Mrs. Smith is obviously frustrated that in her golden years she has enormous anxiety because of the high cost of the prescriptions. Under one version of the prescription drug bill, the version that I am a cosponsor of with my colleague from Florida, BOB GRAHAM, Mrs. Smith would only have to pay $25 a month premium for a Medicare prescription drug benefit. If she chose to have a brand name prescription, she would pay a copay of $40, but if she wanted a generic prescription, Ultram—that drug that I mentioned she takes at 150 bucks a month—it does have a generic alternative so she would only have to pay $10 for the prescription for the generic. That coverage for Mrs. Smith would begin upon enrollment, and Mrs. Smith would not be subject to any initial deductible, as is the case in the legislation that passed in the House.

It is another personal example, a real-life example, of why we ought to have a prescription drug benefit enacted to modernize Medicare.

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

The Senator from Minnesota.

Mr. WELLSTONE. I thank the minority leader for his courtesy. I ask unanimous consent that I be allowed to follow the minority leader.

The PRESIDING OFFICER. Is there objection?

Mr. GREGG. Reserving the right to object, is the Senator going to be debating the drug issue?

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is closed.

Mr. GREGG. Yes, but I believe the Senator from Minnesota wishes to proceed after the minority leader.

Mr. WELLSTONE. That is correct.

GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT OF 2001—MOTION TO PROCEED

The PRESIDING OFFICER. Under the previous order, the Senate will now resume consideration of the motion to proceed to S. 812, which the clerk will report.

Mr. WELLSTONE. I say to my colleague, I would like to speak for about 10 minutes.

The PRESIDING OFFICER. If the Senator will withhold.

The assistant legislative clerk read as follows:

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

Mr. LOTT. Madam President, what is the parliamentary situation at this time?

The PRESIDING OFFICER. The Senate is on the motion to proceed to S. 812.

Mr. LOTT. Madam President, I ask unanimous consent that I be allowed to speak under my leader time, probably for 8 or 10 minutes, on the issue that is related to this motion, and others may want to add to it.

Mr. WELLSTONE. Madam President, with the indulgence of the Senator from Massachusetts, I wonder if I could have 10 minutes after the minority so I could go back to a markup?

The PRESIDING OFFICER. The Republican leader has the right to speak at this time.

Mr. LOTT. Madam President, I know others are going to want to speak on the pending motion.

Mr. KENNEDY. Will the Senator yield so I can respond?

Mr. LOTT. I yield to Senator KENNEDY if he wants to make some clarification.

Mr. KENNEDY. We were going to get started. We all are under pressure, but I would be glad to have the Senator from Minnesota speak.

Mr. WELLSTONE. I thank my colleague.

Mr. KENNEDY. Then we will move on the regular order with the presentation of the legislation.

The PRESIDING OFFICER. The Republican leader.

Mr. LOTT. Madam President, I understand there was discussion last night, and in the HELP Committee, about how to proceed on the substantive issue, and there was some understanding that some language would be worked out. I do not know the details of it, but I am hoping that whatever was agreed to in committee can be resolved in a satisfactory way.

Without getting into how it was reported out of the committee and how we will proceed once that is clarified, I want to talk about the overall situation that causes me major concern. The Finance Committee has been meeting off and on for probably 5 years trying to decide the best way to proceed on prescription drugs. We have had repeated bipartisan meetings of the full committee, even this year. I have met, I think five times for as much as a couple of hours talking about the substance but it has always been a general discussion with no markup.

Last week, even though we did two minor bills, there was no markup on prescription drugs in the Finance Committee. This week we were scheduled to take up another bill, but the meeting at 10 was cancelled and now the meeting at 2 was cancelled because I assume the chairman realized that the so-called tripartisan bill was going to be offered in the Finance Committee to whatever bill might have been brought up.

This is legislation that has been developed by Senator BREAUX, Senator SNOWE, Senator GRASSLEY, Senator JEFFORDS, and Senator HATCH. It is truly a bipartisan bill and tripartisan because it does have the support of Senator JEFFORDS.

There is a determination not to allow the Finance Committee to act on this bill. The Finance Committee, for years, has been known as one of the most effective and bipartisan committees, whether it is welfare reform or trade legislation, Medicare, whatever it may be, but in this instance the Finance Committee is basically being told if they cannot get the votes for the so-called Kennedy-Graham-Miller proposal, they cannot act.

I think we are beginning to debate once again in the wrong way on the Senate floor on a very important issue. The majority leader has twice before tried to ignore the Finance Committee and basically come straight to the floor. We saw what has happened, how long it takes for us to work through a bill that has not gone through a committee markup. That is why I continue to urge that the homeland security issue go to a regular markup in the Governmental Affairs Committee, and I am being told that is what is going to happen, because so many of the problems can be resolved at the committee level. If we bring these important issues to the Senate floor without them having been worked through committee, it is a prescription for a real problem, long debate and in this case likely no result.

Last fall the majority leader and the Finance Committee chairman rammed a partisan stimulus bill through the Finance Committee. We told them at that time that process would fail because it set up a situation where we had to get 60 votes and we more than likely could not do that.

Two months ago, the majority leader used a flawed process to bring trade legislation to the Senate floor, and we saw as a result of that it took us, I think, about a month to get it done, even though it was a bill that had bipartisan support on both sides. Four bills were brought together, the trade promotion authority, the Andean trade provisions, the GSP provisions, as well as trade adjustment assistance. It was very difficult to get that work done.

But what we have today worries me even more. We are calling up the drug pricing and patents bill out of the HELP Committee. Then I understand at some point, a prescription drug bill, or bills, will be offered. No matter what is offered, it will have to get 60 votes.

Prescription drugs would have to get 60 votes in the Senate. Why is that? One, we do not have a budget resolution, so we are going under the existing law which says a prescription drug bill cannot be brought up that exceeds, I believe it is $300 billion. If it does, it takes 60 votes. Also, a bill that is brought to the floor without going to the Finance Committee requires 60 votes.

So we have two things that are happening with no budget resolution: we have a limit with the amount. If a bill exceeds $300 billion, it takes 60 votes. If it has not come through the Finance Committee, it will have to have 60 votes.

I do not know what the scoring is on the so-called Kennedy-Graham bill. As

of last Friday, or even yesterday, it was not clear. I am under the impression that it is well in excess of $800 billion, probably closer to a trillion over 10 years. It is a universal coverage provision, without being targeted to catastrophic problems or the elderly poor. We do not know for sure what the costs will be. I am being told that the costs might be less because, instead of it being for 10 years, it will be for 5 years, or maybe even 4 years.

So we are setting up a situation where we cannot act. I think that is a tragedy. It is time we provide the elderly poor who are sick an opportunity to get help with their prescription drugs.

Some States are dealing with this issue, but they are to the limit of what they can do. Others have not been able to deal with it.

I certainly do not agree with this strategy, and the tragedy is that we are going to wind up without getting a result once again. Why not allow the Finance Committee to act?

Let us see what is reported out. Maybe it would not be the tripartisan bill or the Kennedy bill. Maybe it would be something more along the lines of what Senator HAGEL and Senator ENSIGN have proposed. I understand there are other Senators on both sides who will try to work together to find a way to get a result, something that can get 60 votes that would produce a result in this very critical issue.

Senator GRASSLEY has always worked to get bills out of the Finance Committee. They have always been bipartisan bills. I know he is disturbed by this and I believe Senator BAUCUS is disturbed that the Finance Committee has been cut out once again and that we are going with this convoluted process which, I guess, will provide some action on the pricing and patent bill.

That is fine. If we want to bring up that bill and have debate and have some action on it, I think we ought to have debate and some votes and we could get to conclusion of that. But I think to use this as a vehicle to avoid the Finance Committee is a very big mistake. It is not just about politics, it is about results.

Do we want to get a prescription drug provision through the Senate? If we want to do this, we can do it. But what we have before us will not produce a result, a product.

Madam President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The senior assistant bill clerk proceeded to call the roll.

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

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

Mr. WELLSTONE. Madam President, I have just very brief remarks. I thank my colleagues. I have to go back to a committee hearing. I will be back for this debate day after day after day for the next 2 weeks because it is so important to the people of Minnesota.

I take exception to the remarks of the minority leader, as is quite often the case. I think it is an honest disagreement. I think, whether it be 50 votes or 60 votes, if we have a will there is a way. We voted 97 to 0 for a piece of legislation last night. We should have passed it. It was extremely important security reform legislation that was critical for people in the country.

Frankly, affordable prescription drug coverage is also critical for people in the country, for senior citizens, and others as well.

So if there is a will there is a way. We need to get started with this debate. I don't think we should be putting it off at all. It is a compelling interest, a compelling issue in people's lives.

In Minnesota, 40 percent of senior citizens have no coverage whatsoever. I remember a couple of months ago, actually, Helen Dewar from the Washington Post came out to Minnesota to cover the campaign. She spent time with different people. I wanted her to go to Northfield, which was really our home where I taught college, because I wanted her to go to the Quality Bakery—just a great place, a family-run bakery.

We were sitting in there talking and she was meeting with people and this man came in. I don't remember his name. I should have, but I did not remember his name, but I recognized him. It was a small town. We shook hands, and as soon as we shook hands I knew he had Parkinson's disease. I know that disease like the palm of my hand. Both my parents had Parkinson's. I could feel the shaking.

We were talking and I said: Are you on Sinemet?

He said: Yes, but there is another drug people are talking about that would be more helpful.

And I said: What about that?

And he looked at me and he said: I can't afford it.

This is unconscionable.

I want to say just a couple of things. These are the principles. Everybody is talking about getting together. That is absolutely critically important, but these are the principles.

No. 1, it ought to be affordable. You can't have the premiums too high. If you are going to talk about a premium or a deductible, we can't just suggest it. People have to make sure it is there. That is the problem with the House. There are suggestions about a deductible, but it is not part of Medicare, not a defined benefit. People don't know for sure.

No. 2, you bet it has to be catastrophic expenses. But if you have, for example, like on the House side it is between $2,000 and $3,700—no coverage at all. People are saying it will not make sense. We are paying premiums and you are not going to help us when we have bills over $2,000 a year—that is when we need the most help.

No. 3, absolutely make sure, for low-income seniors, they are not having to pay a lot or maybe anything. But if you are going to say that, then don't have stingy means tests where you say if they have a car worth more than $4,500, or a burial fund worth more than $1,500, they could be disqualified. Don't do that. Don't do that. Make sure it is affordable.

Finally, make sure as a matter of fact there is some way that people know this is really, again, going to be a benefit for them, and it will make a real difference.

I think that is why you put it on Medicare.

I understand what is going on here. The pharmaceutical industry—any bill that sort of meets their test is a little bit suspect. I know they are not interested in having the affordable coverage. I know they are not interested in broad coverage. And they are also, of course, not interested in any potential cost containment. If it becomes a part of Medicare, it is absolutely true that at a certain point in time we may very well say: Look, what we are doing here is giving a blank check to the industry, and you are filling in the amount and it is exorbitant prices and there has to be some cost containment.

I want to make a humble suggestion. It is a bill I will be bringing out with Senator DORGAN, Senator STABENOW, and others. Here is one thing we could do that could be a part of our overall getting the work done for people right here in the Senate. We could pass a provision which would say that our citizens, American citizens, can reimport back from Canada these prescription drugs meeting the strictest, same FDA guidelines, consumer protection guidelines. They ought to be able to do so. That not only helps senior citizens, it helps all the citizens.

Do you know what is interesting? You are talking about widely used drugs for depression, for cancer, for heart disease, at 30, 40, 50 percent discount. This is a winner, colleagues, and I believe that ought to be part of the mix as well.

I think the minority leader is wrong. Time is not neutral. I think people are expecting us to do the work. I think we should. If we believe we ought to do this, there ought to be a strong vote for it. I think the Graham and Miller and Kennedy bill is an extremely important start. I think there will be other amendments to strengthen it. But the main thing is we make this part of Medicare. It is not a suggestion. It is a benefit people can count on. We make sure it is affordable in terms of the premiums and the payments, and we make sure it covers the catastrophic bills that put people under.

I don't want to talk about the problems anymore. We have been talking about the problems forever. Let us talk about the solution. Let us get going. Let us start the debate. We should

start. We should not delay anymore. We should have amendments out here. I am ready with an amendment and a provision which I have worked on for years on drug reimportation. Other Senators have amendments. We should get this work done.

My last point is that I think people are counting on us. There is a critically important issue. There is important work to be done. No more delay; let us all come out here and have the debate. Let us be accountable.

I yield the floor.

The PRESIDING OFFICER (Mr. REED). The Senator from Massachusetts.

Mr. KENNEDY. Madam President, today is a very important day for all American families, and certainly for families who have suffered and have been diminished in a very important and significant personal way because of the high cost of prescription drugs. The Senate of the United States is debating an issue introduced by our colleagues and friends, Senator SCHUMER and Senator MCCAIN, to reach out a helping hand to the families of this country in order to get a handle on the cost of prescription drugs.

The cost of prescription drugs as well as the accessibility and the availability of prescription drugs are very closely related. We will have an opportunity to debate that issue later in the week. We are hopeful we will be able to work through this process in a way that will command broad bipartisanship on the floor of the Senate.

We invite the American people to give focus and attention to this debate. Certainly for me, this is most important because it is related to a commitment that we as a country made to our senior citizens back in 1964 and 1965 when we enacted Medicare. It is an issue which is front and center to every family in America today. It was an issue to families early this morning when many of our seniors went to their drugstores and tried to get the prescription drugs which are absolutely necessary for them and found that the costs have been continuing to escalate and wondered whether they could afford the prescription drugs and the food they need. It will be there this afternoon, at noontime, or this evening when workers return and they need prescription drugs to try to help a sick child.

The issues are front and center for every family. I don't think we will debate an issue which is of such central importance to every American family as this one. This issue is not a new issue for this body, but it is a new issue by the fact that we are debating this or have an opportunity to debate it on the floor of the Senate today.

Prescription drug legislation has been introduced and referred to committees over the last 5 years which has never emerged from those committees. I won't take the time of the Senate to go back prior to even 5 years ago. In 1978, Senator THURMOND and I introduced prescription drug legislation. We were never able to get it to the floor of the Senate. Now we will have a debate on this.

I take a moment of time to respond very quickly to the comments of my friend, the Republican leader, about the process of procedure.

Legislation is now before the Senate. It was voted on in our committee 16 to 5. We had a very similar vote on the legislation we just concluded, as a matter of fact. We found after the debate and discussion that we were able to get a unanimous vote on that legislation. We might not end up with a unanimous vote on this, but let us not discount the possibility that we can do something that is important for our seniors.

The point has been made about whether this procedure is consistent with the Senate rules. Clearly, it is. The legislation we are considering was reported out in a bipartisan way. I am hopeful and confident that we will consider other legislation to expand the access to prescription drugs.

I will not take much time to remind our Republican friends about actions they have taken on important legislation that also circumvented committee action. There were a number of instances. I think that is important. I think the needs of families in this country are by far more important.

I regret very deeply that we are going to have to take the Senate's time before we are permitted to actually get consideration of the bill. All Members know we are facing effectively a filibuster on the motion to proceed to this legislation. It is under the guise that some technical language wasn't satisfactory to the members of the committee. I reviewed last night the history on that technical language indicating that if it was just technical in nature, we would be glad to consider those proposals this morning and to clarify the language. If it is substantive, let us get on to the debate and let us get on to amendments. Why delay the Senate of the United States from considering this legislation?

We shouldn't be surprised that there are powerful financial interests that do not want this legislation, that are strongly opposed to this legislation, and that want Members in this body to filibuster to their last breath. This is because they have been taking advantage of the existing legislation to expand their profits at the expense of consumers in ways which we will describe during the course of this debate—the greed and collusion with other companies in order to deny quality drugs and generics being available at cheaper prices.

What this debate is about in many respects is corporate greed by those companies that are ripping off the public. They are able to get, in effect, a delay by this body in considering this important legislation. Let us make no mistake about what is going on. We will see it over the continuation of this debate.

There was a strong belief that we would never have the opportunity to report this legislation out of Committee. We were successful in doing it in a strong bipartisan way. We are grateful to our Republican friends for their support. But we don't underestimate the strong opposition that has been voiced by drug company after drug company that are abusing the process under the old Hatch-Waxman. As a result of that, they are experiencing incomes of billions of dollars more than they ever should, and they are receiving that at the cost of the American consumer. They do not want to lose that privileged position. As a result, they are in support of delay, delay, delay, delay, delay, delay. That is what is happening. Prescription drug legislation is going to be opposed by those that are profiteering.

There are many within the drug industry who support our efforts to try to work through a process because they understand the importance of the health factors that are involved in this. We are grateful to them. We hope we can work with them in trying to come up with real legislation that can benefit people. But we should not have to spend a great deal of time in reviewing what has been happening in terms of the escalation of the costs of prescription drugs.

The cost of prescription drugs has been escalating and far exceeding the average cost of living. It has been going up at the most extraordinary levels.

We see from this chart the fact that the increase in the cost of prescription drugs has been going up and exceeding the cost of living by about three or four times in recent years.

In 1996, we had a 3.23-percent rate of inflation, CPI, and the increase in the cost of prescription drugs was 10 percent. The increase in the cost of prescription drugs was 14 percent in 1997, 15 percent in 1998, 16 percent in 1999, 17 percent in 2000, and 17 percent in 2001. Look at the yellow bars that indicate the rate of inflation.

Why is it so important? It is important, obviously, for the health and consideration of our fellow citizens. But the fact remains, in 1965, when we passed the Medicare legislation, we went on record—the Congress went on record—with a solid commitment to our seniors and to the American people: Work hard, pay into the system, and at the time you are 65 years of age, you will have health security in this country. That was our commitment, and we did it. We have done it with regard to physician services, and we have done it with regard to hospitalization.

But what we have not done this with is prescription drugs. Every single day we fail to enact a prescription drug benefit program that is affordable, accessible, and available to seniors we are violating that solemn commitment and promise to our seniors—every day, every day; today, tomorrow. And that is a solemn commitment.

We will hear: We have X provision or Y provision that isn't clarified. The seniors understand what is out there. They understand what is important. We have a responsibility to meet the needs of our senior citizens, and to do it in a way that is affordable and accessible.

This legislation that is before the Senate now will have a significant impact in terms of the escalation of costs, make no mistake about it—if we are able to, and when we are able to, get a debate for the consideration of it. But what we are being told now, with only 3 weeks left before the August recess, is: No, we are not satisfied. No, we are not going to be able to take this up. No, we are not going to be able to consider this legislation.

If they have differences, let's hear those differences. Let's consider those amendments. Let's debate those amendments this afternoon. Let's vote on those amendments. But let's not just hide behind the questions about clarifications of language.

We have seen what has happened in terms of our senior citizens with regard to the coverage on prescription drugs. If you look at this particular chart, you will see where our seniors are now with regard to prescription drugs.

Thirteen million of our senior citizens have virtually no coverage whatsoever in the United States today. Ten million have employer-sponsored plans. We will come back to that. But keep that in mind: 10 million have employer-sponsored plans. Five million are under Medicare/HMO. Two million are under Medigap. Three million are under Medicaid.

The only Americans who can be guaranteed prescription drug coverage that will be available and accessible are those under Medicaid. Those are the only Americans who are not at risk today. We are trying to do something about it. But the drug companies say no. They will not even let us begin the debate on it. They say, no, we are not going to permit you to even proceed to the debate on this issue, even though we are finding out what is happening to our seniors.

We have 10 million who have employer-sponsored plans. Let's take a look at what happens to those who have employer-sponsored plans. If you take the employer-sponsored plans, the firms that have offered the prescription drug program for our seniors, look what has happened to those 10 million people. These individuals have retired. Let's look at what is happening to their coverage. It is dropping like a stone in a pond. It was 40-percent coverage in 1994; and it is going right on down and dramatically being reduced. That is as a result of the employers cutting that program out.

And 13 million do not have any coverage. As I said, 10 million have employer-sponsored plans. And this is what is happening to the employer-sponsored retirement coverage: The coverage is dropping like a stone in a pond.

Let's look at what is happening in terms of the HMOs. We said we had about 5 million who were covered by the HMOs. Take a good look at this particular part of the chart. This is Medicare coverage. HMO drug coverage is inadequate and unreliable. A drug benefit is offered only as an option, and 30 percent offer no drug coverage. And 5 percent of Medicare beneficiaries in rural areas have it.

But look at this bullet line: Medicare/HMOs are reducing the level of drug coverage. Seventy percent of Medicare/HMOs limit their drug coverage to $750 or less—$750 or less.

Fifty percent of the Medicare/HMOs with drug coverage only pay for the generic drugs.

So you can say we have all of those who are covered by employers. That is phony because the bottom is falling out for them. You can say you have 4.5 million of them covered by HMOs. This is increasingly phony because they have a limitation of $750. And about 18 percent of all of the seniors will benefit under that particular program.

So we go on and see what happens in terms of the next group, which would be the Medicaid coverage. We will find out that some 3 million have that program. And then, finally, you have those who are involved in what they call Medigap, where the average cost has gone up so high that it is increasingly out of range.

Our seniors are in a crisis. Our seniors are in crisis with the explosion of drug costs and the failure of coverage, and we are being told out here on the floor of the Senate we cannot even bring up the bill, even though there has been a prescription drug bill for 5 years in the Senate, and we have not had a debate on these issues.

So the question is, which way is the Senate going to go? Is the Senate going to go with the drug companies and the wealthy corporations that today are abusing and colluding with some generic companies to deny the lower prices for families in this country? Or are they going to stand up and say: We want to get this legislation passed that can make a real difference in the cost of their drugs?

If that is what they want, they should be letting those forces know here in the Senate—the Republican leadership on down—that this is the time for debate and action on this. We do not accept the fact that it is going to be complicated, it is going to be difficult, it is going to be hard to try to reach a coalition.

We are committed to getting something done. We believe we have the way to be able to do it.

I want to also mention another feature. We know that the House of Representatives took some action recently in order to try to address this issue. We welcome the fact that at least they passed some legislation. We would not be able to get legislation unless, obviously, the House passed it and the Senate passed it. We would not be able to get legislation unless we were able to have the House of Representatives pass legislation.

But I want to just review, very quickly, with the Members about what happens in the Republican proposal in the House of Representatives.

First of all, there is an assets test. What they have is an assets test. You will hear: The Republican program really covers and reaches out and covers individuals in the lower income levels. That is where the real need is.

Right, that is where the real need is. There is a great need when you figure two-thirds of seniors have incomes below $25,000. The average income is less than $14,000.

We talk about individuals, wealthy seniors. When two-thirds of them have an income of less than $25,000 and the average income is $13,000, certainly our seniors are hard pressed to be able to do this.

It is interesting. It has been suggested that for low-income people, they won't have any premiums. They won't have deductibles. They will not have any copays. That sounds good, but just take a look at the print. There is the assets test. Any senior can't have any more than $4,000 in savings. You can't have a car that is worth more than $4,500 or you are out. You are telling seniors who might be driving around in the cold of winter that they can't have a dependable car in order to go to the drugstore to get their prescription drugs or have a car in the heat of the summer, in the areas of this country that are scorching hot and have a decent car to be able to make sure they get to the drugstores. If they do, they will lose eligibility.

Burial expenses worth more than $1,500—isn't this wonderful? If it is more than $1,500, it moves against the assets test and moves to disqualify them. Personal property, a wedding ring, no more than $2,000 in furniture or personal property. A wedding ring counts as personal property. Let alone if it goes over that $2,000, it counts in the assets test, as does $4,000 in savings. In other words, you have to just burn every nickel and dime that you have been able to save over your lifetime in order to qualify for this.

Not only is this process unconscionable and it has been rejected by Senator GRAHAM and Senator MILLER in their particular proposal, but it is a very important part of the Republican program in the House of Representatives. It is not only that this is demeaning, but what do we ask our elderly people to do? Go in to fill out a little form. Can you imagine how demeaning that is? People who need that prescription drug as a lifesaver have to go in there to try to qualify. They have to count their wedding ring, their furniture, personal property, and whatever is in their savings when they go to qualify for this program. That is when we know from a financial statement that they are individuals in need.

Beyond this, you have the paltry coverage benefits under the Republican

plan. On this left side you have the percent of seniors that purchase, for example, 18 percent spend $250 or less on drugs; 18 percent spend $250 to $1000; 17 percent spend $1,000 to $2000; 23 percent spend $2,000 to $4,000; and 7 percent spend $4,000 to $5,000. The beneficiary payments and the Medicare benefits, if you are spending $250 on drugs costs, you are still going to pay $658 because you are going to pay the premium and the deductible. So virtually we are telling these 18 percent of the Americans under the Republican program, no benefit, none. You don't get any at all.

If you are at 18 percent and you have drug costs of $1,000, you pay the payments and you pay the deductible. You pay your premiums and you pay your copay. That is $808. The Medicare payment is $192. The cost paid by the senior citizen is 81 percent. Some help and assistance that is.

The list goes on. The 17 percent with drug costs of $2,000 pay 65 percent of the cost themselves. Those with drug costs of $4,000 pay 83 percent; and the 7 percent with drug costs of $5,000 pay 82 percent. Some drug benefit that is.

It is important we have a debate to find out exactly what program does what. But we are denied that opportunity. We are denied that opportunity in the Senate to get on to what is happening with costs. We are strongly committed on our side to try to do something about one aspect of it, and that is the escalation in the drug costs to the American consumer.

We have a strong bipartisan proposal sponsored by our friends and colleagues, Senator SCHUMER and Senator MCCAIN, strong bipartisan legislation that came out of our committee and can save as much as $71 billion over the next 10 years and make a real difference. There are other ideas that our colleagues have in the Senate that can show how the consumers can get an additional break in terms of the high cost of prescription drugs. We ought to have the opportunity to debate them.

But no, we can't do that. We can't do it today. We are prepared to get into the debate. We are prepared to get into amendments. We are prepared to have votes in the Senate. But, no, we are told by our colleagues from the other side of the aisle that we can't because there are language changes in here that are not satisfactory. If it is not language, it is substance. I might say that we are glad to work out language. And if it is not language, if it is substance, let's get to it in terms of a vote. We are being denied not only to consider the basic underlying bill, the Schumer-McCain proposal, but we are unable to consider other amendments that can also have a positive impact in reducing the cost of prescription drugs. We are denied that opportunity.

There are several of those. I see my friend from Michigan in the Chamber now. She knows a number of those and she will be an effective advocate for many of those. We can have an important debate, and we can have action that can have a meaningful impact in terms of seeing a leveling down of the escalation of the cost of prescription drugs in the future. But, no, we can't consider that.

There are certainly those who would say, if we are going to take that very important step, that will be important in and of itself, but what about the coverage? We are being denied consideration of various proposals including those by Senator ENSIGN, Senator HAGEL, and the tripartite group. However, we are unable to even consider and debate those. We are being closed out.

We will have to take the time of the Senate this week to just go ahead with what this body has done so well over a long period of time on prescription drugs, and that is to talk and talk about it but not take action.

We are prepared to take action. Majority Leader DASCHLE said weeks ago that we would take up legislation dealing with prescription drugs. He has met that commitment. That is a strong position of those of us on this side of the aisle. We were able to get that legislation out. We don't just say that it is only the Democrats who are interested, as I have said repeatedly; we have strong Republican support for the underlying legislation. If it had been so egregious at the time, I would have expected they wouldn't have supported it.

So we have important legislation. It is bipartisan in nature. We agreed, Republicans and Democrats, we want to take action, but we know where many of the drug companies, not all, but many of the drug companies are. They are saying: No, we do not want action on this bill. No, we do not want action on coverage. No, we don't want to have consideration of this legislation. No, we don't want any action whatsoever to protect the seniors and sick people of this country in terms of prescription drugs.

There are many of us who reject that attitude and that position.

We are strongly committed to having action here in the Senate on this proposal. We believe that the quicker we get to this legislation, the better off we are going to be.

The PRESIDING OFFICER. The Senator from New Hampshire is recognized.

Mr. GREGG. Mr. President, there have been a lot of representations by the Senator from Massachusetts as to why we are in this position. He need only turn to himself to answer that question.

When we marked up this bill in committee, there was an unequivocal, unquestioned agreement, in my opinion, that we would reach accommodation on two parts of this bill. There was significant discussion about the 45-day rule and about the fact that what the language in the bill represented, what the sponsor of the bill represented the language to do, was the opposite of what the language did. It was agreed to by the Senators there—both Republican and Democrat—that that language would be corrected. There was an agreement between the Senator from North Carolina and the Senator from Tennessee that the language dealing with the bioequivalency issue, which is critical in this bill, would be corrected before it got to the floor.

The essence of this bill was presented to the committee on Thursday and marked up. Now it is on the floor. That is rather prompt action, to say the least. But the understanding was that, before it got to the floor, these two items would be corrected so that the bill would be in the proper form when it reached the floor.

The reason there is delay occurring is that there continues to be a stonewalling of the agreement that was reached in the committee as to correcting those problems. It is pretty hard to reach an agreement in the committee and suddenly find it means nothing when you get to the floor. It makes it very hard to do business around here when that happens. But that is the reason for the delay of this bill being available for amendment.

The debate is going forward rather intensely. The Senator has numerous charts, and I am sure other Senators will be down here with numerous charts to discuss this bill. But I thought it was important we make the point that when an agreement is reached in committee during a markup that the bill will be corrected before it gets to the floor, on two specific and important points, that agreement should be upheld.

Now, obviously, at some point we are going to go to this bill and we will start amending it. It doesn't look as if the agreements that were reached in committee are ever going to be fulfilled, which is regrettable and inappropriate, in my opinion. It makes future markups very tenuous, because how can you mark up something and have an understanding, and then suddenly find that the understanding was meaningless once you agreed to move forward with the bill? It changes the whole tempo of how you do things around here.

So it has nothing to do with greedy drug companies. I am sure there are a lot of greedy companies out there. We have seen that everywhere. It has to do with the appropriate process in the Senate and the movement from the committee to the floor, as to why we are delaying this specific bill's ability to be amended. We are not delaying the ability to discuss the bill. There is a great deal to discuss, and I will take a few minutes to do that.

I am talking about the underlying bill, not the drug bills that are going to be coming as amendments to this bill. The underlying bill, which was Hatch-Waxman and has been amended by Edwards-Collins, has a very legitimate purpose: To get generics to the market quickly but at the same time protect the incentive of brand name companies to do research and have protection in

the research and the products they produce, but at the same time allow generics onto the playing field quickly. It is a very technical bill, with technical language, which will have a big impact on the ability of Americans to buy drugs more cheaply and also to have new drugs come to the marketplace, which drugs will be able to save lives.

You have to remember that. I think something is often forgotten in the demagoguery of ''let's reduce the price of drugs,'' which dominates the political marketplace today, as buses drive to Canada and people claim they can buy this or that at cheaper prices. The basic benefit that we as the American society have is that we have a vibrant research community in the area of producing new drugs. That has taken us from being a society where people were operated on all the time, and put under the risk of a knife, to a society where in health care drugs are able to take care of many of the issues that were not able to be cured before; and if they were not, you were put at risk of being put under a scalpel.

We need to continue to expand that, to have an expanding research base in the area of drug production. But in doing that, we see the costs going up. So how do we address that? The hope is that, as the drugs come on the market and after the people who have developed the drugs have a reasonable period of time to get a return on that so that they recover the costs—and it takes about 12 years and $500 million to bring a new drug to market—that was the last number I saw; maybe it is higher. But once the costs have been recovered at a reasonable rate in a typical market system, then you allow other people to produce the same drug. That is called the generics. They come in and produce it at a much lower cost.

What we don't want to do, as we are making those lower cost drugs available, is wipe out the incentive of people to go out and produce new drugs for the marketplace. So it is a very delicate balance, and it cannot be effectively handled by suddenly going to the Canadian system. The reason the Canadians are able to offer low-cost drug prices is that they take our research and they basically don't pay us back for it. They sell the drugs in Canada without the research factor as part of the cost.

Of course, there are other things we can do in this area—and, hopefully, we will get into those debates—such as marketing drugs and how you control the cost more effectively. Those are other issues. But this question of how we balance bringing generics into the marketplace versus creating continued incentive to research is absolutely a critical question of maintaining a healthy society and getting more drugs to the market, which will benefit more people within our society.

Hatch-Waxman has been an extraordinary success. When it was drafted by Senator HATCH and Congressman Henry Waxman, I don't think they would have anticipated they would produce something so successful. It has accomplished its goal very effectively. But, unfortunately, as so often happens, as time has gone on, we have seen some holes in it. It has mutated a bit, and smart lawyers have figured out ways around it. As a result, unfortunately, both the brand companies and the generic companies have found ways, in some instances—not all but some—to game the system. Brand companies are keeping generics out of the market longer by using the mechanisms available under Hatch-Waxman, and keeping other generic companies off the playing field by also using the mechanisms under Hatch-Waxman.

So there has been an attempt to reform it. It began with a bill called McCain-Schumer, which mutated into Collins-Edwards, which actually took as its base a significant amount of language that I developed for an amendment within the committee. So the underlying bill is basically moving in the right direction and is a good bill.

It has four major problems, however, two of which I thought had been fixed before we got out of committee—at least I think it was pretty clear that everybody at the markup believed there was an agreement that they would be fixed before it got to the floor. Two of the others still require amendment activity—or they are all going to require amendment activity now, but they should not. Only two of them should have to require amendment activity.

Where are these problems? They are technical in nature, but they have a huge impact on the process. The FDA has looked at the bill, and it has found these problems to exist. They are not my creation. They are not some brand name drug company's creation. They are not even the generics companies' creation. They are a problem which is highlighted by the way the language is drafted.

I want to read now the FDA's concerns because they basically make the case for these problems. The FDA, I believe, is the fair arbiter of this issue. In a memo dated July 10 from Frederick Ansell of the FDA to Diane Prince and Patrick McGarey, he points out a variety of issues. I will highlight the ones I think are the most significant.

The introductory paragraph:

> This memorandum follows up on my July 9 memorandum on technical issues with S. 812's substitute amendment. This memorandum addresses substantive concerns—

Substantive concerns—

about the legislation.

The first point they make deals with something called civil actions. This is a change in patent law which is rather dramatic. It deals with the 30-month stay issue and how that works.

> Civil action to correct or delete patent information. The civil action can be brought against patent holder to ''correct'' patent information required to be provided under the bill. Since there is no requirement that the plaintiff have filed a par. IV certification, does this mean there is an alternative available to an ANDA holder to file suit in lieu of certifying under par. IV? That language also means that a suit can be brought not only to delete a patent that should not have been listed, but over whether the listing was ''correct.'' If the incorrect or missing information means that the NDA or patent holder ''fail[ed] to file information on or before the date,'' (even if it is later ''corrected,'' since the correct information was not filed as of the due date), then a potentially technical failure to provide information will make the holder ''barred from bringing a civil action for infringement of the patent against a person'' who filed an ANDA.

Skipping a few sentences:

> This is a change in the patent law that would provide pharmaceutical patents less protection than any other category of patent and would presumably harm innovation in drug research area.

I reemphasize this point: This language ''would presumably harm innovation in drug research.'' That is the FDA evaluating the effects of the 30-month rule as it is structured in this bill.

Going on to another section, the 45-day rule. This was something on which we thought we reached an agreement in the committee. It is a complicated issue, but the 45-day rule means that under the bill as it is drafted, if the holder of the patent, the brand company, the primary developer of the patent does not bring a suit in 45 days, they essentially lose their ability to bring suits against anybody, not just the generic company that filed a plan against their patent—against anybody.

This is a radical departure and would essentially mean that for most brand companies, they would just have to file suits interminably or else be put at risk of losing any rights to their patent.

To quote the FDA, which is summarizing their view of this language:

> The same considerations raised about barring patent lawsuits altogether raised about an earlier provision of the bill apply to this language concerning patents that would not, following the notice and suit, permit a 30-day stay.

Skipping down again:

> That may make preparing an infringement case sufficient to obtain a preliminary injunction difficult, making illusory the ability to protect the patent or forever be barred.

Making illusory—emphasizing ''the ability to protect the patent or forever be barred.''

Essentially this language, which we had thought we had agreement to correct, in the FDA's view would make ''illusory the ability to protect the patent or forever be barred''—obviously not constructive to creating new research in the area of drugs.

The third area is the 180-day issue, which is a major issue. If a generic company files a challenge under the present law and comes on the playing field, so to say, then they get 180 days exclusively to put their product in the marketplace. This is an attempt to encourage generics to come into play.

The Edwards-Collins bill has an incredibly complex new system to try to

address this issue. The language I proposed would have essentially eliminated the 180 days if there had been collusion between the brand name company and the generic company.

One way the system is gamed is a brand name company and a generic company get together. A generic company comes in, files, and, as a result, with the consent of the brand name company, essentially locks down the product for another 180 days, and then they continue to roll that out.

In an attempt to address that, I proposed language which would basically be use-it-or-lose-it language. In other words, if they came in and did not produce their product, they would not get their 180-day exclusivity.

The Edwards-Collins bill sets up a very convoluted system where you can have a rolling 180 days and can actually end up with this going on forever. The FDA memo describes this, and then it says in conclusion:

And if in that circumstance, the second applicant cannot go to market within 60 days, then the third applicant obtains 180 day exclusivity.

Talking about how this becomes a rolling event.

Then it says:

This does not seem to make a great deal of sense, given that the supposed purpose of exclusivity is to encourage a challenge to a patent by a generic. It is also possible that exclusivity could roll and roll on forever. It also means that it will not be clear which applicant if any should receive exclusivity. Finally, whereas under current law, only one applicant (the first) or none can receive exclusivity, the ability of one of multiple applicants to receive exclusivity means that there will be more instances of exclusivity, delaying the date that the public will be enabled to obtain generic versions of a drug generally, and at a cheaper price, than during the duopoly of the innovator and the generic with exclusivity.

In other words, the language actually works against bringing generics to the market according to the FDA view.

We have these four major issues, the fourth one being the fact that a new cause of action is created under this bill which is a private cause of action and which, in our opinion, is a very bad idea and very poor policy, and I will enter into the RECORD a number of letters, including one from Susan Estrich, reflecting the view that this is bad policy, to create this new cause of action.

The reason I raise these points is to make clear that this bill, which was first introduced on Thursday, which came out of committee on Thursday and which is now on the floor, has some substantive problems with it. Some of these substantive problems could have been corrected if the markup procedure had been followed. They were not. But I do believe it is appropriate we have a few days to air the issues so people can get a little window of knowledge on this bill before we suddenly jump into it. That is what we are asking for as a result of this delay in the ability to amend the bill.

The Senator from Massachusetts made the statement, or at least he was reported to have made the statement, that the first he heard of these concerns was 5 minutes ago—or to quote, ''the first I heard there was an objection was 5 minutes before.''

I presume before the objection, quoting Senator KENNEDY. That was in an AP story by Janelle Carter.

The fact is, that is not accurate. We had made it very clear that we expected the agreement in the markup to be followed, and one would presume if the agreement was not followed there would be an objection. How else would one proceed?

So the 5 minutes either implies that he was not at the markup, or that if he was at the markup he did not hear the agreement. The fact is, there was an agreement. So it is not reasonable to say that we were delaying this bill when, in fact, all we are trying to do is accomplish what was represented to us was going to be done originally, when the bill was ran through committee.

To lay the blame for this delay at the hands of greedy corporations is to throw red herrings and smokescreens over a process which, in my opinion, is being abused from the standpoint of the markup process. It has nothing to do with winners and losers under a delay. As a practical matter, this delay is probably going to have virtually no impact on this bill, or on the drug bill, because the debate is going to go forward today and we are going to discuss all the different issues, as I have outlined the problems—the FDA memorandum and the other issues which are of concern. Then when we get to the amendment process, people will be up to speed. Hopefully, a little more light will have been shined on this bill, which needs light on it, and then hopefully we can pass it. Of course, this bill is going to be totally overwhelmed by the actual bills that are going to deal with the overall drug bill.

While we are on that topic, let me make a couple of points. The Senator from Massachusetts held up a chart which showed a line that went straight down about drug coverage and other coverage that insured individuals are getting. He also held up another chart with a line that went straight up about people being added to the marketplace who were uninsured. I suspect he will probably refer to the fact there are so many uninsured.

It is a little like that story of the fellow who kills his parents and then goes to the court and throws himself on the mercy of the court because he is an orphan. The fact is, the reason the amount of coverage is going down and the reason the number of uninsured is going up is because this Congress continues to pass mandates on to the price of the premium, all sorts of different things which feel good, sound good, are good ideas but each new mandate significantly increases the cost of insurance for everyone. As a result of increasing that cost, either the other items of insurance have to be reduced in order to keep the price stable—which sometimes is what happens in reducing the availability of drug coverage or dental coverage or something else that one might have had before the new mandate hit—or you have to increase the price of the insurance, thus people and businesses cannot afford it, especially small businesses, so more people become uninsured.

We are complaining coverage is less and that more people are uninsured while we are basically creating the problem by adding more and more mandates into the marketplace, which inevitably forces up the price of insurance and inevitably forces people out of coverage. In the end, it may be the goal of some in this body and in the other body to accomplish that so there will be more pressure to generate a national health care plan along the lines of what was presented by Senator CLINTON back when she was First Lady, a plan which would basically have the Federal Government take over all health care so everybody would have some form of coverage, much like the Canadian or the British system. If more uninsured are created, there will be more pressure created, obviously. That may be the goal of some. The goal of others may be: I am especially concerned about this ailment or that ailment and I really want it to be covered by insurance; I have an anecdotal experience in my life that says this part of health care definitely needs to be covered because I know somebody who did not have coverage and who had this problem. So we add that as a mandate.

Whatever the reasons are, the facts cannot be denied: Every time we add these new mandates, we increase the cost of insurance or we reduce the other coverages under insurance, and the result is we are adding more uninsured to the marketplace, or alternatively we are reducing the availability of various types of coverage in other areas that are not mandated. And that is why that chart occurs. That is why we are seeing drops in coverage; it is us.

It is like the famous Pogo cartoon: We know the enemy, and he is us.

On that issue, the Senator from Massachusetts attacked aggressively the House-passed plan. The House plan does not happen to be the Senate plan—and that would be the Senate Democrat plan or the Senate Republican plan or the tripartite plan or bipartite plan, or however many different plans we have floating around. There are some very legitimate plans that have been proposed in the Senate, though, and if we are talking about procedure and how we get these plans discussed and properly voted on, one must ask the question: Why is the Finance Committee being bypassed? Why is this new drug plan being written in an office across the hall instead of in an open committee room where it should be written?

The answer is very simple. Because if the Democratic leadership went to the Finance Committee, it is very likely

that a bipartisan bill would be reported out and it would be the tripartisan plan which has been offered by Senator BREAUX, Senator JEFFORDS, and Senator SNOWE. That plan, I suspect, has a majority vote—I do not know because I do not serve on the committee, but I certainly heard this from a lot of members of the committee—that plan has a very reasonable chance of having a majority on that committee. That is why the committee is being bypassed, because the Democratic leadership does not like that plan for some reason. I guess it does not cost enough.

That plan costs about $400 billion. That is still over the $300 billion we had in the budget, but it is nowhere near the pricetag of what I suspect will be the plan we will see proposed by the Democratic leadership, which may be scored as high as $700 billion, which is a huge amount of money, which leads me to the next question: When Senator KENNEDY talks about how little coverage the House plan had—or maybe others in this body do not feel the Snowe-Jeffords-Breaux bill has enough coverage and they want to expand that coverage dramatically by reducing copays or reducing deductibles or essentially reducing the catastrophic threshold, and so they get up to a number of $700 billion in their scoring of what their bill ends up costing, which is a huge amount of money. The $300 billion is a lot of money, I think; $700 billion is two and a half times that, almost. So that is really a lot of money.

Somebody has to ask the question: Where does it come from? We do not have a surplus. Where is the $700 billion going to come from, this extra $400 billion on top of the $300 billion that we have? It comes from the younger generation. It comes from those Americans who are working today, going to be working tomorrow, and going to be working 10 years from now, and who are going to have to support the baby boom generation when it hits retirement—my generation, the generation of Bill Clinton, the generation of George W. Bush, the generation of the Senator in the chair, the Presiding Officer.

Our generation is huge, absolutely huge. We know that. In every segment of American society that we have impacted, from when we started a dramatic run on baby carriages and cribs back in the early 1950s, to when we pushed the limits of our educational systems in the 1960s and 1970s, to our music in the 1980s—we have changed fundamentally the way this society has worked, simply by our size.

When we hit retirement we are going to have a huge impact on this society and the impact, the most significant impact we are going to have is that we as a massive generation that will be in retirement will have to be supported by the smaller generations that are younger than us who are working for a living—our children and our grandchildren. We are going to end up passing on to them huge costs to maintain the standard we have set and which we think is reasonable as a society for senior citizens to have, both in the area of health care and in the area of retirement benefits—Social Security. We know the Social Security system is headed toward a crisis because of this generation, because of our generation, and the demands we are going to put on the system.

When we add a new drug benefit, of which we are basically going to be the biggest beneficiaries—obviously people who are in the system today will benefit significantly, too, but the big cost of the benefit is going to kick in when we start to retire, beginning in the year 2008, which is not that far away—that cost is going to be passed on to our kids in the form of taxes. Their taxes are going to have to go up. They are going to have to work harder or they are going to take home less in order to support their young families so we can get that drug benefit.

When we start throwing out these new benefit ideas on the floor of the Senate, and we start to malign other programs—whether it is the House program or whether it is the tripartisan program put forward by Senator GRASSLEY and Senator BREAUX and Senator COLLINS and Senator JEFFORDS, or whether it is the proposal put forward by Senator ENSIGN and Senator HAGEL—when we start to malign these programs because they do not cost enough, they do not give enough benefit, somebody should be asking the question: Who is going to pay the bill for the increase to bump these programs up above what they are proposed at?

They are all extremely generous, $300 billion being the floor for these programs. Who is going to pay the cost? It is going to be younger Americans; our children and our grandchildren who are going to pay that cost. We need to be careful about what we do to them because if we continue on this path as our generation retires, we are going to significantly impact their quality of life. We are going to reduce it because we will have put so many burdens on them to support us.

Let's put some balance into this debate. Let's not just talk about how many new benefits we can put on the books. Let's talk about how many new benefits we can afford to put on the books, how many new benefits can our children afford to pay so we can help in the area of drug coverage.

Yes, we need a drug package. We need a Hatch-Waxman reform package absolutely—in fact, I drafted a large part of the package we are debating today, the Collins-Edwards package. That was borrowed from language which I was successful in putting in.

I appreciate the fact the Senator from North Carolina and the Senator from Maine chose to use language which I had developed because I believe very strongly that we need a strong generics industry and we need to have the capacity of generics to compete aggressively in the marketplace, coming quickly—or as quickly as reasonable—after you have a reasonable return to the brand companies, to accomplish the goal of reducing prices of drugs.

The basic bill is a good bill with some significant reservations, the most significant being the ones I have outlined.

Of course a new drug benefit for senior citizens is critical. We have gone from a society where, as I mentioned earlier, we treat people by putting them under the knife to where we treat people by giving them these miracle drugs. They are expensive. If you are a senior and you are trying to make ends meet and you get hit with a drug bill, it can be very difficult, in some instances. So we need a benefit. Low-income seniors especially should be completely covered—and all these programs do that and do it effectively. Middle-income seniors should have some sort of relief. Certainly anybody who has a catastrophic event which involves the cost of drugs over a threshold of any significance should have coverage. We can design a plan to do that.

But in doing that, let's be sensitive to the fact that it is costing somebody something. This is not money that grows on trees. This is money that comes from somebody's hard day's work. And that hard day's work is going to be done by our children and our grandchildren. They would like to have that money to maybe help them educate their children or their grandchildren or buy a new car or live a better life. So we have to be judicious in our approach, not simply be political.

Let me, for the record, put in the record, parts of the record of the markup so that it is clear at the markup there was an understanding, I believe, reached that this language would be corrected.

The first issue went to the ''use it or lose it'' language. I quote Senator CLINTON.

My staff at least believed that it was intended to be as I have described it, that generic ''X''——

And then Senator EDWARDS intervened and said:

Why don't we just clarify it—Mr. Chairman, if we can just clarify this language. I think Senator GREGG is right about intent, and I actually read the language the same way he does—

Then I speak and I say:

Well, that is a major step in the right direction.

That went to that issue. Then on another issue—this may be the same issue actually—Senator CLINTON said:

—so I think we need to go back to the drawing board to clarify this.

Senator EDWARDS said:

Yes, we can fix this.

Further to this issue why we—I, not we—have delayed going to this bill until tomorrow when cloture ripens, and the point about the representation being made by the Senator from Massachusetts that it was because of the

greed of some corporations out there, that they want to delay, my representation is that there was an understanding in the markup—in the markup that was very clear, in my opinion—that two items in the bill would be corrected, two major items, one dealing with the 45-day rule, and the other dealing with bioequivalency, and that had to do with Senator FRIST, that those would be corrected before we took the bill to the floor.

Because of the rapidness of the bill coming to the floor without a report, within less than a week of its being actually filed in the committee, it seems to me that it was reasonable to shine some light on these two issues before we move to the bill—to actually amending the bill.

So I want to return to the language here of the markup to make it clear why I believe my presentation is correct on this point. The first item I quoted was Senator EDWARDS saying:

Why don't we just clarify it—Mr. Chairman, if we can just clarify this language. I think Senator GREGG is right about the intent. . . .

This deals with the 45-day issue, and the question of whether or not it cuts off all lawsuits, all rights of remedy if you do not bring a suit; it cuts off all rights of remedy under the patents so that a person—the company basically loses its patent if it doesn't bring a lawsuit against filing generically in that 45 days. You lose your patent against everybody. Nobody wanted that, but that is what the bill ended up doing in its present language.

Then the second part of that discussion went to—Senator CLINTON:

—so I think we need to go back to the drawing beard and clarify this.

Senator EDWARDS says:

Yes, we can fix this.

Then I said:

Good.

The Chairman said:

All right. Now we are going to instruct the staff to make that clarification, along with the rest of the bill.

That is my point.

There was, at the same time, some discussion of language which Senator COLLINS was straightening out. I believe that was actually straightened out.

Then I went on to say:

I think that significant progress has been made here in these discussions, obviously on the 45-day issue and on Senator COLLINS' proposal.

I believe there is middle ground that can be reached on the new cause of action, and much of this bill is excellent. In fact, it came out of ideas that I strongly endorse and was supportive of and hoped we could reach agreement on.

With the cause of action language in its present structure, I cannot vote for the bill, but certainly I hope that by the time we get to the floor and as we move through the floor that we can adjust it enough so that I can feel comfortable with voting for the bill.

I was talking about cause of action.

That is really a point on which I still hope we can reach agreement. If we can, the bill becomes, in my opinion, a very workable piece of legislation that should be passed.

Then wrapping up, I said:

I would also note for the record that we do wish to have our procedural days which are available to us to review this, and I would hope during this time we could work out the few—obviously, get the language straightened out—but work out the few substantive kinks and get this to a point where it could have unanimous support.

The Chairman. We will certainly work with you and your staff in working out the language on this.

That is more vague and not as much to the point as the 45-day exchange. But the point I was making there was that the traditional way we bring a bill to the floor is we do a report. The minority then has 3 days to file. Then there are 3 more days. You usually have 6 days after a report is filed under a bill before the bill comes to the floor. That has been totally shortened.

By not filing the report, the majority was able to put themselves in the position where they can call up a bill after 1 day. That is their right. That is the rule. But it is not the traditional way things have happened when you report a bill out of committee. You usually have the report and then have 3 days to respond to it. I was under the assumption, wrongly obviously, that we would have 3 days to work this out, put some light on the bill, and address the issues which were highlighted by me here.

There was another exchange—unfortunately, I don't have a copy—between Senator FRIST and Senator EDWARDS in which Senator FRIST raised the point about the bioequivalency issue that goes to whether or not the generic drug comes to the market and is actually equivalent to the drug that it claims to be copying. If it is not, you have significant health questions. I don't want a drug out there that comes to market claiming to be equivalent but is not equivalent, because then you have different absorption rates. As a result, you could have serious medical problems.

This was the point that Dr. FRIST made very well. Obviously, he is a doctor. Senator EDWARDS said to Dr. FRIST rather specifically: All right. We will work that out. I understand your concern. I am paraphrasing. We can work that out. Unfortunately, that was also not worked out.

Those are the reasons. Those are the issues that lie here on the question of why we are holding this bill over for 48 hours before we proceed to the amendment process, which will begin occurring tomorrow after cloture is voted, or cloture is vitiated. Either way, I do think it is appropriate that we have this time to discuss the bill because it is a complex bill and it needs to be aired.

I yield the floor.

The PRESIDING OFFICER (Mrs. CARNAHAN). The Senator from North Dakota.

Mr. DORGAN. Madam President, I must say that is one of the more tortured explanations I have heard about why a bill has been delayed coming to the floor of the Senate. Of course, everyone has that right.

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

Mr. DORGAN. I haven't finished the first sentence. Of course, I will yield to my friend.

Mr. GREGG. Does the Senator consider it tortured that a Senator feels a representation made in markup is not being pursued?

Mr. DORGAN. No. Let me just say that I heard the explanation the Senator gave, and I heard the explanation also by Senator KENNEDY on the floor that, in fact, we have people who do not want to bring this bill to the floor of the Senate. They never wanted it on the floor of the Senate.

They described a ''good'' bill in the House which was passed by the House. It is referred to as a credible bill. A senior with $1,000 in annual drug costs would still pay 81 percent out-of-pocket costs under a bill passed by the House. Is that a good bill? I don't think so.

A senior citizen with $2,000 in yearly drug expenditures would still pay 65 percent of the cost out of their pockets. Is that a good bill? I don't think so.

A senior citizen with $3,000 in annual drug costs pays 77 percent of the money out of their pocket. That is not a drug benefit that makes sense.

My only point is to say there is no reason to delay. Let us just proceed with the legislation, understanding that we are going to do a bill that deals with prescription drug benefits and Medicare. Let us proceed with the amendment process. If there are representations that need to be honored, let them be honored.

I think everyone understands that the chairman of the committee who brought this bill to the floor is an excellent legislator, and he works with everyone in this Chamber. I am certain that before the final consideration of this bill, the concerns that were expressed and the representations that were made in that committee, if they have not been fully met at this point, they will be met.

My only point is that was a long, tortured explanation of why to delay this bill. They do not need to delay this bill. The fact is, we all understand what needs to be done. We ought to get about the business of doing it now—not later, not tomorrow, and not the day after tomorrow.

It is true, as the Senator from New Hampshire said, that not too many decades ago most health care was treated under a knife. If you had a big problem, you went and had surgery.

It is also true that now we have miracle, lifesaving drugs that have been created in this country, in large part

by public research at the National Institutes of Health, by research funded all across America, and also by private research by pharmaceutical manufacturing companies, which, incidentally, we provide a tax credit for that research. I support that tax credit. But the fact is, we have produced miracle, lifesaving drugs and those prescription drugs are now available to people who have problems with their health. The difficulty, however, is that you can only see a miracle happen with miracle drugs, or you can only save a life with lifesaving drugs if the person who needs them can afford them.

We have so many people living so much longer these days who reach their retirement years and declining income years who can't afford these lifesaving drugs. That is the reason we ought to put a prescription drug benefit in the Medicare Program.

My colleague who just spoke said: Who is going to pay for this? I found that interesting because we never heard any of those questions when recently we had a bill on the floor of the Senate and we were talking about repeal of the estate tax for the highest income earners in America. One of my colleagues said: Well, at least let us just repeal it for everybody under $100 million. And only people with more than $100 million will have to pay any estate tax at all. But that wasn't good enough. They voted against that. Who is going to pay for the estate tax of people whose estates are higher than $100 million? Did anybody ask that question? No. They only ask the cost when it comes to trying to provide some help for senior citizens—those who live on $400, $500, or $600 a month who are 80 years old, have heart disease and diabetes, and who have to take several different kinds of prescription drugs and can't afford them.

The two issues we are going to deal with are coverage; that is, shall we, will we, can we put a prescription drug benefit in the Medicare Program? The answer to all of those questions is yes. It is long past the time to do that.

We should provide coverage for prescription drugs in the Medicare Program, but it ought not be an illusory kind of coverage. It ought not be the case that we passed the bill and let us just tell everybody we passed a bill. Is it a good bill if you have $3,000 in prescription drug costs and the House of Representatives says, oh, by the way, we have given you a prescription drug benefit and you still get to pay 70 percent of your $3,000 cost out of your pocket, and we will cover the rest? That is like giving someone a $5 coupon and saying go buy a Mercedes. It isn't worth anything. But they say: We gave a discount with the coupon.

We have to provide coverage. We have to provide effective coverage that really does provide help.

I have described, before, meeting many senior citizens, especially senior citizens who are affected by drug prices. One evening, at a meeting in a small town in North Dakota, at the end of a meeting a woman came up to me, perhaps 75 or 80 years old, and she grabbed me by the elbow and said: Mr. Senator, can you help me? I said: I will sure try. What is the problem? She said: Well, I have these health problems that are very serious, and my doctor says I have to take this prescription drug medicine, but I can't afford it. As she spoke, her eyes welled with tears and her chin began to quiver. She began to cry. She said: I can't afford it. I don't have the money to get the medicine the doctor says I need.

This happens all across the country. We need to do something about that. That is why we want to put prescription drug coverage in the Medicare Program.

The second thing we need to do—and very important, in my judgment—is to do something that puts downward pressure on prices, because if we just put a prescription drug coverage provision in the Medicare Program and do nothing about prices, we will have done very little in the long term, because last year's prescription drug costs—that is, spending on prescription drugs—increased nearly 18 percent in this country; the year before that, 16 percent; the year before that, 17 percent. We will hook up a hose to the Federal trough and suck it dry. We can't do that.

We have to provide a prescription drug benefit in the Medicare Program, one that works, one that is sensible, thoughtful, and provides real benefits to senior citizens. But if that is all we do, we have failed miserably, in my judgment. We must also put downward pressure on prescription drug prices—for the benefit not only of the Medicare Program that will be saddled with these costs, but also for the benefit of all other Americans who are also required to take these prescription drugs.

Let me say—I have said it before on the floor of the Senate—we have prescription drug manufacturers that are good companies. I am not here to tarnish all companies that manufacture prescription drugs. We have some great companies out there. We have great men and women doing terrific research.

Incidently, I support the tax credit they have that exists for that research, experimentation, and development. I have always supported that tax credit. So good for them. I support those companies. But I do not like their pricing policies. So I am going to offer an amendment.

The underlying bill, incidentally, deals with generic drugs, the ability to substitute a virtually identical drug to be sold at a lower price. That is the underlying amendment. I support that. I and my colleagues—Senator WELLSTONE, Senator STABENOW, Senator SNOWE, and many others—intend to offer an amendment dealing with the reimportation of prescription drugs, as well, that will put downward pressure on prescription drug prices here in this country.

I do not want Americans to buy prescription drugs elsewhere. That is not the point of it. I want to force a repricing of prescription drugs in this country. I do not want to force Americans to go to Canada, for example.

The question is, Why should an American citizen have to go to Canada to get a fair deal and fair price on prescription drugs that were made in America? That is the question.

Let me, if I might, by unanimous consent, show several pill bottles on the floor of the Senate.

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

Mr. DORGAN. Just to make the point: This is a drug called Zocor used to lower cholesterol. In fact, there is a football coach whom you see on television almost every day in this country who talks about his heart problems. He had surgery, and now he takes Zocor for a healthier life.

Zocor, likely, is a wonderful drug. You will see, it is sold in two different bottles. For this bottle, sold in the United States, it is $3.03 per tablet. If you buy it in Canada—the same drug, put in the same bottle, by the same company, FDA inspected—it is not $3.03, it is $1.12 per tablet. That is Zocor—nearly triple the price in the United States.

Let me demonstrate another prescription drug and the pricing policies. This is Vioxx, used for arthritis. It is sold in identical bottles in the U.S. and Canada. It is an FDA-approved prescription drug. If you buy it in the United States, it costs $2.20 per tablet. If you buy it in Canada, it costs 78 cents per tablet. Why nearly three times the price in the United States for the U.S. consumer?

Finally, if I might demonstrate one additional prescription drug, this is the prescription drug Paxil. It is used to treat depression. It is sold in identical bottles, made by the same company. It is the same tablet, produced by the same company. It costs $2.20 for the American consumer, 97 cents for the Canadian.

These examples beg the question about pricing policy: Why does the U.S. consumer pay the highest price in the world? My colleague from New Hampshire said that is because we are paying for all the research and development. That is not the case. It is just not accurate.

In fact, 37 percent of the research and development of prescription drugs is done in Europe; 36 percent is done in the United States. Slightly more is done in Europe than done in the United States, yet every European consumer is paying less money than the United States consumer for prescription drugs.

So that is not an argument that works. They try it, and I assume we will hear it again, so we will trot out these studies again to demonstrate it is not accurate.

We need to do two things, as I indicated. We need to provide a prescription drug benefit to the Medicare Program. We are going to do that, if not

this week, next week. We have the patience to get this done. It needs to be effective. It cannot be what the House did, which is essentially a hollow vehicle that says: Hey, we passed a bill. They passed a bill that provides precious few benefits to senior citizens.

We are going to pass a piece of legislation that has a prescription drug benefit to it. We are also going to pass some legislation—and I hope a reimportation amendment, which is bipartisan and, incidentally, received 74 votes the last time it was addressed here on the floor of the Senate. We have narrowed it and changed it so it now deals with only reimportation from Canada, which has nearly an identical chain of custody supply and then can be accessed only by licensed pharmacists and licensed distributors in the United States.

So there is no safety issue. All there is, is a price issue. We are going to offer a reimportation amendment. We had 74 votes for it previously. I expect it to be added to this bill.

I expect, at the end of the day, we will have done something very important: Added a prescription drug benefit in the Medicare Program and also imposed some cost containment measures. By cost containment, I am saying, let the market system and the global economy apply downward price pressure on prescription drugs.

So there has been a lot said. My colleague from New Hampshire also talked about us running out of money in Social Security. I might observe that those who are trying to create privatized accounts in Social Security, and hook them to the stock market, might take a look at the market in recent days and see whether they might run out of money really quickly with their plan.

I think it would be nice to debate that plan one of these days. They have been pushing for the notion of privatized accounts inside the Social Security system, which falls about $1 trillion short. They create a $1 trillion hole but then connect Social Security to the stock market.

One might enjoy, it seems to me, having a discussion about the merits of that idea one of these days. There is very little enjoyment talking about what is happening in the market. This is a very important, serious issue in the country.

I just wanted to make the point that there are those who talk about the Social Security problem, and I will tell you how you make that problem much worse, and that is, embrace those who want to connect the Social Security revenues to the stock market in some way. And that includes the President and those in Congress who feel they want to do that.

This would be a good time, perhaps, to have a discussion about the dangers of taking the Social Security Program, which has the word ''security'' in it, and connecting it with the stock market.

But getting back, finally, to the question of prescription drugs, let me say to the Senator who chairs the committee, the underlying bill you brought to the floor of the Senate is a good bill. I held a hearing on this in my Consumer Affairs Subcommittee in the Commerce Committee.

This bill makes great sense. I fully support it. I hope, of course, for his support, and others', on the issue of reimportation, which is the amendment we will offer to try to impose some downward pressure on prescription drug prices. And then it is my fervent hope we find a way to do something that the House of Representatives could not or did not do, and that is to pass a prescription drug benefit in the Medicare Program that provides real benefits.

There are so many people in this country, senior citizens and other citizens as well, who just cannot afford lifesaving drugs. There is nothing lifesaving about a prescription drug you need but can't afford. That is what we are trying to address in the Senate.

I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Madam President, earlier in the debate, there were questions about what was agreed to and what was supposed to be clarified. For those who have any question, I will reference two provisions that were discussed during our markup and also what was included in the bill.

As I have indicated, several times last evening and earlier today, if it is technical language, we are prepared to address the technical language now during the lunch break. We were also prepared to address these last evening. But if it is substantive, we ought to have a change in the form of an amendment. That is the way we proceed around here.

We agreed with Senator FRIST to technical language to clarify one provision. That language is in the bill. It deals with the section:

Shall not be construed to alter the authority of the Secretary of Health and Human Services to regulate biological products under the Food and Drug and Cosmetics . . .

He was concerned about whether it did or didn't and whether the language was sufficiently clear. We have included that particular section in it. Those who want to look at this can see that.

We agreed with Senator GREGG to instruct the staff to make a clarification on another provision stating that a patent can still be enforced against subsequent, future generic applicants. That technical language was added last Thursday. Senator GREGG received it last week but raised no objections. That language is on page 35:

The owner of a patent shall be barred from bringing a civil action for infringement on the patent in connection with the development, manufacture, offer to sell, or sale of a drug for which the application was filed or approved under this subsection.

That is new language. The last three lines, 18 through 20, are new language. That language was available to the minority last Thursday night. We were not notified Friday or Saturday; we were not notified on Monday. We were notified about 10 minutes after the leader indicated he was going to offer the motion to proceed to the bill. I don't think it really carries much weight.

Before we recess for the lunch hour, I want to discuss the abuses of the existing legislation that the proposed legislation will remedy. Also, I would like to discuss why it is important to close these loopholes because of the impact it will have on the costs of drugs to consumers.

In 1984, Congress enacted the Hatch-Waxman Act, which provided a framework for allowing generic drugs to come to market while protecting the patents of new medicines that are breaking new ground each and every day. But as recent hearings before our Health Committee and the Committee on Commerce have revealed, there are abuses of the Hatch-Waxman Act by both name brand and generic drug companies that have delayed the approval and marketing of generic drugs. These findings are confirmed by numerous studies by the Federal Trade Commission and other independent experts.

The basic structure of the Hatch-Waxman Act remains sound. It has been a tremendous success in promoting competition and innovation. But there are clearly weaknesses in the Act which are being exploited to delay competition and shore up the bottom lines of drug companies with empty pipelines.

These abuses force American consumers to pay four times more on average for some prescription drugs.

This must be stopped.

Everyone agrees that 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.

When we passed Hatch-Waxman, we believed we were going to see a whole series of breakthroughs in new prescription drugs, but that hasn't really taken place. What the drug companies have done is reshuffle the old formulas, put them out, and tried to maintain their privileged position under the patent laws. That is what has happened. We have had these abuses.

We have seen the patent abuses, as this chart indicates, where we show the cost to date to consumers, the additional cost to date, and now the various prescription drugs themselves. This delay has benefitted the patent holder.

Instead of having the patent expire and the generic being able to come on and offer this drug to consumers at a considerably lower price, the generic is not being made available.

Here's what we're talking about. Today, of the top fifteen best-selling

drugs potentially subject to generic competition, the basic patents on at least five of them have long expired. Their exclusive rights to market their drugs have long expired. Yet, there is no generic competition.

Drug spending rose at double digit rates between 1996 and 1999, and experts expect the growth in prescription drug spending to continue to outpace the growth in health care spending. Some of this increase is due to increased use of drugs. But 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.

These savings are easy to understand. For patients and health plans alike, the costs for a brand drug are four times higher than for a generic equivalent. 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 four 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.

Prozac is a clear example. This antidepressant recently went off-patent after 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.

There are two key loopholes in the law that our legislation will end. The first is the practice of ''ever-greening'' patents, filing patent after patent, many of them entirely frivolous, to try to bar generic competition long after the basic patent on the medicine has expired. The second is the outrageous tactic used by some drug companies of buying off a potential generic competitor to prevent it from marketing its drug and using a quirk in the law to bar any other competitors from the market.

Those are the two loopholes and abuses. This legislation is targeted to the abuses. The abuses result in billions of dollars for drug companies, and that is why many of the major drug companies are so strongly opposed to this legislation.

Schumer-McCain closes the evergreen loophole by permitting only one 30-month stay to apply to each generic drug. For the other patents, the drug companies are free to defend its patents the same way any other company does.

A second tactic used by the 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 which gets to market has that exclusive right for six months before any other generic can compete. In some cases, brand drug companies have bribed the generic drug company never to go to market. The clock on the six months exclusivity never starts to run, and every other generic competitor is locked out forever. But the ones who pay for these unconscionable sweetheart deals are American patients.

Those are the two abuses. Schumer-McCain prevents collusion between brand name companies and generic competitors by opening generic challenges to invalid patents. Closing those two loopholes will make an extraordinary difference.

Finally, Gov. Bill Janklow of South Dakota told our committee that the savings for his State's Medicaid Program would be enormous. He added:

That's a drop in the bucket compared to what the real costs are out there for the General Motors of this world, and Roy's Blacksmith Shop, and everyone in between. It's some individual or retired person that's paying for their own on Social Security, or a working person. The point is, they all pay more.

Madam President, we will all pay more until Schumer-McCain becomes law. That is what we are about with this legislation. That is why it is so important. It is going to have an important impact in calming down the increase in the cost of drugs for the American consumer, and we think the quicker we get on this bill the better.

There are other ideas that can also help us in getting a handle on the escalation of costs. Then, hopefully, we will have an opportunity to consider the issues of coverage as well. I know there has been a previous agreement for the lunch break.

I yield the floor.

Mr. REID. Madam President, I ask unanimous consent that I be allowed to speak for a few minutes.

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

Mr. REID. Madam President, at 2:15, or thereabouts, either Senator DASCHLE or I will offer a unanimous consent request to move on to the Military Construction Subcommittee appropriations bill. We have been working on this for more than a week. I have spoken to the Republican leader and I have spoken to the Senator who has been stopping this from going forward.

Everybody should be aware, as I have told the Republican leader and the Senator who is objecting to this, we are going to do this this afternoon. I hope that during the Republican conference they will work things out so that we can move to this legislation.

I was in the White House this morning. The President wants us to move forward on the appropriations bills, especially MILCON. This will be our first appropriations bill. I think it is a shame there are issues that normally are not handled in this bill, and it should not hold us from moving forward. Under the agreement we will propose, we will finish the bill in a little over an hour and have an appropriations bill sent to the conference committee and we can wrap it up quickly. In the next week, this bill could go to the President.

I think it is too bad we are being held up from moving forward on this bill. The two leaders of the committee, Senator BYRD and Senator STEVENS, have worked extremely hard to get us to this point. I repeat that, this afternoon, we are going to ask unanimous consent to move forward on this. I hope there is no objection to it.

Madam President, I simply say this. I have been listening to the debate this morning, and if this were a jury, like I used to have when I practiced law, this would be a quick verdict. We have the merits on our side. The American people support what we are trying to do, and I want the RECORD spread with how much I appreciate and applaud the leadership of the Senator from Massachusetts. This is something he has been working on not for days, weeks, or months but years. It is too bad we are being prevented from moving forward.

RECESS

The PRESIDING OFFICER. Under the previous order, the hour of 12:30 p.m. having arrived, the Senate now stands in recess until the hour of 2:15 p.m.

Thereupon, the Senate, at 12:32 p.m., recessed until 2:15 p.m. and reassembled when called to order by the Presiding Officer (Mr. CLELAND).

The PRESIDING OFFICER. The Senator from Idaho.

Mr. CRAIG. Mr. President, I ask unanimous consent to speak as in morning business for no more than 1 minute.

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

EXPLANATION OF VOTE

Mr. CRAIG. Mr. President, I was absent yesterday during that most important vote that was cast on S. 2673. Friday morning I spoke to the importance of that legislation and the importance that we move it rapidly. I was extremely pleased that happened. I knew I would be in Idaho yesterday. The Secretary of Energy was with me in Idaho Falls to announce a new mission for our National Laboratory, the INEEL, so I was unable to make that vote.

Had I been here, I would certainly have been with the unanimous majority who supported that very important piece of legislation. It is time we restore within the American people confidence that corporate America is doing all it can to manage its affairs appropriately and honestly for the integrity of the stock in which the citizens of our country invest.

That is important legislation. I hope we can move quickly now to get it to