. Mr. President, how much time remains on our side?

The PRESIDING OFFICER. The Senator from Massachusetts has 6 minutes 45 seconds.

Mr. KENNEDY. I yield 2 minutes to the Senator from Michigan.

The PRESIDING OFFICER. The Senator from Michigan.

Ms. STABENOW. I thank the Chair. Mr. President, this is it today. We have a very real choice to make. I believe it boils down to this: The drug companies of America like the system the way it is today. They want nothing to happen. The seniors of America are counting on us to stand up and do the right thing: Not privatizing Medicare with a private plan that sets up insurance HMOs which, by the way, was written in the House in part by the drug companies knowing that this is the approach that is least likely to lower prices but, rather, protecting, preserving, and modernizing Medicare.

This is a bipartisan effort. I commend colleagues on both sides of the aisle who have stepped up to say we are going to make a downpayment on modernizing Medicare to cover prescription drugs. That is what this is. Everyone gets help. Everyone's prices go down. And for those who need it the most, those who are the sickest, they will, in fact, receive comprehensive coverage. No premium. No deductible. They will get the help they need.

I am proud to stand today with my colleagues, Senator GRAHAM, Senator SMITH, and others on both sides of the aisle who have put this together with AARP and with the senior groups in America to say the time has come. The time has come for us to place this downpayment on modernizing Medicare and move forward until we completely provide comprehensive Medicare coverage for all seniors and the disabled in this country.

I cannot imagine why we would not want to keep this process going to get the bill in front of us. It can always be fine tuned. We can continue to work together. But today is yes or no on whether we proceed to help the seniors of America and stand with them. Stop talking about it; let's act together and let the seniors know that we are willing to provide the leadership necessary—all of us together—to get this done. I thank the Chair.

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

Who yields time?

Mr. FRIST. Mr. President, I yield 2½ minutes to the Senator from Oklahoma.

The PRESIDING OFFICER. The Senator from Oklahoma.

Mr. NICKLES. Mr. President, I urge my colleagues not to waive the Budget Act with respect to the point of order for a lot of different reasons. One, I wish we had a budget. Somebody said we could have passed a budget. Maybe the Budget Committee was going to pass a higher number.

Unfortunately, this is the first time since 1974 that we have not had a budget pass the Senate. Maybe one of the most fiscally irresponsible things we have not done is not pass a budget. We are still under the constraints of last year's budget.

Last year, we overwhelmingly passed a budget and set up $200 billion, $300 billion, and it was passed by the Finance Committee. Really what we should do is direct the Finance Committee to pass a bipartisan bill.

I looked at the last 22 years, and the Finance Committee has dealt with major Medicare and Medicaid reforms, every one of which passed with bipartisan support except one. Only once did we bypass the committee.

Unfortunately, the Democrat leadership said: We are not going to go

through the Finance Committee because we think it will report out something we do not like. So they came up with a partisan bill, and we are playing ping-pong.

I looked at the amendment we are considering right now. It is 102 pages. It was still warm off the press, and nobody on this side, with one exception maybe, had seen this amendment before it was offered yesterday.

This is the most important expensive expansion of Medicare in its history, and we find out that most of the expansion is not in Medicare but Medicaid, and the cost to States is in the billions of unfunded mandates to the States because we did not just expand Medicare, we expanded Medicaid, and we are telling the States they are going to have to come up with matches to provide this brand new free benefit. Thirty-one States are going to have to pay for half of this new benefit. There is an increase in S–CHIP match, a 100-percent match for some, but 31 States have a 74-percent match. They have to go up to 120 percent.

All of that is on the States, or at least their matching portion. The estimated cost of unfunded mandates is $70 billion.

We have not had a hearing. We have not had a markup. This may be a classic example of the best way not to mark up legislation that is this important.

Let us step back a little bit. Let us work with the Finance Committee. Let us work in a bipartisan way. We can certainly get that done. We have the month of August and part of September. We can report a positive bipartisan bill that can become law. What is before us, unfortunately, is well short of that goal.

The PRESIDING OFFICER. The Senator has used 2½ minutes.

The Senator from Massachusetts.

Mr. KENNEDY. I understand there are 4½ minutes remaining.

Mr. SCHUMER. There are 4 minutes 11 seconds.

Mr. KENNEDY. I yield 2 minutes to the Senator from North Carolina.

Mr. EDWARDS. Mr. President, I hope the Senate, given this opportunity, will do something about providing a drug benefit for all those Americans who desperately need it. This is obviously a compromise, but great work has gone into this effort and it is important we do something for all those people who need help.

I want to say a word about the underlying bill because while we are providing the prescription drug benefit, we need to make that benefit affordable, No. 1, and, No. 2, we need to do something about the cost of prescription drugs in this country.

The Presiding Officer, Senator SCHUMER, led the way, along with Senator MCCAIN, in doing something about the cost of prescription drugs in this country in getting generic drugs on to the marketplace, providing competition, and bringing down the costs for all Americans. In the HELP Committee, Senator COLLINS and I, working with Senator SCHUMER and Senator MCCAIN, built on that work that had already been done and provided a way to deal with the problem of brand name drug companies abusing the patent process to keep generics out of the marketplace.

What was happening was this: Brand name companies were filing frivolous patents. The result of filing those frivolous patents is the generics were not able to get into the marketplace. The brand names used the litigation process to keep generics out of the marketplace. What this underlying legislation does is to close those loopholes. It provides specifically for a mechanism to eliminate the use of frivolous patents to, in fact, give brand name companies protection when they have a real, new, creative, and innovative product, but at the same time it eliminates the patent and litigation abuses that have been occurring. It eliminates things such as brand name companies getting a patent on putting their pills in a brown bottle. Those are the kinds of abuses that have been occurring. In the past, they have kept generics out of the marketplace.

What the underlying legislation will do is it will save $60 billion for American consumers over the next 10 years. It is critically important that we do this drug benefit, but it is also critically important that we do something about the cost of prescription drugs for all Americans.

The PRESIDING OFFICER. The Senator has used his 2 minutes.

The Senator from Massachusetts.

Mr. KENNEDY. Five years ago, the first prescription drug legislation was introduced in the Senate. We have waited and the seniors have waited 5 years to see whether the Senate of the United States was going to take action. Under the leadership of Senator DASCHLE, we have the opportunity to do that. That is because the Democratic leader said so.

A week ago, the Republicans said no to the comprehensive program that was introduced by Senator GRAHAM and Senator MILLER that would have provided the comprehensive approach about which so many have talked.

I have listened to my friends on the other side of the aisle. They are using a favorite technique. That is to misrepresent and distort what is before the Senate, and then differ with it.

Senator GRAHAM has given the facts on this program. The basic issue before the Senate now, in the next few minutes, is whether we consider prescription drugs a priority for our senior citizens. If we vote with Senator GRAHAM and Senator SMITH, we are saying they are a priority.

This bill is not going to solve all the problems, but it is a downpayment. It is a downpayment on those prescription drugs. Every one of us who is going to support that position is committed to coming back next year and the year after to make sure we have the comprehensive issue. That is what is before the Senate: Do we take the problems of our senior citizens seriously or are we going to get behind some kind of facade and say let us put it off for another day?

Seniors have listened to that every single year since the time we passed Medicare in 1965. Now is the time to do something about it. This is a downpayment on prescription drugs, and I think it is time the Senate take that action, and take it today.

I understand our time is up.

The PRESIDING OFFICER (Mr. NELSON of Nebraska). The Senator from Tennessee controls 2½ minutes.

Mr. FRIST. Mr. President, we are about to vote on an amendment that very clearly costs more and covers fewer people than the tripartisan bill we debated last week.

I yield the remainder of our time to one of the sponsors of that tripartisan, more comprehensive plan that seniors deserve better than the underlying bill on which we are about to vote.

I yield the remainder of our time to the Senator from Louisiana.

The PRESIDING OFFICER. The Senator from Louisiana.

Mr. BREAUX. I thank the Senator from Tennessee for yielding.

Mr. President, now is the time to do something about prescription drugs, but this is not the thing to do with prescription drugs. How do I go back to Louisiana, as in every State, and tell the Medicaid Program in Louisiana that this bill is going to cost my State $85 million, which we do not have, through our State Medicaid Program to have the State pick up part of the costs of this prescription drug program? How am I going to go back to my State of Louisiana and tell the 240,000 people in Louisiana that, yes, Congress passed a prescription drug program but, guess what, you are not part of it. You are going to pay 95 percent of all of your costs of prescription drugs, and the Federal Government is going to pick up 5 percent.

Now is the time to do something about prescription drugs, but this Congress can do much better than this. What we ought to do is combine the best of what Government can do with the best of what the private sector can do, and come up with a program that fits Medicare that is universal, that is comprehensive, that covers all seniors, not just some of the seniors, and gives them all a program of which they can be proud. That is the concept of what Medicare was 37 years ago. We should not now divert from that concept and say one group of seniors is going to have one plan, the other seniors are going to get left by the wayside.

Certainly, I think this Congress can do better than that, and we will have the opportunity to do that, working with our colleagues over the August recess to put together that type of plan.

I yield the floor.

The PRESIDING OFFICER. The majority leader.

Mr. DASCHLE. I will use a minute of my leader time. I know we are scheduled to have a vote.

I simply remind my colleagues that almost every senior organization has endorsed the Graham amendment. Not one senior organization has endorsed the Republican plan. What does that tell us? The drug companies endorse the Republican plan. The insurance companies endorse the Republican plan. We do not find one senior organization endorsing the Republican plan. So what is wrong with this picture? Why is it that we cannot get bipartisan, overwhelming support for something every senior organization endorses?

This is our opportunity to make a downpayment, a first step, and we ought to support it. I applaud the Graham amendment. I hope our colleagues will look at it carefully and support it. This is a critical moment. Senior organizations agree. They endorse it. They want this to pass.

I yield the floor.

Mr. FRIST. Mr. President, has all time expired?

The PRESIDING OFFICER. The time is 29 seconds for the minority.

Mr. FRIST. Mr. President, a point of order will be filed very shortly.

In closing, it is important that people recognize the bill is inadequate. Seniors deserve more. A proposal has been discussed, the tripartisan bill, which is a more comprehensive approach for less money. This bill promises less, gives less, fewer benefits, for more money. I urge the defeat of the underlying bill.

I yield back the remainder of our time.

The PRESIDING OFFICER. All time has expired.

Mr. FRIST. I make a point of order that the Graham amendment No. 4345 violates section 302(f) of the Budget Act.

The PRESIDING OFFICER. The Senator from Florida.

Mr. GRAHAM. Pursuant to section 904 of the Congressional Budget Act of 1974, I move to waive the applicable sections of that act for purposes of the pending amendment, and I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The question is on agreeing to the motion. The clerk will call the roll.

The assistant legislative clerk called the roll.

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

I further announce that if present and voting the Senator from North Carolina (Mr. HELMS) would vote ''no.''

The result was announced—yeas 49, nays 50, as follows:

[Rollcall Vote No. 199 Leg.]

YEAS—49

Akaka	Dodd	Mikulski
Baucus	Dorgan	Miller
Bayh	Durbin	Murray
Biden	Edwards	Nelson (FL)
Bingaman	Feinstein	Reed
Boxer	Graham	Reid
Byrd	Hutchinson	Rockefeller
Cantwell	Inouye	Sarbanes
Carnahan	Johnson	Schumer
Carper	Kennedy	Smith (OR)
Cleland	Kerry	Specter
Clinton	Kohl	Stabenow
Collins	Landrieu	Torricelli
Conrad	Leahy	Wellstone
Corzine	Levin	Wyden
Daschle	Lieberman	
Dayton	Lincoln	

NAYS—50

Allard	Feingold	McConnell
Allen	Fitzgerald	Murkowski
Bennett	Frist	Nelson (NE)
Bond	Gramm	Nickles
Breaux	Grassley	Roberts
Brownback	Gregg	Santorum
Bunning	Hagel	Sessions
Burns	Harkin	Shelby
Campbell	Hatch	Smith (NH)
Chafee	Hollings	Snowe
Cochran	Hutchison	Stevens
Craig	Inhofe	Thomas
Crapo	Jeffords	Thompson
DeWine	Kyl	Thurmond
Domenici	Lott	Voinovich
Ensign	Lugar	Warner
Enzi	McCain	

NOT VOTING—1

Helms

The PRESIDING OFFICER. On this vote, the yeas are 49, the nays are 50. Three-fifths of the Senators duly chosen and sworn not having voted in affirmative, the motion is rejected. The point of order is sustained and the amendment falls.

AMENDMENT NO. 4299, AS AMENDED

The PRESIDING OFFICER. Under the previous order, there are 2 minutes of debate equally divided before the vote on the Dorgan amendment.

Who yields time?

Mr. REID. Mr. President, I yield the time.

The PRESIDING OFFICER. All time is yielded. The question is on agreeing to the Dorgan amendment, as amended, Without objection, the amendment, as amended, is agreed to.

The amendment (No. 4299), as amended, was agreed to.

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

Mr. DASCHLE. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

CLOTURE MOTION

The PRESIDING OFFICER. Under the previous order, the Chair lays before the Senate the pending cloture motion, which the clerk will report.

The legislative clerk read as follows:

CLOTURE MOTION

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

Harry Reid, Jon S. Corzine, Byron L. Dorgan, Ron Wyden, Maria Cantwell, Paul S. Sarbanes, Debbie Stabenow, Richard J. Durbin, Tom Daschle, Daniel K. Akaka, Jack Reed, Kent Conrad, Zell Miller, Charles E. Schumer, Ernest F. Hollings, Hillary Rodham Clinton.

The PRESIDING OFFICER. There are 2 minutes of debate equally divided.

Mr. KENNEDY. Mr. President, this is an important issue, and the Senate is not in order. We have 2 minutes of discussion on this, and important comments will be made by our colleagues who deserve to be heard.

The PRESIDING OFFICER. The Senate will be in order.

Who yields time?

Mr. KENNEDY. Mr. President, I yield 1 minute to the Senator from New York.

The PRESIDING OFFICER. The Senator from New York.

Mr. SCHUMER. Mr. President, I think many of us regret that we could not succeed on the last amendment. But there are still things we can do, and must do, to make the cost of drugs lower for all citizens. The Schumer-McCain generic drug bill, the underlying bill, does just that.

For people who are paying $100 per prescription, they will pay $30 or $35 or $40. It will reduce the cost of overall drug spending by $60 billion. It will take some of the burden off our hard-pressed States as their Medicaid rates come down.

It will also apply to everybody: the young and the old, the senior citizen who needs these drugs, as well as the family with a child who cannot afford a desperately needed drug to make that child better.

It is supported by a large group, not only senior citizen groups and consumer groups and labor groups but GM and Caterpillar and Kodak and Ford.

Please let us move forward on this amendment. We have a lot to do in the area of making prescription drugs cheaper, and this is a very vital first step.

I urge my colleagues to vote for cloture.

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

Who yields time?

The Senator from New Hampshire.

Mr. GREGG. Mr. President, the underlying bill, which is the generic drug bill, has not really been addressed as we have moved through these debates on the overlying issue of whether we should have a prescription drug program for seniors.

This underlying bill still has many significant issues in it. Probably the most significant issue is the fact that it creates a new cause of action, a whole new set of lawsuits which have never been used before. This cause of action has never been tried before, never been used before, involving patent law and the FDA. It really will be a lawyer's relief act rather than an act which is going to relieve our citizens of the high costs of drugs.

We should have the opportunity to amend this bill. It can be improved. The basic concepts of this bill are good,

but the bill can be improved. That is why we should not have cloture at this time. We simply have not had a chance to properly address this underlying bill because it has been sort of sidetracked as we have addressed the prescription issue for seniors. So I would hope we would vote against cloture.

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

By unanimous consent, the mandatory quorum call has been waived.

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

The yeas and nays are required under the rule.

The clerk will call the roll.

The legislative clerk called the roll.

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

I further announce that if present and voting the Senator from North Carolina (Mr. HELMS) would vote ''No.''

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

The yeas and nays resulted—yeas 66, nays 33, as follows:

[Rollcall Vote No. 200 Leg.]

YEAS—66

Akaka	Durbin	Mikulski
Baucus	Edwards	Miller
Bayh	Feingold	Murray
Biden	Feinstein	Nelson (FL)
Bingaman	Fitzgerald	Nelson (NE)
Boxer	Graham	Reed
Breaux	Grassley	Reid
Byrd	Harkin	Rockefeller
Cantwell	Hollings	Sarbanes
Carnahan	Hutchinson	Schumer
Carper	Inouye	Sessions
Chafee	Jeffords	Shelby
Cleland	Johnson	Smith (NH)
Clinton	Kennedy	Smith (OR)
Collins	Kerry	Snowe
Conrad	Kohl	Specter
Corzine	Landrieu	Stabenow
Daschle	Leahy	Torricelli
Dayton	Levin	Voinovich
DeWine	Lieberman	Warner
Dodd	Lincoln	Wellstone
Dorgan	McCain	Wyden

NAYS—33

Allard	Domenici	Lott
Allen	Ensign	Lugar
Bennett	Enzi	McConnell
Bond	Frist	Murkowski
Brownback	Gramm	Nickles
Bunning	Gregg	Roberts
Burns	Hagel	Santorum
Campbell	Hatch	Stevens
Cochran	Hutchison	Thomas
Craig	Inhofe	Thompson
Crapo	Kyl	Thurmond

NOT VOTING—1

Helms

The PRESIDING OFFICER. On this vote, the yeas are 66, the nays are 33. Three-fifths of the Senators duly chosen and sworn having voted in the affirmative, the motion is agreed to.

The PRESIDING OFFICER. The question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed for a third reading, and was read the third time.

Mr. SCHUMER. Mr. President, before I get to discussion of the underlying bill, I would first like to thank Senator KENNEDY for his long-time leadership in ensuring access to affordable prescription drugs and especially for the strong fight he and Senators GRAHAM and MILLER have led here on the Senate floor for the past two weeks to add a meaningful prescription drug benefit to Medicare.

I would also like to thank Senator KENNEDY for his leadership in the HELP Committee in bringing Hatch-Waxman abuses to light, and for working with our Leader to move Schumer-McCain to the floor.

I also want to thank my colleague Senator MCCAIN, with whom I introduced the GAAP Act—as well our colleagues who introduced the bill in the house, Congressman SHERROD BROWN and Congresswoman JO ANN EMERSON—for all their hard work in drawing attention to this issue and pushing to get this bill passed this year.

When this Hatch-Waxman debate began, the Senate had two choices:

First, we could choose not to act, and let loopholes in the law continue to let drug prices skyrocket; or, second, we could pass this bill, close the loopholes, and bring down drug prices for all consumers.

Today, as the Senate approaches a vote on the Schumer-McCain bill, the Greater Access to Affordable Pharmaceuticals Act, the choice is clear.

Consumers win. PhRMA loses.

Not only was the bill passed out of committee on a strong bipartisan vote; not only have we heard strong messages of support from our colleagues on the floor; but the public, too, has spoken.

Major corporations have spoken. Labor has spoken. Senior groups have spoken. Consumer groups have spoken. Governors have spoken. Insurers have spoken. Pharmacists have spoken. Disease groups have spoken.

And they want to see action. They want to see the loopholes closed, and they want to see competition in the pharmaceutical marketplace.

Last week we also heard from CBO. Its message: This Bill will bring the relief the public wants. A conservative estimate shows the bill will save consumers $60 billion on drug costs over the next 10 years. And it will mean nearly $8 billion to the Federal Government. When we pass a Medicare drug benefit, it will mean even more savings.

Yesterday, we heard from the FTC. The report the Commission issued illustrates the abuses and tells Congress clear as day to plug up the loopholes in Hatch-Waxman. Their recommendations lead to one inexorable conclusion: pass Schumer-McCain.

The study makes clear that lawyers for the pharmaceutical industry have picked the Hatch-Waxman law clean and that the law needs significant and immediate reform.

The one group that doesn't want to see action is the group representing the name brand drug industry, PhRMA.

Why is the support so widespread? It is quite simple, really. As most things do, it comes down to cold, hard, cash. Drug expenditures have been rising at double digit rates—at nearly 18 percent per year—throughout the 90s.

These increases are simply unsustainable. And closing the loopholes in the patent laws is a common sense way to do something about them. They will mean real savings for consumers, businesses, States, and seniors.

We looked at 15 name-brand prescription drugs whose expiring patents will pave the way for billions of dollars in savings if blockbuster drug companies don't block the less expensive generic versions of these drugs from coming to market when they should.

These drugs are used to treat a variety of illnesses, including allergies, high cholesterol, asthma, and depression. You have probably seen commercials for some of them on TV—Claritin, Zocor, Zoloft. You might even remember Cipro from last fall's anthrax scare.

All of the drugs are scheduled to come off patent by 2005, which in English means that their less expensive versions can then go on sale.

The savings consumers will see on these drugs alone will be at least $4.15 billion annually by 2008 when these less expensive generics are fully phased in.

The biggest savings would come on the popular antidepressant Zoloft, which would see consumer savings of over $735 million if users opt to use the low cost generic version.

Other savings would come on the popular allergy medicine Claritin which would see savings of $501 million and on the cholesterol medicine Zocor, which would see savings of $577 million.

For the individual consumer, these projections are a dream come true.

If you look at what three popular pharmacy chains charge for five commonly prescribed drugs—Claritin, Cipro, Zocor, Zoloft, and Singulair—the individual consumer would see individual savings ranging from $42 to $75 a month on these drugs if generic alternatives were available.

Those filling a Singulair prescription at Walgreens, for example, to treat asthma would save about $54 on the generic version, paying only $34 as opposed to the current price of $87.99. Those filling a Cipro prescription at CVS to treat a urinary tract infection would save about $58, paying only $37 for a 20 pill supply as opposed to the current price of $95.59.

Zocor users would save $45, paying an estimated $70 for a 30 pill supply to control high cholesterol instead of the $115.53 they currently pay at Rite Aid.

The good news is that these numbers show that these drugs can one day be within reach of working Americans.

The bad news is that if we in Congress don't act, the chances of the blockbuster drug companies ever letting that happen are about as likely as the Yankees asking me to pitch Game 7.

We have heard time and time again from the big drug companies that patent protection is the key to innovating

new drugs. And as I have said time and time again, I could not agree more.

When drug companies innovate new drugs which benefit the patient, they are indeed preventing disease and saving lives. And they should be rewarded for doing so with a period of time to exclusively market the drug.

That is how the system is supposed to work and that's how it did work for a very long time.

But over the almost 20 years since Hatch-Waxman was passed, the drug companies have taken advantage of this system, devising new ways to extend the period of exclusivity they get when they patent a life-saving drug.

Today, I want to debunk some of the myths that the drug companies are perpetuating about the way they are using the patent laws and how the bill Senator MCCAIN and I have introduced will impact innovation in the pharmaceutical industry.

PhRMA has been circulating a list of claims that it has been calling a ''reality check.'' If a bank tried to cash that check, it would bounce.

Today, I want to shine a light on some of the PhRMA claims and ensure that the public knows the truth about what is going on in the drug industry.

The reality is that the drug companies are not spending all their time innovating new drugs, they are innovating new patents.

Instead of devising new ways to further medical science, they are focusing on furthering company profits. And that often means keeping the competition at bay.

But before I go on, I want to make clear that the Greater Access to Affordable Pharmaceuticals Act is not about robbing pharmaceutical companies of legitimate patent protection. It's not about theft of innovation, it's not about taking steps to enact laws that are not in the best interest of consumers.

In fact, it is about just the opposite. It is about examining competition in today's marketplace and revisiting a compromise which was struck nearly 18 years ago.

That compromise—the Hatch-Waxman Act—was intended to strike a balance and help save consumers billions of dollars on pharmaceuticals while rewarding brand name companies for their innovations.

But, in recent years, as the profits and stakes have become higher, as I said, the drug industry lawyers have picked the Hatch-Waxman law clean.

Companies are aggressively pursuing extended monopolies through filing weak or invalid patents and engaging in deals which the FTC is increasingly scrutinizing for anticompetitive motives.

We must put an end to these abuses.

The GAAP act does not intend to cut innovators off at the knees and it isn't a freebie for the generic drug industry. It is a pro-consumer bill that restores the balance intended by Hatch-Waxman.

The bill would limit the delay to one 30-month stay, for brand companies who file suit against a generic challenger. And the only patents eligible for this automatic stay would be the brand company's original patents.

For any patents listed after the brand drug is approved, the brand company would instead have to allow a court to decide whether their case merits a stay against generic competition.

It would prevent abuses like those we are discussing here today by reducing incentives to list patents that are not truly innovative, but instead are intended solely to extend monopolies.

The GAAP act reforms the so-called ''180-day rule'' by closing the loophole that enables a brand name company to pay a generic manufacturer to stay off the market, effectively putting the kibosh on competition.

Closing this loophole would prevent problems like the Hytrin case where Abbott Laboratories allegedly paid Geneva Pharmaceuticals $4.5 million per month to keep their hypertension drug off the market.

Now PhRMA will tell you that the law is not broken.

They will tell you that generics' share of the prescription market has increased from 18 percent in 1984 to 47 percent today.

But what they won't tell you is that generics have been stuck right around 45 percent for at least the past 6 years.

They will also tell you the games are not causing delays. But this chart shows that in 2000, 20 of the 30 drugs that were supposed to come off patent were delayed. In 2001, 23 out of 26 were delayed—88 percent of the drugs supposed to come off patent have been delayed, and most of these delays continue today.

PhRMA will tell you that ''patents on new products never delay generic versions of old ones.'' And if we were talking about patents on new drugs, that would be a true statement. But that is not what we are talking about. We are talking about new patents on old drugs.

The drug companies are coming up with different formulations or dosage forms, or other unapproved uses for old drugs whose patents have either expired or are about to expire in order to keep low-cost generic competitors off the market.

Since a generic has to show that it doesn't infringe on these new patents before it can enter a market, the drug companies buy some extra time and can extend their market exclusivity.

The changes Senator MCCAIN and I have proposed protect the brand companies from having their patents infringed on. But they also prevent the brand companies from abusing their patents and keeping generics off the market.

Let's take a look at some of the ''innovations'' that brand companies are listing in the FDA's Orange Book. It is these kinds of patents which can automatically delay competition.

For Ultram, a pain medication, the brand company has come up with a new dosing schedule—because it's a strong medication, they suggest that you could take one-fourth of a pill at a time and slowly build up to taking a whole pill. This is a dosing method which doctors and pharmacists have used on many drugs, in many instances. Yet, somehow, J&J got a patent on it. And now that patent is preventing generic competition.

On Fosamax, a drug for osteoporosis, the brand company has come up with a ''kit'' inside which the pills are arranged. This may be a great little kit, but its patent shouldn't be listed in the Orange Book where it can delay generic competition.

On Pulmicort, an asthma medication, the company has a patent on the container the drug is in—and that patent is listed in the Orange Book, where it cause an automatic 30-month stay against a generic.

On Thalomid, a cancer drug, the company has come up with not one—but two—computer programs that pharmacists can use when doling out prescriptions. Computer programs—not new drugs—computer programs.

Cyclessa, similar to Fosamax, has a patent on a kit which reminds you how to take the medicine. Well the generics can make their own kit.

A new piece of plastic shouldn't keep an old pill off the market.

These patents are real. Sure they may be on things that are novel, but they have nothing to do with the drug substance that is helping the patient. They are put in the Orange Book for the sole purpose of extending a company's monopoly.

PhRMA says the automatic 30 month stays never extend a patent. Well, they may not extend the amount of time a company can exclusively sell its particular container, but stacking them one after the other certainly extends the amount of time that the brand can keep its competition away from its customers.

And brand companies are getting better and better at timing the filing of their patent applications so that their new patents are issued just as their original patents are expiring. This practice causes a delay in generic competition, which is nothing less than a de facto extension of the original patent.

The delays caused by these additional patents are real, and they mean real money to consumers.

Take Neurontin, a drug used to prevent partial seizures. The basic patents expired in July of 2000. By listing patents which do not even relate to the originally approved form of the drug, the brand company has already succeeded in preventing generic competition for 21 months—a delay which may have already cost consumers over $800 million.

Further, by listing an additional patent with the FDA, and overlapping the automatic 30-month stays, the brand

company has effectively converted the original 30-month stay into a 54-month stay against generic approval, and they didn't even have to prove to a court that the new patent had any merit at all.

Or take, for example, Paxil, a drug with $2.1 billion in sales used to treat depression.

The basic active ingredient in Paxil was discovered back in the late 1970s by a Danish company, Ferrosan. But it wasn't marketed as a drug until Glaxo SmithKline licensed the original patents, did the clinical trials and got it approved by the FDA.

The company deserves a reward for bringing this old chemical to market, and under Hatch-Waxman, that reward was intended to be 5 years of market exclusivity—5 years during which a generic can't even put in an application on the drug.

But that wasn't enough for Glaxo. Before marketing the drug, they made a slight—and some would argue unnecessary—change to the basic compound in order to get a new patent, a patent which would add an additional 8 years to their monopoly their monopoly on a drug they didn't even discover.

Enter Apotex, the first generic challenger, which has gone to court claiming both that they do not infringe this new patent and that the new patent is invalid.

The case has been in court for 3½ years. Even if the companies come to resolution on this first patent, Glaxo has, in the meantime, applied for and been issued nine additional patents on Paxil—patents on yet other slightly different chemical substances, as well as patents on different formulations of the drug. The last of these patents expires in 2019.

These new patents have already invoked multiple 30-month stays against generic competition for Paxil. The automatic stays already granted add up to a delay of over 60 months. To be fair, if Glaxo prevails in court, these stays won't extend the time on their patent. But if Apotex wins the suit, these multiple 30-month stays will still be hanging out there preventing the generic from coming to market. And there's nothing to stop Glaxo from getting even more patents before these delays expire. Each year Glaxo can delay generic competition costs Paxil users up to $500 million.

What has happened with these drugs is that the drug companies saw their original patents about to expire and then created new ones to maintain their control over the market.

These kinds of practices have become the norm in the drug industry. These companies figure out a new way to keep the dollars rolling in, stooping to new lows every day to maintain their exclusivity rights.

I have heard from the big drug companies that they are in the failure business. Well, if it's the failure business that tops the Fortune 500 lists, sign me up.

The big pharmaceutical companies may make their claims, but we in Congress know the reality. Insurers and State Medicaid directors know the reality. Corporations know the reality. Our seniors know the reality.

The reality is that prescription drug prices are skyrocketing at a rate of 17 percent per year, generic penetration into the market has been stagnant for the past eight years, and loopholes in our patent laws are making the reality even worse.

They are crippling consumers and seniors who can't afford to purchase or take the drugs they need.

I agree that patent protection is important to saving lives, but I am sure those who dedicate their lives to finding new cures would also agree that a drug can do no good if it is financially out of the reach of patients who depend on it.

As Congress continues to wrestle with the complexity of crafting and paying for a meaningful Medicare prescription drug benefit, we must not overlook a straightforward solution to the escalating drug prices facing seniors, businesses, insurers and consumers today.

If we can ensure fair competition in the pharmaceutical marketplace—a level playing field for both brand and generic companies—then everyone will win.

I ask my colleagues in the Senate to vote yes today to S. 812: to vote yes for fair marketplace practices, vote yes for robust competition in the pharmaceutical marketplace, vote yes for access to affordable drugs—and vote yes for consumers.

I ask unanimous consent that further material be printed in the RECORD.

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

COMMONWEALTH OF PENNSYLVANIA,
OFFICE OF ATTORNEY GENERAL,
Harrisburg, PA, July 24, 2002.

Hon. JOHN MCCAIN,
U.S. Senate,
Washington, DC.
Hon. CHARLES E. SCHUMER,
U.S. Senate
Washington, DC.

DEAR SENATORS MCCAIN AND SCHUMER: As Attorney General of the Commonwealth of Pennsylvania, my constituents make me aware every day about how the high cost of prescription drugs adversely affects their lives. For that reason, I endorse the Greater Access to Affordable Pharmaceuticals Act of 2001 (S. 812) which you are sponsoring.

Pennsylvania has the second largest number of senior citizens of any state in the country. As you are well aware, Medicare does not provide a prescription benefit for most drugs. Therefore, senior citizens without private insurance, Medicaid or a special government program like Pennsylvania's PACE program, pay for prescription drugs themselves. Even though Pennsylvania's PACE program is a model for other state and federal senior citizen prescription benefit plans, the program does not cover every senior citizen. Thus, there are many Pennsylvania citizens living on fixed incomes who find that their income and standard of living is being eaten away by prescription drugs that can cost more than $100 a month. Senior citizens who are on two or three medications can face monthly prescription costs of $500 to $1000.

One factor in the high cost of prescription drugs is attempts by brand name drug makers to forestall entry by generic competitions. The Hatch-Waxman Act of 1984 was intended to spur generic competition with brand name pharmaceuticals. Unfortunately, brand name drug makers have been using that act in unintended ways to block or delay rather than foster generic entry. In particular, two provisions have been misused. One allows for an automatic 30-month stay of a generic's drug application upon the filing of a patent infringement suit by a brand name manufacturer. The other grants the first generic drug applicant for a drug a 180-day period of exclusivity before other generics can enter the market. These two provisions can be misused to delay generic entry by years. I believe that the Greater Access to Affordable Pharmaceuticals Act of 2001 provides a reasonable remedy for these abuses which balances the interests of consumers and the pharmaceutical industry.

While I believe that pharmaceutical companies should be compensated for their discoveries and innovation with appropriate patent protection, I object to those patents being lengthened by misuse of the current law. Passage of your bill will address those misuses. Thank you for your work and consideration on this matter.

Very truly yours,

D. MICHAEL FISHER,
Attorney General.

STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL,
New York, NY, July 24, 2002.

Senator EDWARD KENNEDY,
Washington, DC.
Senator JUDD GREGG,
Washington, DC.

DEAR SENATORS KENNEDY AND GREGG: I write to express my support of the Greater Access to Affordable Pharmaceuticals Act of 2001 (''GAAP''), which amends the Hatch-Waxman Act of 1984 (the ''HWA''). I attach a Policy Statement which details the arguments made in this letter.

In the past several years, State Attorneys General have filed five antitrust suits to remedy the harm caused by brand-name and generic manufacturers' manipulation of loopholes in the Hatch-Waxman Act (''HWA''), thereby delaying generic entry. These are:

State of Ohio, et al. v. Bristol-Meyers Squibb, Co., concerning the anti-cancer drug Taxol127 (the ''Taxol litigation);

State of Alabama, et al. v. Bristol-Myers Squibb Co., et al., concerning the anti-anxiety drug Buspar127 (the ''Buspar litigation'');

State of New York, et al. v. Aventis, S.A., et al., concerning the anti-hypertension drug CD127 (the ''Cardizem litigation'');

State of Florida, et al. v. Abbott Laboratories, Inc., concerning the anti-hypertension drug Hytrin127 (the ''Hytrin litigation''); and

Commonwealth of Pennyslvania v. Schering-Plough Corp. et. al, concerning the potassium supplement K-Dur 20 (''the K-Dur 20 litigation'').

Through these cases, and other multi-state investigations, this Office has gained substantial experience with the shortcomings of the HWA. GAAP will be an important step in correcting these problems, and in ensuring consumers access to affordable medication.

GAAP specifically alleviates two critical problems caused by the HWA, which the cases brought by the Attorneys General illustrate:

The Thirty Month Stay—Under the HWA, brand-name manufacturers list unexpired patents with the FDA in a compendium known as the ''Orange Book.'' The FDA does not evaluate the merits of the listing, and relies on the manufacturer's representations as to the listing's validity. An Orange Book listing carries a rich reward—an automatic 30-month stay against certain potential generic entrants whome the manufacturer has sued for patent infringement, despite the absence of any court finding that the infringement claim has any validity whatsoever.

Problems caused by this provision are illustrated by the facts of the Buspar litigation. In that case, Bristol-Myers Squibb (''BMS'') sought to extend its patent monopoly for its profitable buspirone anti-anxiety medication. As BMS's buspirone patent was about to expire, BMS received a patent for a metabolite that the body naturally produces—which BMS claimed was the result of introducing buspirone into the body. BMS then had the FDA list the patent in the Orange Book eleven hours before the first generic alternative to buspirone was to otain FDA approval. Although BMS explicitly stated to the United States Patent Office that its new patent did not cover buspirone, it Orange Book entry made precisely the opposite claim. As a result, generic makers of buspirone were barred from the market, and consumers paid millions more than they would have paid, had a generic alternative been available.

GAAP helps alleviate this problem in two essential ways. First, a brand-name manufacturer will no longer be able to obtain the 30-month stay for follow-on patents. Had GAAP been in place, BMS's scheme would not have been possible. Second, in certain instances, GAAP allows generic manufacturers to challenge fraudulent Orange Book listings in court.

The 180-day exclusivity period—HWA gives certain generic entrants who are the first to seek FDA approval for their drugs a 180-day exclusivity period during which no other generic alternative to the same brand-name drug may come to market. While this provision was intended to provide an incentive for generic entry, in several instances, brand-name manufacturers have paid their generic counterparts to staff off the market, without generic forfeiting its right to exclusivity. This creates a perpetual bar to entry by other generics. Thus, in both the Hytrin and Cardizem cases, no generic version of the brand-name drug could be sold until litigation and investigations by the Federal Trade Commission led the parties to cancel their agreements.

GAAP would render impossible such permanent barriers to generic entry. Under the pending bill, if generic entry does not take place within sixty days of the generic drug's approval, the next generic manufacturers in line may enter the market. Conduct now being challenged in costly and time-consuming litigation would simply not have taken place had GAAP been in effect.

Case-by-case and after-the-fact investigations and litigation are no substitute for fixing the problems inherent in the HWA. For that reason, I applaud the efforts of Senators Schumer and McCain, and those of other GAAP sponsors, and urge the speedy passage of this important and beneficial bill.

Sincerely,

ELIOT SPITZER.

July 24, 2002.

STATEMENT ON S. 812, THE GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT OF 2001

In a letter issued today, Attorney General Eliot Spitzer has written in support of the Greater Access to Affordable Pharmaceuticals Act of 2001 (''GAAP''), introduced by Senators McCain and Schumer to amend the Hatch-Waxman Act of 1984 (the ''HWA''). This statement explains in greater detail the arguments set forth in that letter, and the problems with the HWA that led to its submission.

Protecting consumers' access to quality health care at affordable prices is one way in which the State Attorneys General serve the American public. To that end, State Attorneys General have, in recent years, brought five antitrust actions arising, in whole or in part, out of efforts by brand-name drug manufacturers to manipulate the HWA's procedures to keep cheaper generic drugs off the market, and to maintain monopoly pricing long after the brand-name drug's patent expiration date. These are:

State of Ohio, et al. v. Bristol-Myers Squibb, Co., concerning the anti-cancer drug Taxol® (the ''Taxol litigation'');

State of Alabama, et al. v. Bristol-Myers Squibb Co., et al., concerning the anti-anxiety drug Buspar® (the ''Buspar litigation'');

State of New York, et al. v. Aventis, S.A., et al., concerning the anti-hypertension drug Cardizem CD® (the ''Cardizem litigation'');

State of Florida, et al. v. Abbott Laboratories, Inc., concerning the anti-hypertension drug Hytrin® (thee ''Hytrin litigation''); and

Commonwealth of Pennsylvania v. Schering-Plough Corp. et al, concerning the potassium supplement K-Dur 20 (''the K-Dur 20 litigation'').

As described in more detail below, these cases starkly illustrate the weaknesses of the HWA.

The New York Attorney General has reviewed the terms of GAAP against the backdrop of this experience, and believes that this bill represents a substantial step towards correcting the HWA's flaws, and restoring the appropriate balance that Congress initially intended between protecting innovation and ensuring affordable drug prices. Indeed, much of the misconduct challenged in these cases would not have been possible had GSSP been in force.

By this statement and in his letter, the Attorney General highlights the need for reform. After a brief summary of the present law, the statement describes state enforcement actions in greater detail, and show how GAAP effectively closes loopholes that allowed for the misconduct addressed by these actions.

By passing GAAP, Congress can protect consumers, lower drug prices, and avoid the need for time-consuming and expensive litigation. For those reasons, the New York Attorney General has strongly urged that Congress enact GAAP into law.

I. Generic Drugs and the Hatch-Waxman Act

Generic drugs are bioequivalents of brand-name drugs in dosage, form, safety strength, route of administration, quality, performance characteristics and intended use. They tend, however, to be priced significantly below their brand-name equivalents. An increase in the use of generic drugs would be an important step in controlling the rising costs of pharmaceuticals, and of health care in general.

In 1984, Congress passed the HWA, which streamlined the regulatory approval process for generic drugs. In particular, the Act permits the manufacturer of a new generic drug to submit an Abbreviated New Drug Application (''ANDA''), which may rely on the safety assessments of the New Drug Application (''NDA'') filed by the ''pioneerr''—i.e., brand-name—drug's manufacturer. An ANDA entails far less expense than an NDA, and can be approved by the FDA far more expeditiously.

Although it is not necessary for purposes of this statement to deve into all the intricacies of the HWA, two elements—the 30 month stay and the 180-day exclusivity period—play an important role in allowing pharmaceutical companies to delay generic entry and deny consumers the benefits of competition, despite the good intentions of the HWA's drafters. These elements are addressed below.

II. The HWA's Loopholes

A. The 30 Month Stay

The Food and Drug Administration (''FDA'') maintains a list of pharmaceutical patents commonly known as the ''Orange Book.'' Upon receiving FDA approval for a brand-name drug, the manufacturer must inform the FDA, in substance, of all patents that would be infringed by the non-licensed sale of a generic equivalent for that drug. The FDA then includes those patents on its Orange Book list. Before marketing a generic drug, an ANDA filer must certify that the listed patents will not prevent sale of the generic version, for any of several reasons, and notify the brand-name manufacturer of its certification. One such certification—the so-called ''paragraph IV certification''—attests that the pioneer drug patent ''is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.'' Once an ANDA applicant—the generic manufacturer—submits a paragraph IV certification, the brand-name manufacturer has 45 days within which to bring a patent infringement action against the applicant. If the brand-name manufacturer initiates such a suit, the FDA's approval of the NADA is automatically delayed for 30 months.

The 30 month period is referred to as a ''stay.'' More accurately, it is an injunction that takes effect immediately on the brand-name manufacturer's filing of its case, regardless of the strength or weakness of its patent infringement claims, and without any judicial oversight whatsoever. The statutorily-created injunction relieves the brand-name manufacturer of the responsibility of satisfying a court that it is entitled to a preliminary injunction against generic entry—a threshold that the brand-name manufacturer would have to meet in the absence of the HWA. The FDA itself lacks the expertise or the resources to evaluate the validity of patents identified for listing in the Orange Book and, in consequence, lists patents solely in reliance on the brand-name manufacturer's listing request.

Given the minimal standard for placement in the Orange Book, and the financial rewards of such a listing—a 30-month roadblock to generic entry—it is no surprise that drug manufacturers go to extraordinary lengths to insure that the FDA list any unexpired patent covering a profitable brand-name drug. Often, as the initial patent for a drug's active ingredient nears expiration, the brand-name manufacturer will seek ''secondary patents'' on specific aspects of the drug, such as mode of delivery—the validity of which may be dubious, at best—and which the manufacturer claims apply to previously approved uses of the drug. Armed with such new patents, manufacturers have been able to suppress generic alternatives, which would otherwise be available to consumers.

The cases brought by the States illustrate the potential for misuse inherent in the 30 month stay provision:

The Buspar litigation concerns, in part, an effort by Bristol-Myers Squibb (''BMS'') to extend its patent monopoly for the profitable buspirone anti-anxiety medication. As BMS's patent for buspirone was about to expire, it received a patent for a metabolite that the body naturally produces—BMS claimed—as

the result of introducing buspirone into the body. BMS then had the FDA list the patent in the Orange Book eleven hours before the first generic ANDA was to be approved. Although BMS explicitly stated to the United States Patent Office that its new patent did not cover buspirone, its Orange Book entry made precisely the opposite claim. As a result, generic makers of buspirone were barred from the market, and consumers paid hundreds of millions of dollars more than they would have paid, had a generic alternative been available.

A federal district judge found that BMS's conduct before the FDA was improper and ordered the patent delisted, thereby permitting the sale of generic alternatives. On appeal, the Federal Circuit held that, as a matter of procedure, generic entrants could not sue to obtain delisting from the Orange Book, and vacated the order without evaluating BMS's behavior before the FDA. This past February, yet another federal district judge found BMS's Orange Book filing to be ''objectively baseless,'' and an effort to ''justify taking property that belongs to the public.''

The Taxol litigation addresses efforts by BMS to preserve its monopoly on Taxol, an important treatment for breast cancer and other tumors that the federal government itself initially developed and then licensed to BMS for five years. In their complaint, the States allege that BMS fraudulently obtained patents for Taxol, listed them in the Orange Book, and then filed litigation for the sole purpose of delaying generic entry into the market via the HWA's stay provision. It took nearly three years before a court rejected BMS's claims, during which cancer patients were deprived of access to less expensive generic alternatives.

In a particularly egregious manipulation of the HWA, BMS entered into an arrangement with generic manufacturer American Bioscience, Inc., by which BMS consented to be subject to a court-ordered temporary restraining order, issued upon ABI filing a lawsuit demanding that BMS list one of ABI's Taxol patents in the Orange Book. Based on the order, BMS had the FDA list ABI's patent in the Orange Book—in an apparent effort to clothe the fraudulent listing with the seeming legitimacy of a court decree. After generic manufacturers and the Federal Trade Commission filed papers challenging the collusively obtained order, the Court ruled that ABI was not entitled to sue BMS to obtain an Orange Book listing, and dismissed the case.

GAAP takes important steps towards resolving the problems addressed by these cases, in two ways. First, GAAP limits drug manufacturers to a single 30 month stay per drug. As initially drafted, GAAP eliminated the 30 month stay altogether. While the original might better encourage pharmaceutical competition, the compromise version passed by the Senate Health, Education, Labor and Pensions Committee represents a substantial improvement over the present legal regime.

In the Buspar case, BMS was able to obtain a 30 month stay for the third patent it claimed barred generic versions of buspirone, after the initial patent had expired and without the need to obtain a court ruling on infringement. GAAP instead requires drug manufacturers that obtain such follow-on patents to protect their intellectual property in the same manner as other patent holders—by going to court, proving that their case has a likelihood of success, and securing an injunction against the alleged infringer. That option provides recourse for genuinely aggrieved patent holders, while prohibiting brand-name manufacturers from gaining an advantage, to the detriment of consumers, solely on the basis of their own assertion of a valid patent and their willingness to file suit.

Second, GAAP would allow generic competitors to seek declaratory relief on the validity of an Orange Book listing at the time an NDA is approved—when, under GAAP, the brand-name manufacturer would still be entitled to a thirty month stay. As the Federal Circuit's Buspar ruling demonstrates, the FDA's decision to list a patent in the Orange Book may not be subject to any judicial review under existing law, and frivolous or fraudulent listings can become impassable roadblocks to generic entry. Although a previous version of the bill would have afforded even greater opportunity for challenging Orange Book listings, this aspect of GAAP would still provide potential entrants with the means to challenge such roadblocks in court, in those cases where the thirty-month stay would still apply.

B. The 180-Day Exclusivity Period

HWA gives the first ANDA filer with a paragraph IV certification a 180-day exclusivity period following a court ruling permitting entry, during which no other manufacturer of a generic version of the same drug could enter. This provision provides an incentive for generic manufacturers to challenge brand-name patents. But as currently structured, the HWA provides a means for brand-name and generic manufacturers acting in collusion to bar new generic competitors for significantly longer periods. In effect, the brand-name manufacturer simply ''buys'' the first ANDA filer's agreement neither to enter the market nor to transfer its exclusivity rights, thereby creating a perpetual bar against other generic competitors. This can have a profound impact on drug prices, because generic drugs are typically not priced at their full discount until the exclusivity period has expired and additional generic competitors are able to enter the market.

Cases brought by the Attorneys General illustrate this abuse of the HWA:

The Cardizem litigation arises from an agreement between brand-name manufacturer Hoechst Marion Roussel, Inc. (''HMRI'') and generic drug manufacturer Andrx Corporation (''Andrx''), under which HMRI paid Andrx nearly $90 million in exchange for Andrx's agreement to keep its cheaper alternative to HMRI's Cardizem CD heart medication off the market. As part of the agreement, Andrx agreed to stay off the market while still prosecuting its ANDA—so as to maintain its right to the 180-day exclusivity period granted the first-filer under the HWA—and pledged not to transfer or sell its exclusivity rights. Thus, the agreement effectively barred any further generic entry. Only after private suits challenged this arrangement and the FTC opened an investigation, did Andrx enter the market, thereby removing the block against additional generic competitors. A federal district court has since held the HMRI/Andrx agreement to constitute a per se violation of the antitrust laws. (That ruling is now on appeal.) In yet another case, the Court of Appeals for the District of Columbia Circuit reinstated a generic manufacturer's claim challenging the HMRI/Andrx agreement.

The Hytrin litigation challenges an arrangement under which Abbot Laboratories (''Abbott'') paid generic manufacturer Geneva Pharmaceuticals, Inc. (''Geneva'') over $60 million, in exchange for Geneva's agreement not to market a generic version of Abbot's hypertension medication, Hytrin. In that agreement—as in Cardizem—Geneva promised not to give up the 180-day exclusivity period as the first ANDA filer. No other generic manufacturers were able to enter the market, and Geneva and Abbott shared the profits from the resulting exclusion of competition. The district court held this arrangement per se unlawful. (That ruling, too, is on appeal.)

Under GAAP, the first ANDA filer loses its right to exclusivity if it does not come to market within 60 days of the date on which it is declared eligible to do so by the FDA. Further, the 180-day exclusivity period runs from either the date of a final court decision on the patent infringement action, or the date on which a settlement order or consent decree is signed by the court, whichever is earlier. These provisions should severely limit the ability of the brand-name manufacturer and first generic entrant to act collusively to bar other generic alternatives from reaching consumers.

III. Conclusion

In the examples above, antitrust suits seeking full recompense for injured consumers helped cause the wrongdoers to cease their misconduct, and may aid in deterring further abuses. But antitrust enforcement on a case-by-case basis will not solve the problems underlying the lawsuits, which are inherent in the HWA itself. As enacted, the HWA affords unscrupulous manufacturers with both means and incentive to extend brand-name monopolies beyond the patent exclusivity period set by Congress.

Not all such misconduct comes to the attention of law enforcers or private plaintiffs; antitrust litigation is time-consuming, expensive and risky; and pharmaceutical companies are learning from previous legal setbacks, and are adopting ways to exploit the present law that may be less vulnerable to antitrust challenges—yet still deleterious to the goal of harnessing competition to provide affordable health care. Amending the HWA so as to remove available avenues for anticompetitive and anticonsumer actions, rather than relying on individual lawsuits for costly after-the-fact remedies, is a far more effective means to protect consumers.

WHOSE SIDE ARE YOU ON?

IN FAVOR OF THE CURRENT SYSTEM

Pharmaceutical Research and Manufacturers Association (PhRMA)

IN FAVOR OF CLOSING THE LOOPHOLES

General Motors Corporation
Ford Motor Company
Daimler Chrysler
International Union, UAW
AFL–CIO
AFSCME
Verizon
Wal-Mart
Kodak
Motorola
Caterpillar, Inc.
K-Mart
Georgia-Pacific
Albertsons
UPS
Kellogg's
Sysco
Constellation Energy Group
Ahold USA
Woodgrain Millwork
Weyerhaeuser
National Committee to Preserve Social Security & Medicare
AARP
Consumer Federation of America
Families USA
Gray Panthers
National Consumer League
Consumers Union
Public Citizen
U.S. PIRG
Governor Howard Dean (VT)
Governor William Janklow (SD)
Governor Bob Wise (WV)

Governor M.J. ''Mike'' Foster, Jr. (LA)
Governor Don Siegelman (AL)
Governor Gary Locke (WA)
Governor Bob Holden (MO)
Governor Jeanne Shaheen (NH)
Governor Tony Knowles (AK)
Governor Benjamin Cayetano (HI)
Governor Ronnie Musgrove (MI)
Generic Pharmaceutical Association (GPhA)
American Association of Health Plans
Aetna
Blue Cross Blue Shield Association
Anthem Blue Cross and Blue Shield
Health Insurance Association of America
Kaiser Permanente Health Plan
HIP
Association of Community Health Plans
National Association of Health Underwriters
National Association of Chain Drug Stores
Advance-PCS
Caremark Rx
American Academy of Family Physicians
National Committee to Preserve Social Security and Medicare
Academy of Managed Care Pharmacy
Alliance of Community Health Plans
National Organization for Rare Disorders
National Hemophilia Foundation
Alpha One Foundation
Gay Men's Health Crisis
Center for Medical Consumers
Treatment Action Group
Interstitial Cystitis Association
The Narcolepsy Network
Pacific Business Group on Health
Midwest Business Group on Health
Washington Business Group on Health
Food Marketing Institute

Mr. KENNEDY. Mr. President, I am pleased today that the Senate has passed the Schumer-McCain bill. This bill is the Senate's answer to the public's demand for action on lower drug prices. The bill would end—once and for all—the drug industry's abuses and close legal loopholes the industry exploits to block competition and keep drug prices artificially high.

The record is clear that the pharmaceutical industry uses loopholes in the landmark Hatch-Waxman Act to drive up the cost of prescription drugs. Each and every day, pharmaceutical companies exploit those loopholes to maintain their monopoly over their drugs, and to keep more affordable generic drugs off the market. America's consumers pay the price, and today the Senate has said loud and clear—it's time to stop the abuses.

Just yesterday, the Federal Trade Commission recommended legislative changes that are incorporated in Schumer-McCain. And here today, the Senate has approved the Schumer-McCain reforms on a strong bipartisan vote. The Senate has spoken and it has said: Stop these abuses. Stop depriving our seniors and our uninsured of safe and effective drugs that they can afford. Stop driving up the cost of health care for employers and health plans and consumers by delaying lower cost generic drugs.

What is it we have done today? Schumer-McCain amends the Hatch-Waxman Act, which provides for the approval of generic drugs. The Hatch-Waxman Act has been a tremendous success in promoting competition and innovation in the pharmaceutical industry. Indeed, both the brand drug and generic drug industries have flourished under it.

Yet there are clearly weaknesses in the Hatch-Waxman Act. Today, of the top 15 best-selling drugs potentially subject to generic competition, the basic patents on at least five have long expired. Their exclusive rights to market their drugs have passed. Yet there is no generic competition. The system needs repairs.

Prescription drug costs are spiraling out of reach of the elderly and uninsured. They are draining the health care budgets of State governments, employers and labor unions. All because brand-name drug companies have exploited loopholes in the law to pocket windfall profits.

Drug prices have skyrocketed at double digit rates annually since 1996, and experts expect this trend to continue. This drug price inflation has been far in excess of the rate of consumer price inflation. And experts agree that spiraling drug prices have accounted for almost two-thirds of growth in drug spending especially the higher prices of new, aggressively promoted drugs.

Generic drugs are clearly part of the answer. Simply put, a 1 percent increase in generic use can decrease the Nation's yearly bill for drugs by a billion dollars. And ensuring the timely approval of generic drugs could save consumers $60 billion over the next 10 years.

These savings are easy to understand. For patients and health plans alike, the costs of brand-name drugs are four times higher than for their generic equivalents. That difference is even higher for the elderly and uninsured, who must often pay full price for their medicines. On average, a month's supply of a generic drug costs a patient $4 and the health plan $16; the costs for a brand drug are 4 times higher: $16 for the patient, $64 for the plan. For the uninsured, and seniors who lack prescription drug coverage, the full costs are either $20 for the generic or $80 for the brand drug.

The antidepressant Prozac is a clear example. Generic companies challenged and defeated a Prozac patent. Today, you can buy 30 generic Prozac tablets for less than $30—less than a third of what brand-name Prozac will cost you.

But some pharmaceutical companies game the system by listing spurious patents with the FDA—patents on unapproved uses, unapproved compounds, or formulations that they don't even market. Then they get automatic 30 month stays delaying approval of generic drugs.

For example, Neurontin is a drug approved by FDA to treat epilepsy. In 2001, Neurontin sales exceeded $1.1 billion. The basic patent on the drug compound expired in 1994, and the patent on the approved method of use expired in 2000. But the company had listed two additional patents on the drug that the generic companies had to certify were invalid or not infringed. These two patents were on an unapproved compound—just the addition of a water molecule to the basic compound—and on an unapproved use, the treatment of neurogenerative disease, patents that never should have been listed at FDA.

The first 30-month stay needlessly delayed generic competition for half a year. But before that stay was up, Neurontin's manufacturer listed a third formulation patent with FDA. The generic applicant had to certify to that patent as well and another 30 month stay will delay generic approval until December 2002. In total, a generic version of this drug will be delayed 30 months, at a cost to consumers of $1.4 billion.

In effect, Neurontin's manufacturer blocked generic competition by obtaining a patent for simply adding a water molecule to its basic drug. That patent meant months of delay in which that company enjoys huge profits while preventing affordable generic versions from reaching the market. This single water molecule will cost consumers at least $1.4 billion in savings for their prescription drugs. We still do not know when a generic will get to market, but we do know that Schumer-McCain will make it far more likely that a generic Neurontin will be available in 2003.

To address the abusive mis-listing of patents at FDA, the ever-greening of patents, and the stacking of successive 30 months stays, Schumer-McCain includes a series of provisions designed to work together to close the loopholes and foreclose future gaming of the system. Schumer-McCain does several things.

First, Schumer-McCain permits only one 30-month stay per generic drug application, and only on those patents listed with the FDA within 30 days of brand drug approval.

Second, for the patents for which no 30-month stay is available, Schumer-McCain provides an expedited process whereby a patent owner can, within 45 days, seek a preliminary injunction to defend its patent against a particular generic drug applicant. If a patent owner elects not to defend its patent against that generic applicant as part of this process, it cannot later enforce that patent against that applicant or others for the manufacture, distribution, sale, or use of that applicant's generic drug. This provision does not preclude the patent owner from enforcing its patent against anyone else, including a subsequent generic applicant that challenges the patent in its generic application. Schumer-McCain includes related provisions that enhance protections for patents. One requires a generic applicant who challenges a patent to provide better information to the patent owner for it to assess the merits of the generic applicant's patent challenge, while the second clarifies that a preliminary injunction in a drug patent infringement case may be granted notwithstanding the availability of monetary damages.

Third, Schumer-McCain clarifies the information that must be filed with FDA on patents that claim a drug or an approved method of using a drug, so that it will be more difficult for drug manufacturers to list inappropriate patents or incorrect or incomplete information with FDA.

Fourth, Schumer-McCain enforces this requirement to list patent information at FDA by saying that failure to list a patent bars the patent owner from enforcing the patent against a generic applicant or others for the manufacture, distribution, sale, or use of a generic drug. This provision does not bar enforcement of the patent against anyone else, in particular against any brand drug company or others for the manufacture, distribution, sale, or use of a brand drug that infringes the patent. In addition, the provision provides that corrections to patent information may be made after it is published by FDA in the unusual circumstance of an inadvertent mistake or clerical error.

Finally, Schumer-McCain allows generic applicants to sue brand drug companies to delist patents or correct patent information on patents that can trigger 30 month stays. This provision allows for the correction of misinformation in and the removal of incorrectly listed patents from FDA's Orange Book.

A second tactic used by brand drug companies is to collude with a generic drug manufacturer to block other generic versions of the drug from getting to consumers. Under the Hatch-Waxman Act, the first generic drug company to challenge a patent on a brand drug has the exclusive right to market its drug for 6 months before any other generic can compete. In some cases, brand drug companies have paid such a generic drug company not to exercise its 6-month right, thereby blocking other generic versions of the drug.

For example, terazosin hydrochloride is used to treat high blood pressure and enlarged prostate. Consumers used about $540 million of the drug in 1998. A generic was scheduled for market in April 1999, but Abbott Laboratories reached sweetheart deals with two generic companies, Zenith Goldline Pharmaceuticals and Geneva Pharmaceuticals, to keep their generic products off the market. That in turn blocked other generics from getting to market for 16 months. Abbott paid Zenith a lump sum of $3 million plus $6 million per quarter under their agreement, while Geneva received $4.5 million per month. The Federal District Court in Florida held that the agreements were illegal under antitrust laws. The result was that consumers paid hundreds of millions more than they should have because generic competition was delayed.

Schumer-McCain closes this loophole and ensures generic challenges to invalid patents. How does it do this? It provides for six situations in which a generic drug company with the 180 days of exclusivity must forfeit the exclusivity—for example, if the generic is found by the Federal Trade Commission to have colluded with a brand drug company, if it withdraws its application, or otherwise delays in getting to market. When the first generic forfeits the 180 days, the generic applicant that is next ready to be approved and go to market can go to market, and consumers immediately enjoy generic competition and lower costs.

If that generic applicant is the second generic to have challenged a patent, it gets the 180 days of exclusivity and subsequent generic applicants are delayed from getting final FDA approval for 180 days. If the generic applicant ready to go to market is not the second generic to have challenged a patent, but rather is the third or the fourth or the fifth, the 180 days of exclusivity disappears and FDA may approve subsequent generic applicants as soon as they are ready.

Either way, consumers benefit because the first generic that is ready gets to market as soon as it can. In addition, the 180 exclusivity remains as an incentive for the second generic applicant to challenge a patent, an incentive that is vital to maintain especially for those situations when a patent must be shown to be invalid. In this way, Schumer-McCain speeds generic drugs to market while preserving the 180 day incentive—an incentive that has encouraged generic companies to break patents on several high-priced blockbuster drugs and saved consumers billions of dollars.

Schumer McCain also makes some other adjustments to the 180-day exclusivity provision. First, it clarifies that the court decision that can start the 180-day period running is the earlier of the date of a final decision from which no appeal, other than a petition for review by the Supreme Court, has been or can be taken or the date of a settlement order or consent decree that includes a finding that the patent at issue is invalid or not infringed. This provision also clarifies that it is any such decision on the patent that will trigger the 180-day period, not necessarily one in the case to which the generic applicant with the exclusivity was a party. Second, the bill clarifies that the 180-day period is available only to the first applicant to challenge a patent on a brand drug, and that subsequent applicants that challenge different patents on that brand drug do not also receive a 180-day period of exclusivity, unless the first forfeits its exclusivity, as provided for by the bill. Third, the bill clarifies that the 180-day period is only applicable to a generic applicant that challenges a patent if that applicant is sued for patent infringement.

Finally, Schumer-McCain includes a provision that is intended to forestall frivolous challenges by brand companies to the legal legitimacy of FDA's bioequivalence regulations, challenges that have substantially delayed the approval of some generic drugs. The court challenges by brand companies have taken several forms, including challenges to the specifics of the FDA's regulations and the FDA's authority to issue the regulations, and have involved drug products such as asthma inhalers and topicals. The challenges themselves frequently start as administrative challenges in the form of citizen petitions and progress to legal challenges. Each challenge delays approval or marketing of the generic, and each one consumes valuable FDA resources in defending against these fundamentally frivolous lawsuits. These lawsuits are also filed notwithstanding the holdings of different circuit courts of appeal upholding the regulations.

The provision says that FDA's current regulations on bioequivalence shall continue in effect as legitimate exercises of FDA's statutory authority. The provision allows FDA to amend its regulations through rulemaking, but it does not preclude judicial review of those amended regulations, nor judicial review of an application of either the current or amended bioequivalence regulations. Finally, the provision makes it clear we are not changing FDA's authority under the Federal Food, Drug, and Cosmetic Act over biological products.

The Hatch-Waxman Act has been a tremendous success in stimulating both competition and innovation. But there are weaknesses in this law that Schumer-McCain rightly closes. Drug companies are entitled to fair profits on their research and innovation. But when patents expire, those companies must innovate to succeed and help patients, not block competition to their old drugs.

I also want to applaud the inclusion of a number of important amendments which will help lower drug costs and ensure drug coverage for all Americans, including Senator STABENOW's amendment to help States negotiate lower prices and Senator ROCKEFELLER's amendment to provide emergency Medicaid relief to States in fiscal crisis.

Schumer-McCain restores the balance of the original Hatch-Waxman Act, ends the abuses that block competition, and closes the gaps in the Hatch-Waxman Act. The Senate has said: Stop the abuses. Now the House of Representatives must act with us.

I thank my health staff for all their hard work on this legislation—David Dorsey, David Nexon, Paul Kim and Michael Myers on S. 812. David Dorsey made a particularly important contribution to this effort, and deserves high praise for his work. I also want to particularly recognize the hard work and unwavering dedication of Missy Rohrbach with Senator SCHUMER. And the record would be incomplete without noting the very important contributions of Carlos Fierro and Jeanne Bumpus with Senator MCCAIN, Kyle Kinner with Senator EDWARDS, Michael Bopp with Senator COLLINS, Debra Barrett with Senator DODD, Sean Donohue

with Senator JEFFORDS, Anne Grady with Senator MURRAY, Steve Irizarry with Senator GREGG, and Dean Rosen with Senator FRIST. And I am so grateful, too, for the excellent contributions of Jane Oates, Stacey Sachs, Brian Hickey, Scott Berkowitz, Amelia Dungan, Kent Mitchell, Jeffrey Teitz, Melody Barnes, Marty Walsh, Jim Manley, Stephanie Cutter and so many others who made this legislation possible.

I ask unanimous consent that letters of support for S. 812 be printed in the RECORD.

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

COALITION FOR A COMPETITIVE PHARMACEUTICAL MARKET,
Washington, DC, July 10, 2002.

Hon. EDWARD M. KENNEDY,
Chairman, Senate Health, Education, Labor and Pensions Committee,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: As a broad-based coalition of large employers, consumer groups, generic drug manufacturers, insurers, labor unions, and others, we are writing to advise you of our strong support for the Edwards/Collins amendment to S. 812, the Greater Access to Affordable Pharmaceuticals Act. We believe it is critical that Congress act this year to pass legislation that would eliminate barriers to generic drug entry into the marketplace. The legislation you will be marking up today clearly would accomplish this long-overdue need.

Prescription drug costs are increasing at double-digit rates, and clearly are unsustainable. Current pharmaceutical cost trends are increasing premiums, raising copayments, pressuring reductions in benefits, and undermining the ability of businesses to compete in the world marketplace. We believe that a major contributor to the pharmaceutical cost crisis is the use of the Drug Price Competition and Patent Term Restoration Act of 1984 clearly in ways unanticipated by Congress, which effectively block generic entry into the marketplace. The repeated use of the 30-month generic drug marketing prohibition provision and other legal barriers have resulted in increasingly unpredictable and unaffordable pharmaceutical cost increases.

Although the compromise amendment being offered today does not totally eliminate the 30-month marketing prohibition provision, as would be our preference, it does make important process changes that will lead to a more predictable, rational pharmaceutical marketplace. We recognize that compromises have been necessary to garner the support of a majority of the Members of the Committee and appreciate your leadership and the hard work of your staff. However, we would strongly oppose any additional amendments that would undermine the intent of this legislation by further delaying generic access or reducing competition and increasing costs to purchasers. We also remain opposed to legislation that would increase costs to purchasers either through extended monopolies or unnecessary and costly litigation.

We are convinced that the legislation you are advocating will make a major difference in increasing competition in the marketplace and enhancing access to more affordable, high quality prescription drugs. We look forward to working with you and other Members of the HELP Committee to ensure that this important legislation is enacted this year.

The Coalition for a Competition Pharmaceutical Market is an organization of large national employers, consumer groups, generic drug manufacturers, insurers, labor unions, and others. CCPM is committed to improving consumer access to high quality generic drugs and restoring a vigorous, competitive prescription drug market. CCPM supports legislation eliminate legal barriers to timely access to less costly, equally effective generic drugs.

CCPM PARTICIPATING MEMBERS

American Association of Health Plans, Aetna, Anthem Blue Cross and Blue Shield, Blue Cross and Blue Shield Association, Caterpillar, Inc., Consumer Federation of America, Families USA, Food Marketing Institute, Generic Pharmaceutical Association, General Motors Corporation, Gray Panthers, Health Insurance Association of America, IVAX Pharmaceuticals, National Association of Chain Drug Stores, National Association of Health Underwriters, National Organization for Rare Disorders, Ranbaxy Pharmaceuticals, TEVA USA, The National Committee to Preserve Social Security and Medicare, United Auto Workers, Watson Pharmaceuticals, and WellPoint Health Networks.

GENERAL MOTORS,
Detroit, MI, July 15, 2002.

Hon. EDWARD M. KENNEDY,
U.S. Senate, Russell Senate Office Building, Washington, DC.

DEAR SENATOR KENNEDY: As the largest private provider of health care coverage in the nation, I am writing to commend you for your leadership in supporting legislation that removes barriers to generic competition and reduces costs to all consumers. At General Motors, we insure over 1.2 million workers, retirees, and their families, and on their behalf, I want to thank you for supporting and passing out of the Senate Health, Education, Labor and Pensions Committee S. 812, the Greater Access to Affordable Pharmaceuticals Act.

We now spend over $1.3 billion a year on prescription drugs, and without relief, these costs are projected to continue to grow at 15 to 20 percent a year. Such increases are clearly unsustainable, and over time will make it impossible for us to compete in the world market.

We are convinced that your support of S. 812 will rationalize the currently distorted marketplace that has led to increasing and unpredictable pharmaceutical costs. This has resulted in increasing premiums, copayments, and pressures to reduce benefits. We believe that this landmark legislation will close the loopholes in the Hatch-Waxman law that currently block generic entry into the marketplace. Moreover, we believe your leadership in supporting bipartisan amendments in Committee strengthen S. 812 and assure much-needed predictability in the health care delivery system.

As a large employer and payer of health care, we are pleased that the Committee process clarified the so-called ''de-listing'' provision. This modification makes clear that the necessary ability for generics to challenge brand-name companies who have inappropriately listed patents in the FDA Orange Book does not in any way provide for civil and monetary penalties, and solely focuses the remedy for the abusive listing on the de-listing of the product from the Orange Book.

Once again, I want to thank you for the work that you and your staff have put in to this effort. We believe that your efforts will make a major difference in increasing prescription drug competition and choice, as well as expanding access to more affordable medications for our current and former employees and their families.

Sincerely,

DICK WAGONER, Jr.
President and Chief Executive Officer.

GENERIC PHARMACEUTICAL ASSOCIATION,
Washington, DC, July 10, 2002.

Hon. EDWARD M. KENNEDY,
Chairman, Senate Health, Education, Labor and Pensions Committee, U.S. Senate, Russell Senate Office Building, Washington, DC.

DEAR MR. CHAIRMAN: We are writing to express our strong support of the Edwards amendment to S. 812, the Greater Access to Affordable Pharmaceuticals Act. As the manufacturers, suppliers, and distributers of more than 90 percent of the nations' generic medicines, the Generic Pharmaceutical Association (GPhA) is all too familiar with the abusive tactics name brand pharmaceutical companies employ to delay consumers access to affordable, quality generic pharmaceuticals and the dire need for Congress to pass legislation to close the loopholes in the law that the name brand industry has grown so proficient in exploiting. We believe the Edwards amendment effectively accomplishes this goal and has earned the tripartisan support it is now receiving.

The high cost of prescription drugs is one of the nation's most pressing public policy challenges today. Senior citizens, the uninsured, major employers, governors, consumer groups and public and private insurers are all looking to Congress for relief from the unsustainable annual increases in prescription drug costs. Increasing consumer access to generic medicines by increasing competition in the pharmaceutical market place can and must play a central role in any legislative plan to control drug costs. The full benefits increased competition can bring to the health care delivery system, however, cannot be realized until Congress closes the loopholes in the Hatch-Waxman Act that are thwarting competition and inflating the cost of prescription medicines.

Abuse of the 30-month stay provision of the Hatch-Waxman act is one of the most effective and most frequently used methods to delay generic competition. The Generic Pharmaceutical Association believes the most efficient way to ensure this provision is no longer used to delay generic competition is to abolish it completely. However, GPhA recognizes that compromises were necessary to bring support for the legislation to its current point and commends you, the other Members of the Senate HELP Committee, and your staff for your unwavering commitment to knocking down the barriers that are blocking access to generic medicines.

GPhA looks forward to working with you to secure the Committee's approval of the Edwards amendment and would oppose any effort to dilute or weaken it with amendments that would maintain or exacerbate the problems in the existing Hatch-Waxman system. As always, we appreciate your leadership on this issue and stalwart commitment to ensuring all Americans have access to quality, affordable health care.

Sincerely,

KATHLEEN D. JAEGER,
President and CEO.

NATIONAL ORGANIZATION FOR RARE DISORDERS, INC.,
Danbury, CT, July 17, 2002.

Hon. EDWARD M. KENNEDY,
U.S. Senate,
Washington, DC.

DEAR SENATOR KENNEDY: For the sake of 25 million Americans with rare ''orphan'' diseases, we want you to know that S. 812, the

Greater Access to Affordable Pharmaceuticals Act (GAAP), and the Edwards-Collins Amendment that was passed by the Senate HELP Committee on July 11, 2002, will help millions of uninsured and underinsured Americans to gain access to affordable medications.

GAAP will close the loopholes of the Hatch-Waxman generic drug law that was enacted in 1984. This will ultimately lead to availability of lower cost generic drugs in a timely manner. When pharmaceutical patents expire, competition would be allowed without undue delay, and competition will drive prices down. We believe that S. 812 will make affordable treatments accessible to uninsured and underinsured people, particularly the elderly and younger Medicare beneficiaries who receive Social Security Disability benefits. In the absence of a Medicare prescription drug benefit, S. 812 is an essential first step in the giant leap forward that Americans desperately need for health care.

We hope that Congress will close the loopholes to the Hatch-Waxman Act and deter the frivolous lawsuits that have repeatedly delayed availability of affordable generic drugs. We hope that this will be the first step in your efforts to add a much needed prescription drug benefit to Medicare.

Very truly yours,

ABBEY S. MEYERS,
President.

CONSUMERS UNION,
Washington, DC, July 16, 2002.

DEAR SENATOR: Consumers Union urges your support of the ''Greater Access to Affordable Pharmaceuticals Act (GAAP Act) of 2001 (S. 812).'' This legislation would streamline and improve the generic drug approval process, saving consumers billions of dollars. We believe that companies trying to bring generic drugs to market face too many unnecessary obstacles and that the removal of these barriers will increase competition and deliver lower-priced drugs to consumers.

We support wider access to affordable medicines for all Americans, especially the uninsured, the underinsured, the elderly, and the disabled. Today, health care costs are spiraling out of control for consumers and employers. Between 1999 and 2000 alone, prescription drug spending increased by 17.3%—the sixth year of double-digit increases. According to a 2002 Brandeis University study, older Americans could save $250 billion over the next ten years through the increased use of generic drugs. The Schumer-McCain bill is a cost-saving measure that will help rein in spiraling prescription drug expenditures—a critical first step toward the implementation of an affordable Medicare prescription drug benefit.

This legislation will improve consumer access to generic drugs by restoring the balance between innovation and competition. We believe that the anticipated cost savings from this measure is a necessary foundation for the Senate to build a comprehensive prescription drug benefit into Medicare.

Sincerely,

JANELL MAYO DUNCAN,
Legislative Counsel.

Ms. CANTWELL. Mr. President, I rise today to express my disappointment regarding our current situation on Medicare prescription drug legislation. I am extremely disappointed that we have not been able to pass a prescription drug benefit, and I believe it is absolutely imperative that the Senate continue to work toward this end.

The fact is, when Medicare was designed in 1965, the system relied on inpatient hospitalization and seldom on outpatient services, preventive care, or patient drug therapies. At that time, prescription drugs only accounted for four percent of all personal health care expenditures.

But as we enter the 21st century, the cutting edge of health care has shifted. Every day, as new preventive and therapeutic drugs replace outdated inpatient procedures, Medicare falls further and further behind in providing basic care.

Medicare was written to cover the most basic health care for seniors. When the original bill passed, the legislation's conference report explicitly says that the intent of the program is to provide adequate ''medical aid for needy people,'' and should ''make the best of modern medicine more readily available to the aged.''

Well, we are not making the best use of modern medicine when millions of seniors cannot afford access to the prescription drugs they need. Prescription drugs that had not even been developed when Medicare was enacted are now an essential aspect of basic health care. We owe it to our seniors to live up to Medicare's original mandate and provide them the best medical care.

Unfortunately, today, beneficiaries' current drug coverage options are often expensive and unreliable. And as a result, nearly seven out of ten Medicare beneficiaries lack decent, dependable coverage for their prescription drug needs, and more than one-third have no coverage at all. Prescription drug expenditures for the average senior in my home State of Washington are over $2,100 every year, over 122,000 of my seniors spend more than $4,000 a year.

On average, one out of every five dollars of every Social Security check to Washington State's seniors is spent on prescription drugs. And seniors with the most serious illnesses spend nearly 40 percent of their Social Security check on prescription drugs. How in the world are seniors on fixed incomes supposed to do this? What happens to them in an emergency?

Last week I visited three senior citizen centers to discuss the current prescription drug debate. This is what my constituents told me: they want prescription drug coverage to be comprehensive, simple to administer, guaranteed, stable, and based on the very best medical technology. And most importantly, they want the benefit run through Medicare, a program they understand and upon which they depend.

I think this is the first point I want to make about HMOs versus Medicare as we continue to debate delivery mechanisms for a new benefit. Seniors do not want their prescription drug benefit run through an HMO or other private insurance company.

According to a June 2002 survey by the Kaiser Family Foundation and the Kennedy School of Government, 67 percent of American people believe we should expand Medicare to pay for part of prescription drugs, but only 26 percent say we should help seniors buy private insurance to pay for prescription drugs costs.

A private delivery model gives insurers complete control over whether to offer a benefit, how much to charge, and whether to cover drugs regardless of whether these drugs are medically necessary. That's too much control over a program that is supposed to guarantee help for seniors.

The very basic issue here is that the private market will not cover such a high-risk population—especially a population at such risk for adverse selection. I don't want to see this benefit be a repeat of the Medicare+Choice program. And if the private insurance model hasn't worked for the full Medicare benefit, it certainly won't work for a single benefit where utilization is expected to be high.

Putting HMOs in charge of prescription drug coverage would be like putting Enron in charge of Social Security.

The second point I want to make is that seniors need a benefit that is comprehensive, one that covers their total prescription drug needs. Thirty percent of Washington seniors—212,000 people—will fall into the benefit hole proposed under the Tripartisan bill. But these same seniors will need to continue to pay their monthly premium, whatever it is as determined by the private HMOs or insurance companies, during that benefit gap. My constituents will not stand for this.

We need to pay very close attention to the catastrophic coverage in all of these proposals and what it means for seniors. What we're talking about is covering medicines for the very sickest seniors, and we know that the very sickest seniors have the very highest drug costs. In fact, just 14 percent of the elderly population account for nearly half of all prescription drug expenditures.

Seniors account for 12.6 percent of the general population, but a third of all prescription drug expenditures. And while prescriptions are expensive, in some cases, prohibitively so, these are the very same prescription drugs that keep people out of the hospital, out of the nursing home, and living vibrant and happy lives. And while it is difficult to quantify in economic terms, prescription drugs preserve health and eliminate unnecessary hospitalization, which is by far most expensive segment of the health care.

Americans are becoming increasingly reliant on more effective, and more complicated, drug therapies. Total health care spending in the United States will total more than $1.5 trillion this year, an increase of 8.6 percent over last year, according to a March report released by the Centers for Medicare and Medicaid Services.

The other part of this debate concerns the need to get generic medications to the market, and to our Nation's seniors and disabled, more quickly. Generic medicines account for 42 percent of all prescriptions dispensed

in America and on average are put on the market at 75 percent of the cost of their name-brand rivals.

But we know that the current prescription drug patent system is broken, and I am extremely concerned that pharmaceutical companies may be acting illegally to extend their patents and prevent less expensive generic drugs from entering the market. To fix it, we need to eliminate patent loopholes that drug companies use to prevent price competition from generic alternative drugs.

We need to strengthen existing statutes, including antitrust laws. We need to stop drug company abuses that prevent generic competition and lower prices, stop illegitimate patent ''evergreening,'' and stop anticompetitive sweetheart deals between brand name and generic companies.

I am pleased that the underlying bill we are considering would get lower-priced generics on the market faster, especially since we know that prescription drug expenditures are the fastest growing segment of the health care market, with spending on outpatient prescription drugs in the U.S. increasing by 17 percent over last year. It is absolutely incredible that outpatient drug expenditures have more than doubled in the last five years.

Drug expenditures in the United States rose from about $5.5 billion in 1970 to a projected $161 billion this year, and CMS predicts that prescription drug expenditures will continue to increase faster than any other category of health care spending throughout the next ten years. Medicare beneficiaries alone will spend $1.5 trillion on prescription drugs over the next ten years.

Those two factors, great dependency on drug therapies and skyrocketing drug prices, put us on a collision course in our efforts to provide affordable health care.

I know that many of my colleagues are concerned that the money isn't there for this benefit, and I, too, have no doubt that a new benefit will be extremely expensive. The Congressional Budget Office estimates that the original Graham amendment will cost $576 billion over 10 years, and it spends about $85 billion a year by the end of the decade.

This new spending is in addition to the fact that the Medicare budget will reach at least $498 billion by 2012, and will begin spending out more than it brings in by 2016. Sustainable financing of the Medicare program is a looming problem that must be addressed.

But while we discuss the potential cost of a new benefit, we also need to discuss national priorities. I believe we can do a prescription drug benefit while living within our budget, and we can do so by having a clear vision for our country's priorities. One of my top priorities is getting a new prescription drug benefit to the Medicare beneficiaries in Washington state. But this may mean making other tough choices.

There is no doubt that if we interject all of these issues into the political debate surrounding the need to provide Medicare coverage of prescription drugs for our elderly and disabled, we have a debate to be rivaled by few others.

But the reality is that the Senate needs to move past the argument of whether or not to include prescription drugs in the Medicare program. We know there is a problem, and it is up to us to find a solution.

Congress is trying to take a reasoned and rational approach to integrating a new prescription drug benefit into the Medicare program.

I strongly believe that we need to include a prescription drug benefit in the Medicare program and I will continue to fight to ensure that all Washingtonians have access to the prescription medications they need.

Finally, I want to briefly address the geographic disparities in Medicare provider payments. I am especially concerned that providers serving a disproportionate number of Medicare and Medicaid patients are facing unsustainable fee reductions.

Every day I hear from my constituents that they are facing increasing difficulty in getting primary care services, and from physicians who can no longer afford to take on new Medicare patients. In fact, 57 percent of Washington state physicians are limiting the number or dropping all Medicare patients from their practices.

We absolutely must ensure that Medicare providers, hospitals, physicians, home health agencies, physical therapists, nursing homes, are paid enough to cover the cost of providing care to Medicare beneficiaries. I certainly hope that the Finance Committee, working with the Leadership on both sides, will pass a reimbursement package before we adjourn the 107th Congress. It will do us little good to provide a new Medicare benefit if there are no physicians willing or available to write prescriptions for Medicare beneficiaries.

Mr. MCCAIN. Mr. President, the Greater Access to Affordable Pharmaceuticals Act, GAAP, provides a real opportunity to benefit all consumers of prescription drugs. In the recently concluded study of the abuses of the Hatch-Waxman act, the Federal Trade Commission concluded that there is a need for Congress to act and to act quickly to end the exploitation of loopholes in current law that has delayed the entry of generic drugs into the market. S. 812 would allow consumers earlier access to generic versions of drugs while protecting the intellectual property rights of the brand name drug innovators—a protection that is necessary for their continued investment in research and development of new and improved pharmaceuticals.

S. 812 would accomplish five important objectives. First, the bill would limit the ability of brand name drug companies to delay the marketing of generic competitors. It does this by limiting brand name drug companies to only one automatic 30-month stay. Under current law, brand name drug companies can prevent generic substitutes from coming to market by suing the generics for patent infringement, thus triggering an automatic stay of up to 30 months on the FDA's approval of the generic drug. By bringing successive patent infringement suits, brand name drug companies have obtained sequential stays, and kept generics off the market much longer than 30 months.

Allowing for only one automatic delay is consistent with the FTC's recent recommendations. In its report, the FTC recommended that only one stay be allowed, and noted that: prior to 1998, only 1 out of 9 blockbuster drugs products involved at least three patent lawsuits, whereas after 1998, 5 of the 8 blockbuster products involved at least three lawsuits. . . .

[C]ases involving multiple patents take longer than those involving fewer patents [to resolve] the FTC wrote, and the Commission found that the multiple stacking of automatic stays delayed the approval of generic drug applications from between 4 and 40 months beyond the initial 30-month period.

There is no doubt that these stays have cost consumers enormous sums of money by preventing their access to cheaper generic versions of drugs. Allowing for one 30-month stay, as S. 812 does, strikes a balance between the rights of brand name drug companies seeking to protect their legitimate patents, and the rights of consumers to access generic drugs without unreasonable delay due to ''gaming'' of the system.

Second, the GAAP Act would modify the provision in current law that allows the first-to-file generic drug manufacturer an exclusive 180-day period to market its drug without competition from other generic manufacturers. The 180-exclusivity period was intended to provide a needed incentive for challenging dubious patents. Like the automatic 30-month stay, however, this 180-day exclusivity has been abused. Brand name and generic drug companies have colluded in deals in which the brand name manufacturer effectively extends its own period of exclusivity by paying the generic drug manufacturer to stay out of the market for the six months during which the generic would otherwise be able to compete. When this occurs, the brand name manufacturer wins, and the generic manufacturer wins, but consumers lose. To prevent this type of abuse, S. 812 modifies current law so that first-to-file generic manufacturers that engage in anticompetitive conduct and do not go to market, lose the privilege of the 6-month exclusivity in the generic market, and, in certain circumstances, that exclusivity ''rolls'' over to the next generic competitor.

Third, the legislation would require generic drug applicants to the FDA to provide a more detailed ''paragraph

IV'' filing. This means that the patent holder will not only receive a general notice that its patent is being challenged, but the generic drug applicant will be required to provide a more detailed legal basis of its assertions regarding the original patent's validity. This is an important protection for the brand name manufacturers because they will receive more information about the nature of the patent challenge as opposed to a simple notice that a generic application has been filed.

Fourth, S. 812 would clarify that the FDA's existing regulations as they pertain to bioequivalence have the effect of law. Currently, bio-equivalence is demonstrated through blood level studies, and only in some circumstances has the FDA allowed for limited human data to be submitted for products where blood studies are inapplicable. S. 812 would allow the FDA to amend its regulations as necessary and clarify its authority over biological products under the Federal Food, Drug and Cosmetic Act.

The fifth significant change to current law relates to how to clean up abuses of the ''Orange Book'', the manual in which the FDA lists all patents on pharmaceutical drugs. S. 812 allows generic manufacturers in certain instances to bring a cause of action to ''de-list'' or ''rename'' a drug patent. Current law provides no means for ''delisting'' a patent, although doing so can speed the marketing of generic drugs, particularly in cases involving patents that are patently frivolous and for which the brand name manufacturers clearly would not win a patent infringement suit. While purging the Orange Book of frivolous patents is important, I understand that some Senators are concerned that the new cause of action to ''delist'' will not speed the availability of generic drugs, but will lead to a snarl of litigation. I hope these concerns can be reviewed in conference.

Over twenty years ago, Hatch-Waxman established the procedures for bringing generic drugs to consumers and set out to strike a balance that would allow drug innovators to protect their innovations, while allowing generic drugs easier access into the market. In large part, Hatch-Waxman succeeded in bringing new lower-cost alternatives to consumers, and encouraging more investment in U.S. pharmaceutical research and development. This has been evident in the years since the enactment of Hatch-Waxman, where research and development has increased from $3 billion to $21 billion. Loopholes in the law, however, have delayed benefits to consumers. It is time to close them.

The Congressional Budget Office, CBO, recently released results of its estimate of S. 812, finding that total drug expenditures in this country over the next ten years, 203 to 2012, will be roughly $4.7 trillion. If the delays resulting from numerous lawsuits and agreements that arise under current law were eliminated, the CBO estimates that S. 812 would result in a savings of up to 7 percent, or $320 billion. For consumers, particularly seniors, the uninsured, and those on Medicare, this is a tremendous savings.

Congress will improve the lives of many Americans by passing the underlying language of S. 812. I urge my colleagues to do this now.

Mr. GRASSLEY. Mr. President, I'd like to say a few words about the Hatch-Waxman provisions that were contained in S. 812 that passed this morning. Ensuring access to affordable prescription drugs is a top priority for me. The challenge is to strike the right balance so consumers have timely access to medicine that's affordable and so that new, groundbreaking pharmaceuticals continue to be developed. I voted for S. 812 because I want Iowans and all Americans to benefit as much as possible from the competition and lower prices that generic drugs bring about in the marketplace. This bill starts to close loopholes in the current Hatch-Waxman law and stop abuses that may have contributed to the delay in market entry to generic drugs and kept drug prices high. I believe that this is a good first step toward recognizing and addressing concerns about abuses in the current system. However, I still have concerns about the drafting of a few of the provisions in this legislation.

For example, I'm concerned abut the new private right of action created by S. 812. The current Hatch-Waxman law does not allow for such a remedy, and this could cause unnecessary and increased litigation. I also share the concerns that Senator Frist expressed regarding the bioequivalency provision. I think that we need to clarify that this provision should in no way adversely impact or lessen public safety. Further, I think that we should clarify that the provision dealing with the 45 day paragraph IV notice does not eliminate all legal avenues with respect to a company being able to protect it's rights with respect to a patent. There might be a few other changes that would be beneficial to the bill. Nevertheless, I'm hopeful that we can improve on this legislation. We need to be able to close the loopholes, but also ensure that we keep the proper balance between promoting timely access to affordable generic drugs and giving brand-name companies reasonable intellectual property protections so they will continue to innovate and find new cures and drugs.

I was disappointed that the Senate was not able to consider an amendment I wanted to offer with Senator Leahy which would have required brand-name and generic companies to file with the Federal Trade Commission and Justice Department any agreements that deal with the 180 day exclusivity provision of the Hatch-Waxman law. The language of our amendment is exactly the language contained in S. 754, as reported out of the Judiciary Committee last November. So everyone knows, this legislation is fully supported by the Federal Trade Commission report that came out just yesterday. In fact, the Federal Trade Commission report said ''we believe that notification of such agreements to the Federal Trade Commission and the U.S. Department of Justice is warranted. We support the Drug Competition Act of 2001, S. 754, introduced by Senator Leahy, as reported by the Committee on the Judiciary.'' I'm putting my colleagues on notice that I will work to get this legislation passed to ensure that lower price drugs get to market as soon as possible.

I want Iowans to benefit from new scientific research and innovative drug products. Patent protections help provide incentives for these developments. With the practice of medicine today being so dependent on prescription drugs and with a new, taxpayer-financed prescription drug benefit on the horizon, I'll continue to work to make sure Congress maintains the right balance between patent protection and access to generic drugs.

Mr. MCCAIN. I would like to take the opportunity to talk about the underlying bill, S. 812, which, until now, has been largely treated in this two week debate as little more than a vehicle for a grander, more politically salient, but also more elusive, prescription drug benefit.

If the Senate fails to pass the underlying bill, the Greater Access to Affordable Pharmaceuticals Act, GAAP, will lose a real opportunity to benefit all consumers of prescription drugs. In a recently concluded study of the abuses of the Hatch-Waxman act, the Federal Trade Commission concluded that there is a need for Congress to act and to act quickly to put an end to the anti-competitive abuses that have delayed the entry of generic drugs into the market. S. 812 would allow consumers earlier access to generic versions of drugs while protecting the intellectual property rights of the brand name drug innovators, a protection that's necessary for their continued investment in research and development of new and improved pharmaceuticals.

While the brand name drug manufacturers have decried this bill, which has been portrayed by some as a boon to generic drug makers, I assure you that these portrayals are not accurate. The consumer is the intended beneficiary of this legislation, plain and simple.

S. 812 would accomplish five important objectives. First, the bill would limits the ability of brand name drug companies to delay the marketing of generic competitors. It does this by limiting brand name drug companies to only one automatic 30-month stay on the marketing of generic drugs. Under current law, brand name drug companies can prevent generic substitutes from coming to market by suing the generic for patent infringement and in

so doing, stop the FDA, for up to 30 months, from approving the cheaper substitute. By bringing successive patent infringement suits, brand name drug companies have obtained sequential 30-month stays, and kept generics off the market much longer than 30 months.

Allowing for only one automatic delay is consistent with the recommendation the Federal Trade Commission made recently in its comprehensive study of anticompetitive abuses of current law by brand name and generic drug companies. In its report, the FTC recommended that only one stay be allowed, and noted that ''prior to 1998, only 1 out of 9 blockbuster drug products involved at least three patent lawsuits, whereas after 1998, 5 of the 8 blockbuster products involved at least three lawsuits.'' ''[C]ases involving multiple patents take longer than those involving fewer patents [to resolve]'' the FTC wrote, and the Commission found that the multiple stacking of 30-month stays prevented the FDA from approving generic ANDAs from 4 to 40 months beyond the initial 30-month stay.

There is no doubt that these stays have prevented or delayed generic drugs from entering the marketplace and increased the price of prescription drugs. Allowing for one 30-month stay, as S. 812 does, strikes a balance between the rights of brand name drug companies seeking to protect their legitimate patents, and the rights of consumers to access generic drugs without unreasonable delay due to ''gaming'' of the system. I understand that there is disagreement regarding which patents should be afforded protection under the automatic stay, however, I believe we can all acknowledge that allowing for one, and only one stay, is the most effective way to prevent frivolous lawsuits that delay consumers' access to less expensive pharmaceuticals.

Second, the GAAP Act would modify the provision in current law that allows the first-to-file generic drug manufacturer an exclusive 180-day period to market its generic drug without competition from other generic manufacturers. The 180-exclusivity period was intended to provide a needed impetus for generic companies to challenge dubious patents. Like the automatic 30-month stay, however, this 180-day exclusivity has been abused. Brand name and generic drug companies have colluded in deals in which the brand name manufacturer effectively extends its own period of exclusivity by paying the generic drug manufacturer to stay out of the market for the six months during which the generic would otherwise be able to compete. When this occurs, the brand name manufacturer wins, and the generic manufacturer wins, but consumers lose. To prevent this type of abuse, S. 812 modifies current law so that first-to-file generic manufacturers that engage in anticompetitive conduct and do not go to market, lose the privilege of 6-month exclusivity in the generic market, and, in certain circumstances, that exclusivity ''rolls'' over to the next generic competitor.

Third, the legislation would require generic drug applicants to the FDA to provide a more detailed ''paragraph IV'' filing. This means that the patent holder will not only receive a general notice that its patent is being challenged, but the generic drug applicant will be required to provide a more detailed legal basis for its assertions regarding the original patent's validity. This is an important protection for the brand name manufacturers because they will receive more information about the nature of the patent challenge as opposed to a simple notice that a generic application has been filed.

Fourth, S. 812 would clarify that the FDA's existing regulations as they pertain to bio-equivalence have the affect of law. Currently, bio-equivalence is demonstrated through blood level studies, and only in some circumstances has the FDA allowed for limited human data to be submitted for products where blood studies are inapplicable. S. 812 would allow the FDA to amend their regulations as necessary and clarify their authority over biological products under the Federal Food, Drug and Cosmetic Act.

The fifth significant change to current law relates to how to clean up abuses of the ''Orange Book'', the manual in which the FDA lists all patents on pharmaceutical drugs. The provision in the current bill, allows generic manufacturers in certain instances to bring a cause of action to ''de-list'' or ''re-name'' a drug patent. Current law provides no means for ''delisting'' a patent, although doing so can speed the marketing of generic drugs, particularly in cases involving patents that are patently frivolous and for which the brand name manufacturers clearly would not win a patent infringement suit.

The cause of action for generic manufacturers to ''delist'' patents was a provision that was added to S. 812 late in the process, and it is controversial. Opponents argue that doing so will significantly increase and complicate litigation without clearly making generic drugs available to consumers more quickly. How the cause of action in S. 812 will work is yet unclear. I hope that during conference on this legislation, we can consider not only the provision in the Senate bill, but also the proposal mentioned in the FTC's recent report to permit a claim for ''delisting'' to be brought, not as an original and separate action, but as a counterclaim in the context of a patent infringement lawsuit. Such an approach may be more appropriate in that it could reduce the number of lawsuits, but still allow generic manufacturers a way to ''delist'' frivolous patents through summary judgments or other motions that can be raised in the context of patent infringement litigation.

Over twenty years ago, Hatch-Waxman establishes the procedures for bringing generic drugs to consumers and set out to strike a balance in the pharmaceutical industry that would allow brand name manufacturers to protect their innovations, while allowing generic brands easier access into the market. In large part, Hatch-Waxman succeeded in bringing new lower-cost alternatives to consumers, and encouraging more investment in U.S. pharmaceutical research and development. This has been evident in the 15 years since the enactment of Hatch-Waxman, where research and development has increased from $3 billion to $21 billion. Loopholes in the law, however, have delayed benefits to consumers. It is time to correct this.

The Congressional Budget Office, CBO, recently released results of its estimate of S. 812 finding that total drug expenditures in this country over the next ten years (2003 to 2012) will be roughly $4.7 trillion. If the delays resulting from numerous lawsuits and agreements were eliminated, the CBO estimates that S. 812 would result in a savings of up to 7 percent or $320 billion. For consumers, particularly seniors, the uninsured, and those on Medicare, this is a tremendous savings.

Congress will improve the lives of many Americans by passing the underlying language of S. 812. I urge my colleagues to do this now.

Mr. LEAHY. Mr. President, I am disappointed that at the very last moment, the acceptance of the Drug Competition Act of 2001 as an amendment to ''The Greater Access to Affordable Pharmaceuticals Act,'' S. 812 was withdrawn. This bill, which enjoys the justified support of the administration's antitrust enforcement agencies, would have brought lower-priced generic drugs to the marketplace. Along with Senator GRASSLEY, I have every confidence that this bill would have garnered the overwhelming support of our colleagues on both sides of the aisle and would have benefitted every American purchasing prescription drugs, and am mystified by the reversal of the agreement to accept it. I thank Senator GRASSLEY and Senator KENNEDY for their support.

Prescription drug prices are rapidly increasing, and are a source of considerable concern to many Americans, especially senior citizens and families. Generic drug prices can be as much as 80 percent lower than the comparable brand name version. S. 812 is a tremendous effort to improve timely introduction of generic pharmaceuticals into the marketplace, and into our medicine cabinets, and our amendment will provide an important tool in making that effort successful.

While the Drug Competition Act is a small bill in terms of length, it is a large one in terms of impact. It will ensure that law enforcement agencies can take quick and decisive action against companies that are driven more by greed than by good sense. It gives the

Federal Trade Commission and the Justice Department access to information about secret deals between drug companies that keep generic drugs off the market. This is a practice that hurts American families, particularly senior citizens, by denying them access to low-cost generic drugs, and further inflating medical costs.

This had been a genuine bipartisan effort, and I must thank all my colleagues, including Senator HATCH who has a long-standing interest in these issues and who has praised S. 754 on the floor in recent days. Also, sub-committee Chairman KOHL has worked with me from the start on this effort, and I particularly want to thank our co-sponsor Senator GRASSLEY, who has worked hard to reach consensus on this bill that will help protect consumers. This bill passed unanimously out of the Judiciary Committee last October, but it has been the subject of an anonymous hold on the floor, presumably unrelated to the merits. Partisan politics should not further delay enactment of this sensible, and universally applauded, bill into law.

In fact, just yesterday the FTC released its long-awaited report on the entry of generic drugs into the pharmaceutical marketplace. The FTC had two recommendations to improve the current situation, to close the loopholes in the law that allow drug manufacturers to manipulate the timing of generics' introduction to the market. One of those recommendations was simply to enact S. 754, as the most effective solution to the problem of ''sweetheart'' deals between brand name and generic drug manufacturers that keep generic drugs off the market, thus depriving consumers of the benefits of quality drugs at lower prices. In short, this bill enjoys the unqualified endorsement of the Republican FTC, which follows on the support by the Clinton Administration's FTC during the initial stages of our formulation of this bill. We can all have every confidence in the common sense approach that S. 754 takes to ensuring that our law enforcement agencies have the information they need to take quick action, if necessary, to protect consumers from drug companies that abuse the law.

The issue of drug companies paying generic companies not to compete was exposed last year by the FTC, and by articles in major newspapers, including an editorial in the July 26, 2000, The New York Times, titled ''Driving Up Drug Prices.'' This editorial concluded that the problem ''needs help from Congress to close loopholes in federal law.'' And while the FTC has sued pharmaceutical companies that have made such secret and anticompetitive deals, as the then Director of the Bureau of Competition Molly Boast testified before the Judiciary Committee in May 2001, the antitrust enforcement agencies are only finding out about such deals by luck, or by accident.

Under current law, the first generic manufacturer that gets permission to sell a generic drug before the patent on the brand-name drug expires, enjoys protection from competition for 180 days, a head start on other generic companies. That was a good idea, but the unfortunate loophole exploited by a few is that secret deals can be made that allow the manufacturer of the generic drug to claim the 180-day grace period, to block other generic drugs from entering the market, while, at the same time, getting paid by the brand-name manufacturer to not sell the generic drug.

The bill would have closed this loophole for those who want to cheat the public, but keeps the system the same for companies engaged in true competition. The deals would be reviewed only by those agencies—the agreements would not be available to the public. I think it is important for Congress not to overreact in this case and throw out the good with the bad. Most generic companies want to take advantage of this 180-day provision and deliver quality generic drugs at much lower costs for consumers. We should not eliminate the incentive for them. Instead, we should let the FTC and Justice look at every deal that could lead to abuse, so that only the deals that are consistent with the intent of that law will be allowed to stand.

This bill would have accomplished precisely that goal. Moreover, it fits neatly into S. 812's provisions requiring a generic drug company that has been granted the exclusive, 180-day period on the market to forfeit that privilege if it makes a deal with a brand name company, or otherwise delays bringing its generic drug into the marketplace. Such a generic company must relinquish that 180-day privilege to the next generic manufacturer that can come to market. Both S. 812 and S. 754 share the goal of ensuring effective and timely access to generic pharmaceuticals that can lower the cost of prescription drugs for seniors, for families, and for all of us.

Mr. KERRY. Mr. President, I am disappointed that the Senate was unable to pass the Graham-Miller-Kennedy amendment last week, as it would have established a comprehensive prescription drug benefit for our Nation's seniors. I strongly supported the Graham-Miller-Kennedy plan, as I believe it offered the best solution to the problem our senior citizens face in finding a way to afford the prescription drugs they need to stay healthy. Given the failure of the Senate to pass the Graham-Miller-Kennedy amendment, which I voted for, I now lend my support to the low-income, catastrophic benefit proposal that has been offered by my colleagues, Senators BOB GRAHAM and GORDON SMITH. While I would rather the Senate take a stand in support of a more comprehensive benefit, the Graham-Smith amendment marks an important first step in making sure that our country delivers on the promise that Medicare made to our Nation's seniors almost 30 years ago.

Medicare was enacted in 1965, under the leadership of President Lyndon Johnson, as a promise to the American people that, in exchange for their years of hard work and service to our country, their health care would be protected in their golden years. But that promise has not been fulfilled. Across our country, millions of seniors have cried out for help in paying for their prescription medication. Too many of our parents and grandparents confess that they are unable to afford the drugs their doctors prescribe for them. Too many of our parents and grandparents have to choose between paying for their rent, getting their groceries or buying the medicine they need to stay healthy.

Prescription drug expenditures are skyrocketing—with the drug prices facing seniors growing at four times the rate of inflation. These costs are forcing our Nation's elders to pile into buses, and travel into Canada and Mexico where they can purchase the medicine they need for 30 percent less of the cost in the United States. These costs are driving Americans across our borders to obtain the prescription medications our very own pharmaceutical companies have developed here at home.

I appreciate the biotechnology revolution being driven publicly, by the National Institutes of Health, and privately, by the pharmaceutical industry. The advancements in modern medicine are truly spectacular, and many of the most inspiring discoveries are being made by biotechnology companies in my own State of Massachusetts. I am proud of the work being done in my state and across the country. With continued investment in research, scientists predict that we may be 5 to 10 years away from major breakthroughs in medical treatment for diseases like Alzheimer's and Parkinson's. But I ask, of what consequence are medical discoveries if they never leave the laboratory or move beyond the shelf of a local pharmacy?

The Graham-Smith amendment will help move those medications from pharmacy shelves into the hands of the seniors whose lives depend on them. Graham-Smith offers all seniors protection against high drug bills, establishing Medicare coverage of all drug costs incurred over $3,300. In addition to catastrophic coverage, the Graham-Smith proposal will provide every senior, regardless of income, up to a 30 percent discount on drugs purchased before they reach the $3,300 stop-loss. For low-income seniors, the Graham-Smith plan provides special assistance, covering all drug costs for those beneficiaries below 200 percent of the Federal poverty level.

The Graham-Smith amendment will provide protection to all seniors against the high cost of prescription drugs. It is not the ideal solution, but it targets the seniors who need help the most. The sickest seniors will be protected from out-of-control costs, which

every senior needs as insurance against a serious illness. Seniors with low incomes are guaranteed the drugs they need so they don't have to choose between prescription drugs and other necessities. This amendment provides a solid first step toward the goal of providing a comprehensive, reliable Medicare prescription drug benefit for our seniors.

I urge my colleagues to join me in support of the Graham-Smith amendment. But let us not abandon our goal of establishing a more complete prescription drug benefit. Graham-Smith is a good first step, but we must continue the journey. Unless we establish a comprehensive Medicare drug benefit, the health of an entire generation will continue to be in jeopardy. We must act to deliver on that promise that President Johnson made 25 years ago. Our Nation's seniors deserve no less.

Mrs. BOXER. Mr. President, I am disappointed that after nearly three weeks of debate, the Senate has been unable to pass a prescription drug benefit for seniors. Millions of senior citizens across the country desperately need this help.

In California alone there are nearly 3.8 million Medicare beneficiaries. According to the most recent estimates, 684,000 of those Californians have no prescription drug coverage. Unsurprisingly, low-income California seniors make up the majority of those currently suffering. However, this is an issue that cuts across socioeconomic lines to affect all seniors, throughout my State and throughout the Nation.

It is easy to listen to numbers and forget that there are faces behind those numbers—real people with real health care problems. But that is precisely why this debate is so important. There are seniors in this country who are being gouged by the prices of prescription drugs, who are choosing to skip doses to make their drugs last, and who are holding off as long as possible before they fill their prescriptions because they simply can't afford it. This is a travesty, and one that we must address.

We had a tremendous opportunity to address this situation and to provide seniors with a comprehensive prescription drug benefit under Medicare. I supported a proposal to provide a voluntary, affordable prescription drug benefit for all seniors under Medicare, with special assistance to those with low incomes. This proposal would provide a reliable benefit for the people who spend the most on drugs and who, in many cases, can least afford it: senior citizens. Unfortunately, because of opposition from the other side of the aisle, that effort failed.

Fortunately, all is not lost. While we were unable to make prescription drugs more accessible to seniors, I am pleased that we were able to take steps to make prescription drugs more affordable for everyone.

I supported—and we passed—a provision that will allow drug reimportation from Canada. In Canada, the exact same drugs often cost one-third the price. However, pharmacies in this country are not currently allowed to buy drugs in Canada to sell in the United States, which would pass these savings on to consumers. That should change as long as those drugs meet strict safety standards before entering our country. This provision will allow that to happen.

I supported—and we passed—a provision that will allow states to negotiate lower drug prices for all of their citizens who currently lack prescription drug benefits. States currently negotiate drug prices for their Medicaid recipients, the poorest of our Nation's citizens. This provision will give States an even larger market power to ensure even deeper discounts for all residents who lack prescription drug coverage.

Finally, I supported—and we passed—a proposal to close the loopholes that currently allow brand-name drug companies to keep generic drugs off the market, even after the original patent on the drug has expired. Bringing generics to market ensures greater competition and ultimately reduces prices. This should not be unfairly stalled by brand-name companies that want to maintain their monopoly on the market.

These are all important ways in which we will be able to bring the costs of drugs down for all Americans, young and old, rich and poor. We must provide seniors with a true Medicare prescription drug benefit, so that they are no longer forced to choose between drugs and food or rent. We may not have succeeded today, but I will keep fighting to see it happen in the very near future.

Ms. COLLINS. Mr. President, I rise in strong support of the Greater Access to Affordable Pharmaceuticals Act, which will make prescription drugs more affordable by promoting more competition in the pharmaceutical industry and increasing access to lower priced generic drugs.

I was very pleased to have the opportunity to work with my colleague, the Senator from North Carolina, in offering this compromise in the Health, Education, Labor, and Pensions Committee, where it was approved by a strong bipartisan vote. I also recognize the leadership and hard work of the Senators from New York and Arizona on this critical issue.

Prescription drug spending in the United States has increased by 92 percent over the past 5 years to almost $120 billion. These soaring costs are a particular burden for the millions of uninsured Americans, as well as for those seniors on Medicare who lack prescription drug coverage. Many of these individuals are simply priced out of the market or forced to choose between paying the bills or buying the pills they need to remain healthy.

Skyrocketing prescription drug costs are also putting the squeeze on our Nation's employers who are struggling in the face of double-digit increases in their insurance premiums. They are finding it increasingly difficult to continue to provide health care coverage for their employees.

Soaring costs are also exacerbating the Medicaid funding crisis that all of us are hearing about from our Governors back home who are struggling to bridge shortfalls in the States' budgets.

In 1984, the Hatch-Waxman Act made significant changes in our patent laws that were intended to encourage pharmaceutical companies to make the investments necessary to develop new drug products while simultaneously enabling their competitors to bring lower cost, generic equivalents to the market. We should acknowledge that, to a large extent, the original Hatch-Waxman Act succeeded. The law has speeded access to generic drugs in the market. As a consequence, consumers are saving anywhere between $8 and $10 billion a year by purchasing lower priced generic drugs.

Moreover, there are even greater potential savings on the horizon. Within the next 4 years, the patents on brand name drugs with combined sales of $20 billion are set to expire. If Hatch-Waxman were to work as it was intended, consumers could expect to save between 50 and 60 percent on these drugs as lower-cost generic alternatives becomes available after these patents expire.

But despite the past successes of this law, it has become increasingly evident that the Hatch-Waxman Act has been subject to abuse. While many pharmaceutical companies have acted in good faith, there is mounting evidence that others have attempted to game the system by exploiting legal loopholes in the current law. The result is, too many pharmaceutical companies have maximized their profits at the expense of consumers by filing frivolous lawsuits that have delayed access to lower priced generic drugs.

Just yesterday, the Federal Trade Commission released its long-awaited study that found that brand name drug manufacturers have, indeed, misused the law to delay the entry of lower cost generics into the market. The FTC found that these tactics have led to delays of between 4 and 40 months—over and above the first 30-month stay provided under Hatch-Waxman—for generic competitors of at least eight drugs—eight very popular drugs—since 1992. Moreover, six of these eight delays have occurred since 1998.

The FTC report identifies two specific provisions of the current law—the automatic 30-month stay and the 180-day market exclusivity provision—as being susceptible to challenges and strategies that delay the entry of lower cost generic alternatives into the market. According to the FTC report, these loopholes ''continue to have the potential for abuse'' and, if left unchanged, ''may have [even] more significance [for consumers] in the future.'' I am pleased to say that these

are the very loopholes that our bill would close.

The Congressional Budget Office estimates that our legislation would cut our Nation's drug costs by an astounding $60 billion over the next 10 years. It is no wonder that our proposal is supported by coalitions representing the Governors, employers, insurers, organized labor, seniors groups, and individual consumers who are footing the bill for these expensive drugs and whose costs for many popular drugs could be cut in half if generic alternatives were more readily available.

I would like to pause for a moment to discuss some of the details of the underlying Edwards-Collins bill. Some of my colleagues have argued that certain provisions of the bill are unconstitutional or that the bill will lead to more litigation. But no amendments have been offered to change any of the provisions of the Edwards-Collins bill. Moreover, the bill itself is the product of months of work and represents a broad, bipartisan compromise that incorporates the views and concerns of a wide spectrum of interests.

I worked particularly hard on carefully wording the cause of action created by the bill, and believe that criticisms of it spurring increased litigation are not well-founded. Our bill creates a new civil action that offers a remedy if companies incorrectly or frivolously listed patents in the Orange Book, so that these patents do not delay the ability of a generic drug to come to market. The bottom line is, the cause of action will help to reduce both the cost of prescription drugs and the cost of prescription drug litigation. It does so by allowing generic drug makers, for the first time, to directly challenge a patent that has been frivolously or incorrectly listed.

I understand the concerns of some of my colleagues who are leery of creating new causes of action. But I would reply that, in many cases, litigating through narrowly-targeted suits can be quicker and less expensive than aggregating a number of claims in one, massive proceeding. Moreover, I have worked to target the new provision as carefully as possible. In Committee, I offered a common sense amendment to tailor the new cause of action in a way that will help minimize unintended consequences while, at the same time, ensuring that it still serves its intended purpose of policing frivolous or incorrectly listed patents. My amendment made it clear that the delisting cause of action is for injunctive relief only and cannot result in monetary damages. It also limited the new cause of actions to patents listed in the Orange Book up to 30 days after a New Drug Application's approval. In doing so, my amendment harmonized the 30-month stay provision and the cause of action, as it should be.

The original Hatch-Waxman Act was a carefully constructed compromise that balanced an expedited FDA approval process to speed the entry of lower cost generic drugs into the market with additional patent protections to ensure continuing innovation that brings us these wonderful lifesaving and life-enhancing drugs.

The bipartisan compromise bill before us restores that balance by closing the loopholes that have reduced the original law's intent and its effectiveness in bringing lower cost generic drugs to market more quickly. I am very pleased we are going to pass this legislation. It really will make a difference for millions of Americans who are struggling to afford the high cost of prescription drugs.

Mr. President, I ask unanimous consent that letters from various groups that are supporting this legislation and worked very closely with us in drafting it be printed in the RECORD.

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

BUSINESS FOR
AFFORDABLE MEDICINE,
Washington, DC July 23, 2002.

Hon. SUSAN COLLINS,
US Senate,
Russell Senate Office Building,
Washington, DC

DEAR SENATOR COLLINS: The Business for Affordable Medicine coalition encourages you to vote for the Hatch-Waxman reform measures in S. 812. By closing loopholes in the Hatch-Waxman Act, Congress will ensure that more affordable prescription drugs reach the market without delays, which will provide prescription drug purchasers with significant cost savings.

The Congressional Budget Office estimates that closing Hatch-Waxman loopholes would reduce the nation's drug costs by $60 billion over the next 10 years. Preventing delays in the availability of generics would also reduce federal spending for prescription drugs by $6 billion while increasing federal revenues by $2.2 billion.

Consumers and institutional purchasers (including employers, and federal and state governments) can no longer afford the anticompetitive practices that are made possible by loopholes in the Hatch-Waxman Act. Please be assured that BAM supports strong intellectual property protections, and we do not believe they are undermined by provisions of S. 812.

BAM corporate members include Ahold USA, Albertsons, Constellation Energy Group, General Motors, Georgia-Pacific, Kellogg Company, Kmart, Kodak, Motorola, Sysco Corporation, United Parcel Service, Wal-Mart, Weyerhaeuser, and Woodgrain Millwork. BAM also includes governors and a number of state labor leaders.

Together, we urge you to support these limited and targeted Hatch-Waxman reform provisions in S. 812 to make timely access to lower-cost generics a reality.

Sincerly,

JODY HUNTER,
Director, Health and Welfare,
Georgia-Pacific Corporation.

COALITION FOR A COMPETITIVE
PHARMACEUTICAL MARKET,
July 17, 2002.

DEAR SENATOR: As a broad-based coalition of large employers, consumer groups, generic drug manufacturers, insurers, labor unions, and others, we are writing to advise you of our strong support for the S. 812, the Greater Access to Affordable Pharmaceuticals Act, as reported out of the Senate HELP Committee on July 11, 2002. We believe it is critical that Congress act this year to pass legislation that would eliminate barriers to generic drug entry into the marketplace. This legislation would accomplish this long-overdue need.

Prescription drug costs are increasing at double-digit rates and clearly are unsustainable. Current pharmaceutical cost trends are increasing premiums, raising copayments, pressuring reductions in benefits, and undermining the ability of businesses to compete. We believe that a major contributor to the pharmaceutical cost crisis is the use of the Drug Price Competition and Patent Term Restoration Act of 1984 in ways clearly unanticipated by Congress and which effectively block generic entry into the marketplace. The repeated use of the 30-month generic drug marketing prohibition provision and other legal barriers have resulted in increasingly unpredictable and unaffordable pharmaceutical cost increases.

Although the legislation as reported out of the Senate HELP Committee does not totally eliminate the 30-month marketing prohibition provision, as would be our preference, it does make important process changes that will lead to a more predictable, rational pharmaceutical marketplace. We recognize that compromises were necessary to garner the support of a bipartisan majority of the Members of the Committee. However, we would strongly oppose any additional amendments that would undermine the intent of this legislation by further delaying generic access or reducing competition and increasing costs to purchasers. We also remain opposed to legislation that would increase costs to purchasers either through extended monopolies or unnecessary and costly litigation.

We are convinced that the legislation currently pending before the full Senate will make a major difference in increasing competition in the marketplace and enhancing access to more affordable, high quality prescription drugs. We look forward to working with you and other Members of the Senate to ensure that this important legislation is enacted this year.

COALITION FOR A COMPETITIVE
PHARMACEUTICAL MARKET,
July 30, 2002.

DEAR SENATOR: As a broad-based coalition of large employers, consumer groups, generic drug manufacturers, insurers, and others, we are writing to urge you to vote for cloture on the bipartisan Greater Access to Affordable Pharmaceuticals Act (S. 812). We believe it is critical that Congress act this year to pass legislation that would eliminate barriers to generic drug entry into the marketplace. This legislation would accomplish this key policy objective.

Prescription drug costs continue to skyrocket—adversely impacting consumers by increasing premiums, raising copayments, pressuring reductions in benefits, and undermining the ability of businesses to compete. We believe that a major contributor to the pharmaceutical cost crisis is the use of the Drug Price Competition and Patent Term Restoration Act of 1984 in ways clearly unanticipated by Congress and which effectively block entry of equivalent generic drugs into the marketplace.

Today's report from the Federal Trade Commission (FTC) supports the kind of reforms contained in S. 812. For example, the report supports limiting the availability of the automatic 30-month marketing prohibition to just one per product, per generic drug application. It also recognizes the value of

having a mechanism that would allow a generic company to remove or correct the listing of a frivolous patent with the FDA. According to the report, the lack of a mechanism to delist an improperly listed patent ''may have real world consequences'' given the FTC's knowledge of ''instances in which a 30-month stay was generated solely by a patent that raised legitimate listability questions.''

The Coalition believes that S. 812 makes important process changes that will lead to a more predictable, rational pharmaceutical marketplace. CCPM members would strongly oppose any additional amendments that would undermine the intent of this legislation by further delaying generic access or reducing competition and increasing costs to purchasers. We also remain opposed to legislation that would increase costs to purchasers either through extended monopolies or unnecessary and costly litigation.

We are convinced that the legislation currently pending before the full Senate will make a major difference in increasing competition in the marketplace and enhancing access to more affordable, high quality prescription drugs. We look forward to working with you and other Members of the Senate to ensure that this important legislation is enacted this year.

Mr. BIDEN. Mr. President, today is a day of profound disappointment to me. We have completed a debate on proposals to provide prescription drug coverage to Medicare beneficiaries, the most vulnerable sector of our population, and we have come up empty.

I applaud my colleagues for their earnestness and conscientiousness as this issue was discussed on the Senate floor, but earnestness and conscientiousness do not help the senior citizen who cannot afford to pay for needed medications. I introduced a bill, the Prescription Drug Benefit Act of 2002, that would have provided an excellent benefit for Medicare beneficiaries by adding prescription drug coverage to Medicare Part B with no new premiums or deductibles, and I still believe that should be our goal. But at this point, we don't even have a consensus for a first step toward a Medicare prescription drug plan for seniors.

Last week, I voted for the Graham-Miller plan, a comprehensive approach to this problem that, although not as good as my own bill, was a worthy compromise. It was defeated. Today, I voted for the Graham-Smith plan that would at least offer us a starting point toward a comprehensive prescription drug plan. It was defeated. I and all of my colleagues who are concerned about the welfare of our seniors are regrouping with an eye toward taking another run at this critical problem in the very near future.

The seniors and the disabled still need their life-saving medications. They still have to pay large amounts out-of-pocket for drugs, even though the legislation we passed today should help reduce the overall cost of pharmaceuticals for everyone. The percentage of the population covered by Medicare is rising. Medical advances are leading to important new drugs for various diseases. Our nation's seniors cannot, and should not, be left behind in the race toward longer and healthier lives. We have moved this debate forward, but it is far from over, and we will need to continue to be resourceful and persistent in the future. The life and health of 40 million Americans hang in the balance.

Mr. KOHL. Mr. President, I rise to strongly support final passage of S. 812, the Greater Access to Affordable Pharmaceuticals Act. I cosponsored this important legislation because I believe it will benefit every American by ensuring that more affordable generic drugs get to market on time and lower costs for consumers as promised. The Congressional Budget Office estimates that this bill will save American consumers $60 billion over the next 10 years.

Prescription drug spending represents 9 percent of all health care costs, but drug spending grew 17 percent in 2001—and it's the fastest growing part of health care. Generic drugs can cost one-quarter of the price of their brand-name counterparts. In a time when health care costs are soaring in the double-digits annually, that is no small point.

The pharmaceutical industry enjoys the highest profit margins of any sector in the American economy. Drug companies argue that high retail costs reflect the high cost of investment in research and development. I applaud the drug companies' efforts to find new lifesaving treatments and cures for patients and I do not argue with their right to make a healthy profit from their work.

It is important to note that many of the gains in pharmaceutical research are made possible by the substantial, taxpayer-funded research investments of the National Institutes of Health and other Federal grants. All Americans should have access to the benefits of that research, and they should expect that once a drug company has recouped their costs, made a healthy profit, and the patents surrounding their drug expire, at that point consumers should benefit from generic competition that lowers drug prices.

Unfortunately, in recent years, many drug companies have used loopholes in our patent laws to keep less expensive generic drugs off the market. This raises health care costs for patients, employers and States that are already struggling with rising health costs.

There are three major loopholes that this bill closes. First, it would stop brand-name drug companies from filing endless, frivolous patents to keep a generic competitor off the market. These patents often border on the ridiculous, such as a patent on the color of the pill. But ridiculous as it may seem, each of these patents triggers a 30-month stay whereby the generic drug is kept off the market while the matter goes to court. And drug companies have every incentive to do this, after all, the cost of litigation is virtually nothing compared to the additional profits they can get by keeping their monopoly just a little longer. For example, the makers of the antidepressent Wellbutrin were able to make another $1.3 billion during the 31 months they were in litigation with the generic company. And the makers of Prilosec earned another $1 billion in just 7 months of delayed generic competition.

This bill would also close another loophole by outlawing sweetheart deals where a brand company pays a generic company to stay out of the market. In the case of Cardizem, which treats high blood pressure, the brand-name company paid the generic company $90 million to stay out of the market. Because the generic had won the right to have 180 days of market exclusivity before other generic competitors could enter the market, this sweetheart deal allowed the brand company to earn another $450 million before other generics could compete.

Finally, this bill puts some common sense back into the process by which brand companies list patents with the FDA in what is called the Orange Book. It enforces the law as it was originally intended by ensuring that only patents that claim the drug product or the approved method of use are listed in the Orange Book. It also gives generic companies the ability to challenge patents that may have been listed inappropriately just to keep generics off the market longer.

I believe that this legislation preserves the original intent of the Hatch-Waxman Act to balance the competing interests of the rights of innovative drug companies and the rights of consumers to affordable medicines. It preserves the ability of drug companies to invest in research and development to find lifesaving cures and treatments, but it also makes prescription drugs more affordable for all Americans by getting generic drugs to the market on time. It also makes any Medicare prescription drug benefit we pass more affordable for seniors and taxpayers.

This brings me to the real disappointment I have about the legislation we are about to pass today. I am extremely disappointed that the Senate was unable to also pass a real, comprehensive, affordable drug benefit within the Medicare Program. I am baffled by the unwillingness of many on the other side of the aisle to work together to help our Nation's seniors with skyrocketing drug costs.

When Medicare was first created in 1965, prescription drugs were a very small part of our health care system. But today, prescription drugs are a critical part of that system, keeping people healthier and living longer. Unfortunately, according to the Kaiser Family Foundation, 38 percent of our Nation's elderly have absolutely no prescription drug coverage at all. Many seniors who do have some prescription drug coverage find their plan inadequate and face large out-of-pocket costs. Too many seniors forgo needed medicines or are forced to choose between buying the medicine they need and buying food or paying rent.

Seniors and the disabled on Medicare need a comprehensive, universal, voluntary, affordable drug benefit, and that benefit should be part of the Medicare program that we've relied upon since 1965. While the Senate considered many different plans, I voted for the Graham-Miller approach because it was the only plan that met those important goals. And it was the only plan before the Senate that guaranteed that all Wisconsin senior citizens would have access to the medicines they need.

By contrast, I voted against the so-called ''tripartisan'' plan because it relied solely on HMOs to provide prescription drugs to seniors. This simply won't work in Wisconsin. In our State, because of inadequate Medicare reimbursement, we've already seen Medicare HMO plans leave every year and offer fewer benefits than in other States. The tripartisan plan had the same Medicare reimbursement problems. There was no guarantee that plans would participate in Wisconsin at all, and those plans that did participate could cover fewer drugs or charge seniors more in Wisconsin than in other States.

In fact, the HMOs themselves have said they are reluctant to offer such plans. And even if they do, there is no guaranteed drug benefit, from year to year, HMOs could change the premiums and copays seniors pay and which drugs will be covered. I do not believe we should hold Wisconsin seniors hostage to the business interests of HMOs. Seniors need a drug benefit that they can rely on every year to be affordable and one that ensures access to the medicines they need. The tripartisan plan did not meet that test.

In addition, under the tripartisan plan, many seniors would still have high drug costs and low-income seniors would not be protected. The HMOs could charge whatever premiums they want; there would be a $250 deductible; seniors would still pay 50 percent of their drug bills; and there is a big gap where there is no coverage at all and the senior pays 100 percent of their drug bills. Seniors would have to pay $3,700 out of their own pockets before they even reach the catastrophic level. And low-income seniors may not qualify for any extra help at all because of a strict asset test that prevents them from being covered if they own a car worth more than $4,500, clothing and furniture worth more than $2,000, or even a burial fund worth $1500. This asset test would automatically eliminate 40 percent of Wisconsin's low-income seniors from being eligible for the extra help they need.

Instead of the false promise of the tripartisan plan, I and 51 other Senators supported the Graham-Miller plan. This program provided a guaranteed benefit through the Medicare Program that would be available to all seniors, at the same price no matter where they live. It was voluntary, so seniors with drug coverage today could keep their plans. It had reasonable premiums and copays, no gaps in coverage, and low-income seniors would get extra help with no restrictive asset test. And it gave seniors choices. Seniors could choose an HMO plan if they wanted to, but the Graham-Miller bill offered them a drug benefit through the traditional Medicare program that seniors have relied on since 1965.

Unfortunately, even though a majority of Senators supported the Graham-Miller bill, it failed to gain the 60 votes that are necessary for any plan to pass under Senate budget rules. At that point, the Senate was faced the possibility of doing nothing and continuing to leave seniors stranded with high drug costs. For me, this was not an option. Seniors have waited too long for Congress to act, and it would be inexcusable for Congress to leave them with nothing.

That's why I supported a bipartisan compromise that represented a solid down payment on a real Medicare prescription drug benefit. First, it would help all low-income seniors below 200 percent of poverty, 45 percent of Wisconsin seniors, by providing comprehensive drug coverage through the Medicare program with nominal copays of $2 per generic prescription and $5 per brand-name prescription. Second, it would provide all seniors above 200 percent of poverty with discounts on prescription drugs of up to 30 percent. The Medicare program would utilize Pharmacy Benefit Managers, or PBMs, to negotiate these discounts the same system that is used today to manage benefits for nearly 200 Americans in the private sector.

Third, the Graham-Smith compromise would protect seniors with very high drug costs of more than $3,300 in out-of-pocket costs, which represents nearly 17 percent of Wisconsin seniors. At that point, seniors would receive full Medicare coverage for their medicines with copays of only $10 per prescription.

Let me be clear that I would much prefer a more comprehensive benefit and have voted for one. The original Graham-Miller plan would have been a comprehensive benefit for all Medicare beneficiaries, and I believe that is the direction we need to go. But the Graham-Smith compromise plan would have taken a real first step toward the universal benefit we need. It would have been a down payment upon which Congress must build so that all seniors have the coverage they need. But again, even this compromise was blocked from passing.

I am extremely disappointed in the outcome of this debate. We missed a tremendous opportunity to pass a comprehensive Medicare drug benefit. And then we were blocked from the opportunity to take even one real step toward that goal. I truly hope that this is not the end of our journey this year. Our senior citizens made our country what it is today, they paid their taxes and they played by the rules. They should not be forced to choose between paying the rent or buying groceries, or buying the life-saving medicines they need to be healthy in their retirement years. It's time to create a reliable, affordable Medicare prescription drug benefit for seniors. I hope the Senate will continue to work toward that goal this year.

Mr. THURMOND. Mr. President, I rise today to speak in favor of affordable prescription drugs. As a life-long health advocate, I recognize that prescription drugs are an important part of improving the health and quality of life for millions of Americans. These drugs allow Americans of every age to live a more productive and more enjoyable life. Our success in this area is due in large measure to our competitive system that allows for many different approaches to meet the many different needs of Americans.

The central features of any prescription drug bill should be increased competition, innovation in the marketplace and increased access to more affordable drugs. However, the current bill does not accomplish these objectives. Instead, it seeks to bypass the excellent consumer protection provided by the FDA, decreases the return on the development of newer and better drugs, and may actually increase the cost of prescription drugs in the long run.

This bill has been hastily assembled and rashly brought to the floor before committee consideration. This bill contains provisions that have not been analyzed for their impact upon our fine health care system. I fear these provisions will threaten the excellent healthcare system we currently enjoy. Indeed, the FTC released, just yesterday, a report entitled ''Generic Drug Entry Prior to Patent Expiration'' that showed that our system was working and that under the current Hatch-Waxman law innovative new drugs were being brought to market even as a thriving generic market was lowering overall drug costs. While the report does show that some minor changes may be in order, the place to make such important and complex changes is not the floor of the Senate after only a few hours study, it is in the appropriate committee with the requisite expertise.

The bill contains a provision allowing for large scale re-importation of prescription drugs. This presents a serious safety concern of a variety of public health officials and has been rejected in the past. I am concerned that the opinions of many relevant agencies on this matter have been disregarded. Agencies which oppose this provision include the Department of Health and Human Services, the Food and Drug Administration, the Customs Service, and the Center ;for Medicare and Medicaid Services.

Another provision which I strongly oppose which is in the bill relates to Medicaid recipients access to medicine. While it is presented as a price control, it will effectively make drugs unavailable to low-income Medicaid patients

by imposing restrictive ''prior authorization'' requirements on physicians. This policy is opposed by many patient groups and should not be part of this legislation.

Finally, I am deeply concerned that this bill does not contain a Medicare drug benefit plan. This is a very important issue that remains unresolved by this body. Therefore, I do not support cloture on this bill, nor do I support final passage of the measure. It is my hope that we will revisit this issue soon and craft a bill which will improve the availability of affordable prescription drugs and ensure advances continue in this industry.

Mr. HUTCHINSON. Mr. President, nearly 482,000 seniors in Arkansas desperately need a Medicare prescription drug benefit. Per capita, Arkansas has one of the poorest senior populations in the Nation, which means, more often than not, Arkansas seniors must choose between putting food on the table and buying much needed prescription medicines. I voted in favor of the Graham-Smith-Lincoln Medicare prescription drug compromise today, which has the full support of the AARP, because I believe in providing prescription drug assistance to as many people as possible and to those seniors who need it most. I regret, however, that it leaves out nearly 40 percent of Arkansas seniors and lacks measures to strengthen and protect Medicare. Rather, I believe that a universal benefit, accompanied by responsible Medicare reforms, is the most sensible approach to addressing the rising cost of drugs for our seniors and ensuring the long-term stability of the Medicare program. But most importantly, I am concerned about the impact of the Graham-Smith-Lincoln compromise on local pharmacies.

Seniors need a Medicare prescription drug benefit just as much as they need access to their local pharmacies, particularly in rural states like Arkansas. The discount drug card established under the Graham-Smith-Lincoln compromise is a concept I opposed last week when I voted against the Hagel drug card amendment. Requiring pharmacies to accept discounts while doing nothing to reduce the price at which drugs are bought could force local pharmacies to foot the bill of a Medicare prescription drug amendment. This is simply not right.

To help fix these problems, I filed an amendment to the Graham-Smith-Lincoln compromise which would have struck the drug discount card provisions in the bill as well as a provision giving special treatment for mail order pharmacies. If the Graham-Smith-Lincoln compromise garnered the 60 votes necessary for passage, I was prepared to offer my amendment so the Senate could have an open debate and vote on the impact of such legislation on local pharmacists. Since the Graham-Smith-Lincoln compromise was rejected, this debate will have to wait until another day. In the meantime, I will continue to work for a bipartisan solution that provides Medicare prescription drug coverage for all seniors, and particularly low-income seniors, while also preserving access to local pharmacies.

The PRESIDING OFFICER. Under the previous order, there are 2 minutes remaining equally divided.

Who yields time?

The Senator from New York is recognized.

Mr. SCHUMER. Madam President, again, I urge my colleagues to support this legislation. Admittedly, it is incomplete legislation. We have not extended access, but in terms of cost cutting, this legislation is strong.

The Schumer-McCain provisions will reduce the costs of so many drugs by 60, 65 percent for the senior citizen. For the family who has a child who desperately needs a drug, instead of $100 a prescription, it will only be $30, $35, or $40 a prescription. That is a godsend to many people these days.

These drugs are wonder drugs, but their cost is so high that if you are not very wealthy or don't have a good medical plan, you cannot afford them, and that is an awful choice for people.

This bill achieves the goal of reducing costs and reducing it very significantly—a $60 billion reduction over the next decade to our citizenry. I ask for your support of this measure.

Madam President, 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. Who yields time?

The Senator from Pennsylvania, Mr. SANTORUM, is recognized.

Mr. SANTORUM. Madam President, I encourage a ''no'' vote on this bill. The Senator from New York says these are wonder drugs. They do not drop out of the air. They come from a tremendous amount of investment from pharmaceutical companies which create new drugs and save people's lives and create a better quality of life for Americans.

We are sacrificing future cures for political payout today, which is cheaper drugs for our folks back home. The long-term consequence of what we are doing today is that more people will die as a result of drugs not being invented because of the reduction in the amount of research and development that will go on because we have now tipped the balance toward generic drug companies, which do no research and investment and create no new drugs.

So understand what you are doing. We are sacrificing, yes, a great vote to say we are going to provide cheaper drugs. But long-term we are providing less cures and a lower quality of life.

The PRESIDING OFFICER. The bill having been read the third time, the question is, Shall the bill pass?

The yeas and nays have been ordered, and the clerk will call the roll.

The assistant legislative clerk called the roll.

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

I further announce that if present and voting the Senator from North Carolina (Mr. HELMS) would vote ''no''.

The result was announced—yeas 78, nays 21, as follows:

[Rollcall Vote No. 201 Leg.]

YEAS—78

Akaka	Dodd	McCain
Allard	Domenici	McConnell
Allen	Dorgan	Mikulski
Baucus	Durbin	Miller
Bayh	Edwards	Murkowski
Biden	Ensign	Murray
Bingaman	Feingold	Nelson (FL)
Boxer	Feinstein	Nelson (NE)
Bunning	Fitzgerald	Reed
Burns	Graham	Reid
Byrd	Grassley	Rockefeller
Campbell	Harkin	Sarbanes
Cantwell	Hollings	Schumer
Carnahan	Hutchinson	Sessions
Carper	Inhofe	Shelby
Chafee	Inouye	Smith (NH)
Cleland	Jeffords	Smith (OR)
Clinton	Johnson	Snowe
Cochran	Kennedy	Specter
Collins	Kerry	Stabenow
Conrad	Kohl	Stevens
Corzine	Landrieu	Thomas
Craig	Leahy	Torricelli
Crapo	Levin	Warner
Daschle	Lieberman	Wellstone
Dayton	Lincoln	Wyden

NAYS—21

Bennett	Gramm	Lugar
Bond	Gregg	Nickles
Breaux	Hagel	Roberts
Brownback	Hatch	Santorum
DeWine	Hutchison	Thompson
Enzi	Kyl	Thurmond
Frist	Lott	Voinovich

NOT VOTING—1

Helms

The bill (S. 812), as amended, was passed, as follows:

Mr. KENNEDY. Madam President, I move to reconsider the vote.

Mr. DASCHLE. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

EXECUTIVE SESSION

NOMINATION OF D. BROOKS SMITH TO BE UNITED STATES CIRCUIT JUDGE

The PRESIDING OFFICER. Under the previous order, the Senate will proceed to executive session to consider the following nomination, which the clerk will report.

The legislative clerk read the nomination of D. Brooks Smith, of Pennsylvania, to United States Circuit Judge for the Third Circuit.

The PRESIDING OFFICER. There are now 5 minutes evenly divided on the nomination. Who yields time?

Mr. LEAHY. Madam President, we have at best a modicum of order in the Senate, but I will proceed.

The record before us does not demonstrate that Judge D. Brooks Smith merits a promotion to the Court of Appeals. He is already serving a lifetime position as a Federal judge, but he continued as a member of a discriminatory club more than a decade after he told