Enough about my concerns about the process. As we look forward to this debate, there are a number of fundamental principles that need to be outlined as we consider various prescription drug options. These are fundamental elements to any serious, responsible, bipartisan prescription drug benefit.

First and foremost, a prescription drug benefit must be permanent, it must be affordable, and it must be immediate. Seniors need help now. With the high cost of prescription drugs, they cannot continue without that assistance. They are hurting today. Seniors often make painful choices between buying food and buying prescription drugs. Seniors need action and results on this issue—not an election year issue in November. Seniors want, need, and, quite frankly, deserve the stability of a permanent drug benefit.

One of my most serious concerns with the majority leader's bill is the fact it will sunset after only a few years. A prescription drug benefit that sunsets after 2010, just a few years after it finally begins, is simply not good enough. Medicare is an entitlement program and seniors deserve permanent benefits they can count on today, tomorrow, 10, 12, 15 years from now. A hollow benefit, with temporary relief that sunsets after 5 or 6 years, does not provide adequate health care security for seniors.

Think about the lunacy of the situation we are in. We seem to be unintentionally on a track of telling seniors they had better die in 2010. We passed elimination of the death tax, but we did not make it permanent, so we tell seniors, you had better die in 2010 or the tax rates are going to jump back up and the death tax is going to spring from the grave. Now we are saying, you can be protected on prescription drugs through 2010, but you had better move on because in 2011 this program sunsets.

Somebody is not thinking. Somebody is not realizing what they are doing. Let's get serious. We need to make the death tax repeal permanent, and we need to make prescription drug benefits for seniors permanent.

Seniors should have the right, also, to choose the prescription drug plan that best meets their needs. They should not be told what they need by a politician or a Washington bureaucrat. I fear the majority leader's bill dictates a one-size-fits-all, Government-run benefit for all seniors and puts the Government in the position of determining what drugs would be covered under the plan. We must protect our seniors from a Government-run drug program that delays, restricts, or denies access to the newest and most effective drugs available on the market.

Seniors should have the right to choose a benefit that best meets their needs and does not restrict access to the newest and most effective drugs. I fear that the majority leader's bill leaves no room for innovation and flexibility in terms of plan design, no choice for seniors, and could limit access to breakthrough drugs. A prescription drug benefit must address the high cost of prescription drugs and attempt to restrain the skyrocketing cost of prescription drugs which cannot be sustained long term.

All existing drug benefits make manufacturers compete to reduce prices and pass along the savings from price competition as larger discounts and lower premiums for beneficiaries. That is the only proven way to keep a drug benefit affordable. The majority leader's bill locks in copayments and premiums for beneficiaries and prevents competition that could lower drug prices.

According to the Congressional Budget Office, bills that rely on public-private-sector partnerships and an element of competition, such as the tripartisan bill, will help manage the cost of drugs. Sadly, the CBO found that bills similar to the bill of the majority leader, because of the lack of competition and inflexibility of the benefit, would in fact increase drug costs. Given the current climate, I simply cannot support a plan that increases drug costs or one that sunsets at the end of 2010.

Finally, a prescription drug benefit should be fiscally responsible and sustainable long term. The best guess we have, without the CBO's scoring, is that the proposal by the majority leader and some of his colleagues would cost at least $600 billion over the next 8 years. In a time of deficit spending and a tight economy, such a benefit would ultimately require cuts in other fields, such as education, Social Security, or national defense, and place a heavy burden on the current generation receiving benefits, the generation paying for those benefits, and the next generation.

Seniors have a right to demand a drug benefit now, but I believe most of them will tell you they do not want to mortgage their grandchildren's future in the process. Seniors must be protected from catastrophic drug costs. No senior should face financial ruin because of an illness that triggers catastrophic drug costs. Our Nation's health care system has changed significantly since Medicare was first created. To make it effective, we must change Medicare as well.

We must work to bring affordable prescription drug coverage to every Medicare recipient. The Senate has the opportunity to pass a bipartisan—tripartisan permanent Medicare prescription drug plan this year. The House has already passed a bill. The President has indicated repeatedly that he wants a prescription drug benefit for America's seniors. With this kind of momentum, the time should be now. I hope we will move forward with an honest and open debate that will produce a responsible, bipartisan bill consistent with the principles I have outlined that fulfill Medicare's promise of health care security for all seniors.

I yield the floor.

Mr. REID. Madam President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

## GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT OF 2001—Resumed

The PRESIDING OFFICER. The clerk will report the pending business.

The legislative clerk read as follows:

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

Pending:

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

Reid (for Stabenow) amendment No. 4305 (to amendment No. 4299), to clarify that section 1927 of the Social Security Act does not prohibit a State from entering into drug rebate agreements in order to make outpatient prescription drugs accessible and affordable for residents of the State who are not otherwise eligible for medical assistance under the Medicaid program.

The PRESIDING OFFICER. The Senator from Nevada.

Mr. REID. Madam President, I am going to send a modification to the desk very shortly, but I want to comment briefly on the statements of my friend from Missouri that were just made. He talked about lunacy of what is going on here. I will use his exact term—lunacy. Talk about the death tax, that is, the estate tax, at the same time you are talking about Medicare prescription drugs, the vast majority of people, the vast, vast majority—over 98 percent—of the people on Medicare have no relevance to the estate tax. Why he would bring up the estate tax at the same time we are talking about Medicare prescription drugs is beyond my ability to comprehend.

I would also say he talks about why we bring up some of these bills without going through the committee. We do not do that very often, but we have done it. When we were in the minority, it was done all the time. We have seen a number of these measures being brought up because of what has gone on after September 11.

Take terrorism insurance. We passed that. It was really good legislation. The President told us how much it was needed. It took us a long time to get the bill up because they objected to it. Now they will not let us go to conference on this bill. It is interesting to note, the majority leader said we should have a 3-to-2 ratio and we had a 3-to-2 ratio. They said no, we want 4-to-3 or we will not go to conference. We gave them 4-to-3, and they still won't go to conference. This is terrorism insurance. That is stopping construction

projects in Nevada, in New York, I am sure in Louisiana, all over the country.

There are other examples, of course—the trade bill. The trade bill is something the President said he wanted. He wanted us to get it to the floor as quickly as we could. We did, and it passed. Only the last couple of days were we able to get conferees appointed.

The farm bill, that is pretty important legislation—the President signed that into law. The energy bill, we finally got conferees there. The President said that was an important bill.

I only mentioned a few of them—the trade bill, the farm bill, the energy bill, the terrorism bill. They couldn't be too bad. They passed the Senate by large margins in every case.

I hope people will understand that we are doing the best we can to work our way through a difficult situation in this country. We are making progress. We passed legislation in spite of the obstinacy we have had—not the least of which is the legislation on which the Senate is now working. We spent all day yesterday on importation. I think we should have been able to do more. I agree about the fact that we finally passed our first appropriations bill.

As I see down the hall, we are completing the very difficult conference on the supplemental. I should be there. I am a member of that committee. I hope to go there in a matter of a few minutes. Senators BYRD and STEVENS, chairman and ranking member of that committee, indicated to me that they expect to complete that conference in the next hour and a half. That will be by 12:30.

AMENDMENT NO. 4305, AS MODIFIED

Mr. REID. Madam President, I have a modification at the desk. I call it up.

The PRESIDING OFFICER. Without objection, the amendment is so modified.

The amendment (No. 4305), as modified, is as follows:

At the end, add the following:

**SEC. ___. CLARIFICATION OF STATE AUTHORITY RELATING TO MEDICAID DRUG REBATE AGREEMENTS.**

Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended by adding at the end the following:

''(1) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as prohibiting a State from—

''(1) directly entering into rebate agreements (on the State's own initiative or under a section 1115 waiver approved by the Secretary before, on, or after the date of enactment of this subsection), that are similar to a rebate agreement described in subsection (b) with a manufacturer for purposes of ensuring the affordability of outpatient prescription drugs in order to provide access to such drugs by residents of a State who are not otherwise eligible for medical assistance under this title; or

''(2) making prior authorization: (that satisfies the requirements of subsection (d) and that does not violate any requirements of this title that are designed to ensure access to medically necessary prescribed drugs for individuals enrolled in the State program under this title) a condition of not participating in such a similar rebate agreement.''.

The PRESIDING OFFICER. The Senator from Michigan is recognized.

Ms. STABENOW. Madam President, I would like to speak to my amendment which is now before us.

I ask unanimous consent that the following Senators be added as cosponsors to the amendment: Senators DORGAN, SCHUMER, FEINGOLD, TORRICELLI, CARNAHAN, LEVIN, JOHNSON, SNOWE, JEFFORDS and DURBIN.

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

Ms. STABENOW. Thank you very much, Madam President.

Madam President, I am very pleased to offer this amendment which is a bipartisan amendment, and hopefully one that we will be able to pass, working together and moving forward on the issue of lowering prices of prescription drugs and also providing Medicare coverage for our seniors and the disabled.

This amendment addresses an issue that our States are facing, the question of allowing States to have the right to have flexibility to lower prices.

This is a simple amendment. It would give States the flexibility to set up programs to pass along negotiated Medicaid rebates and discounts to their citizens who do not have prescription drug coverage and are not covered by Medicaid. So the States will have the ability to negotiate and pass on those similar discounts to their citizens who are without coverage and who are not on Medicaid.

This is critical. States should have the ability to provide similar discounts to all of their uninsured citizens. Since Medicaid only covers low-income people, and lower and middle-income citizens, they do not have the ability to get the same negotiated discount. Some States are setting up programs to do that.

One of the biggest challenges, as you know, and as we all know—we will be debating it this week and next—is the challenge facing not only our citizens, our families, and our seniors but also the business community, which I have talked about frequently. Also, State governments are addressing this issue of the rising cost of prescription drugs and the implications to Medicaid.

In fact, the National Governors Association is meeting right now. Earlier in the week, I shared a newspaper article where all of the Governors of the United States were speaking about their biggest challenge. Their biggest challenge, according to the article, is the rising price of prescription drugs and the rising cost of Medicaid to the State budgets. This is a critical issue for them.

We know that from 2000 to 2001 prescription drug prices rose about 17 percent. This is not unusual. It has been that way every year. This is causing health care expenditures and health insurance premiums to go up for business, for States, for individuals, and most certainly for those who do not have any insurance and don't have the clout to negotiate a discount. Those citizens are paying retail, which, in fact, is the highest price in the world right now.

In an attempt to respond to the skyrocketing prices, 30 of our States have enacted laws with some type of prescription drug coverage for those without insurance. They are looking for ways to be innovative—to use what we often have heard on the floor from our colleagues—the innovations of the States, the laboratories of democracy, and the ideas that come from our States. About 30 of them are looking for ways to enact something that relates to prescription drug coverage—looking for ways to lower prices and expand coverage. That is according to the National Governors Association.

However, unfortunately, the drug companies' trade association—PhRMA—has mounted legal challenges against several of those States, including my own State of Michigan. They have been opposing State efforts to lower prescription drug prices and increase coverage for those without insurance.

Specifically, they filed lawsuits against Maine and Vermont for their programs because the drug lobby does not want them to extend the Medicaid discounts to those without insurance who are hard-working citizens. In fact, we know that a majority of the people without insurance in this country work in small businesses. They are working. Their small business is trying to get health care coverage for themselves and their workers. Those individuals have no access now to any kind of group purchasing power or to any kind of discount. States are trying to use their group purchasing power for Medicaid and extend that same discount—usually 15 to 20 percent—to their employees. Many work in small businesses and don't have any insurance.

While Maine's two programs have been upheld in court, Vermont's program has not. It was actually struck down by the courts. Both States are embroiled in a very lengthy appeals process.

Specifically, the Maine Rx program is now pending before the Supreme Court. The current administration is supporting Maine's right to implement their program.

I commend President Bush and the administration for siding with the State of Maine and their right to make decisions about their citizens and how to operate their businesses for their State.

In fact, the Solicitor General, Ted Olsen, filed a brief on behalf of the Federal Government urging the Supreme Court to allow Maine's Rx program to go forward without further delay.

I argue that this amendment, in fact, is supported by both parties, people on both sides, and that administration certainly has indicated—I have not heard directly regarding the amendment, but they certainly have indicated support for the program on which this amendment is based. I appreciate their leadership on this issue.

These legal challenges are very costly to taxpayers. They just deter other States from establishing other similar demonstration projects, such as the underlying generics bill. Unfortunately, the drug companies are trying to stop these kinds of innovations.

This amendment would, in fact, try to stop the drug companies from using the legal system to keep their prices high. We all know that they will dispatch their high-priced attorneys whenever they can to, unfortunately, keep their profits as high as possible.

Since the price of prescription drugs is soaring, States have the unfettered ability to pass on Medicaid rebates to their residents. They should have that ability to pass those rebates on to their residents.

I hope we will agree to this amendment because even if Congress passes a Medicare prescription drug program this year, it will be several years before it is fully phased in.

I hope and pray that we will come together and pass a Medicare prescription drug benefit. It is long overdue. But we know it will take several years to phase it in.

In the meantime, our States are struggling to help their citizens. I believe they need our support.

The Rx flexibility-for-States amendment would seek to remove the legal hurdles that are preventing States from providing lower priced prescription drugs to their citizens.

Specifically, States would be able to extend their Medicaid rebates and discounts for prescription drugs to non-Medicaid-eligible persons.

State governments are close to the people. I know our Presiding Officer was in the State government, as was I. We understand that States and local governments are on the front line hearing from people, and wanting to respond. We have States that are responding, and are being stopped through the legal system right now by the drug company lobby. The solution to higher prices, higher prescription drug prices, is not just in Washington. It is not just in the Senate, or in the House of Representatives. But it is in capitals all across the country where our Governors and our State legislators are working to respond to what is critically one of the most fundamental issues that families and seniors and businesses face to today, which is the explosion in health care costs, predominantly coming from the rising cost of prescription drugs.

Today we have a chance to send a very important message to our colleagues and to States across the country.

I ask my colleagues to join with us, on a bipartisan basis, as we have in this amendment, to adopt this amendment and to tell the States that we are standing with them as they fight to lower prices for their citizens and make lifesaving medicines available.

If we fail to pass this amendment, many States could be faced with legal challenges from PhRMA as they try to come up with programs to lower prescription drug prices. Right now, we have the ability to stop the dollars going into the lawsuits and redirect those to lowering prices and making prescription drugs available.

I invite and urge my colleagues to join with us. This is an opportunity for us to stand together in support of our State governments. Let the Governors know, this week, as they are meeting, that we understand what they are going through and we want to back them in their efforts to make sure that lifesaving medicines are available to their citizens.

Madam President, I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Madam President, I commend my friend and colleague from Michigan for this absolutely excellent amendment. I am hopeful we can get strong support for this amendment because it is so compelling in its logic and reason, and the result will be so important to our fellow citizens across the country.

Just to catch up to where we are, Madam President, the underlying bill, the Schumer-McCain legislation, tries to halt the gimmicking that the drug companies use to get around the Hatch-Waxman bill that was passed a number of years ago. They have gimmicked the rules, and they do it in ways that completely circumvent the spirit and the understanding of the law, in order to keep prices artificially high. And every family and every user of prescription drugs knows the challenges families are facing with high drug prices.

Under the McCain-Schumer legislation, we have tried to deal with that issue. I think we have dealt with it effectively. That is the matter that is before the Senate.

We had a good debate yesterday on different measures that continue to put downward pressure on the escalation of drug prices. I think we had a very good debate on that, both in support of the underlying legislation and in support of the Dorgan amendment, yesterday. Now we have the Stabenow amendment before us, which will, in a very important way, continue this effort to exert downward pressure on the prices of drugs in this country.

I am amazed at the opposition to this amendment. For a good part of the afternoon yesterday, we listened to talk about the free market system that urged us to get away from price controls and use the free market system. But when the States use the free market system, in order to bargain for the lowering of the prices, what happens? What is the reaction of the drug companies? The drug companies go ahead and sue the States to try to restrain them from using the free market system.

This isn't Government intervention, it is the States themselves, States that have Republican Governors and Democratic Governors. The States themselves are trying to use the States' power in order to get the best price for the neediest citizens in their States: the poorest individuals, the ones without insurance. And here comes PhRMA with their legal actions to make sure the States are not going to be able to do that.

When does that greed stop? When does that greed stop? When do they stop wringing the final few cents out of the poorest individuals in this country? That is what this is all about.

The States are trying to negotiate lower prices for the poorest individuals in these States, and PhRMA says no. They gimmick and circumvent the clear spirit and language of the Hatch-Waxman law in order to perpetrate billions and billions of dollars of additional profits.

Then we hear a great deal of debate in this Chamber and much admonition from many of those who are opposed to the underlying legislation saying: Let's let the free market work.

We had hours and hours of discussion about price controls in Canada. We are not for price controls, as in Canada. We want the free market to work. But what is happening when the free market works in the State of Maine, the State of Florida, the State of Michigan, and other States? In comes PhRMA, and they say: No, we are not going to let it work. We want to stop them from doing it.

This is the same kind of action that is underlying the basic measure.

So I want to review, very briefly, the situation. I understand the problem we are looking at.

Under the terrible burden of skyrocketing drug prices, the State governments are trying to use their authority and bargaining power to help residents—and our constituents—obtain lower prices.

Already, 30 States have passed laws to extend drug coverage or lower prices. But PhRMA has done it again, suing the States to stop our ''laboratories of democracy'' from fighting the drug industry on behalf of American consumers.

The drug industry has sued the State of Maine. They have sued Vermont, Michigan, Illinois, and Florida. The drug industry is waging war against our Governors and our State legislatures in the courts.

The Stabenow amendment puts the question to the Senate: Will you stand with the States or will you stand with the drug industry for higher drug prices?

Many of my colleagues are former Governors themselves. I hope they take particular note that just yesterday the Nation's Governors issued a statement of solidarity with the administration in its legal fight with PhRMA over the Michigan Medicaid waiver that reduces the State's drug costs.

Let me read from the NGA statement of July 15, which quotes Michigan Governor Engler:

The nation's governors are extremely disappointed with the course of action chosen by PhRMA. It is unfortunate that their organization feels compelled to use the court system to manipulate public policy.

That is a Republican Governor.

The Governors, the administration, and consumers all support State efforts to reduce drug prices. Now, with the Stabenow amendment, it is the Senate's turn.

The amendment is based on a simple but powerful idea: Extend the scope of an existing Federal law to help the States supplement the rebates we require under Medicaid.

Medicaid already collects ''best price'' rebates from the drug industry, thanks to a 1990 law we passed under the leadership of Senator David Pryor from Arkansas, a champion of lower drug prices.

I was always impressed by the work and the commitment of Dave Pryor and his strong desire for protecting the consumer. And this tradition follows with Mark Pryor in Arkansas today: they are strong protectors of consumers and lower drug prices.

The Stabenow amendment simply permits States to negotiate similar State rebates to help lower-income residents afford their drugs. All this amendment does is let the States use the same negotiating tools used today by the private sector to lower their drug bills. I do not see why those who otherwise support the free market would oppose this amendment.

We find out that large companies use their negotiating ability. HMOs use their ability. Why not permit the States to use their ability? But PhRMA says: No, we are not going to let them do that, particularly when they are using it for the lowest income citizens.

The amendment empowers the States to use the same tools and negotiations used by the private sector to lower its drug costs. If a drug company refuses to negotiate with a State, its drugs would still be available but would be subject to ''prior authorization.'' This is precisely what the State of Michigan is doing. This is precisely why PhRMA is suing the administration. And this is precisely why the Stabenow amendment is needed.

Here is what the drug industry did when the State of Maine and the State of Vermont enacted State laws to lower drug prices.

Naturally, the industry sued the States. No surprise so far, given their abuses of the Hatch-Waxman Act. But then the drug industry instructed its front group, the so-called Citizens for Better Medicare, to run TV, radio, and print ads in Maine and Vermont attacking the laws. That is what the drug industry does to keep the prices sky high.

They sue our State governments and waste taxpayer dollars defending against their frivolous lawsuits. And they run attack ads.

Lest anyone question whether the so-called ''Citizens for Better Medicare'' is anything but a front group for the drug industry, let me quote the June 18 Wall Street Journal—

[T]im Ryan, PhRMA's past marketing director, founded the grass-roots-sounding ''Citizens for Better Medicare'' at the behest and expense of major drug companies.

There it is. Enough is enough. The American public is sick and tired of the drug industry's abuses. Let's support the Stabenow amendment, and help our States lower drug prices for all Americans.

I see others who want to speak on this issue. I want to mention to our colleagues an excellent report being released today. It is a review of the impact of the three principal proposals that have been advanced on coverage. What this study does is take your State, the key features of each of the programs that have been advanced, the Republican House program, the Graham-Miller program, which I am proud to cosponsor, as well as the tripartite program. Then it takes the numbers of citizens who would be impacted, the number of elderly, senior citizens, and disabled on Medicare, and it runs through how each of these programs would impact the seniors in your State.

It reviews for each of the programs who would be affected, what the impact would be on each of the seniors in the State, who would benefit the most, and who would benefit the least.

We will be releasing this report this afternoon at 2 o'clock. We can say without question that in the review of all 50 States, their powerful, compelling, and overwhelming conclusion is that if you want to make drugs available, accessible, affordable, and dependable, there is one plan that stands out head and shoulders above all the others, and that is the one introduced by our friend from Florida, Senator GRAHAM.

There are others who wish to speak on this. I will come back and address it later.

The PRESIDING OFFICER. The Senator from New York.

Mr. SCHUMER. Madam President, I ask unanimous consent that following my remarks, the following Members be recognized to speak: Senator HATCH and Senator FRIST, in that order.

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

Mr. SCHUMER. Madam President, I rise in strong support and as a proud cosponsor of the Stabenow bill. It is worthy legislation. What I will do for a few minutes is talk about the underlying bill and the Stabenow bill and what they have in common.

The Senator from Massachusetts outlined it. These are free market approaches to lowering drug prices. The one, the Schumer-McCain bill, allows more competition. What could be more all-American than more competition.

The second, the Stabenow bill, allows people within the market to gather together in the form of their government and negotiate a lower price. We do this every day in America. That is what a corporation is in certain ways. That is what a union is in certain ways. Here we have the State doing the same thing.

As the Senator from Massachusetts said, there were some yesterday who talked about the Canadian bill and price controls. These are not price controls, but we just saw yesterday or 2 days ago Pfizer and Pharmacia merge. What were they trying to do? Well, in a free market way, they were trying to aggregate to increase their bargaining power. Doesn't it make sense to say that the citizens of Maine or Vermont or Massachusetts or Utah or New York can aggregate to equal that—well, they will never equal it, but at least to gain a little leg up on that bargaining power and get some help?

Both of these proposals are free market. There are some people whose view of the free market is to let big companies do whatever they want. I am a little worried that over at the FCC, the whole idea is, let us have one big communications empire. Actually, the free market needs some competition. But the free market has also said, as it has evolved since the Adam Smith days, that combinations to try and increase our bargaining power are legitimate, recognized ways that the free market works.

I see that my colleague from Utah is in the Chamber. I first want to pay him some tribute. I said this in committee a year or 2 years ago. I think Hatch-Waxman has been one of the greatest consumer advances we have done in the last quarter of the last century. When I said it, it was still the previous century. But he has done a great job there.

Our goal, in terms of the Schumer-McCain bill, is to restore the balance of Hatch-Waxman. The bottom line is a simple one: That in 1984, we had a very simple template. We said: God bless companies that come up with innovative drugs. They research them; they make a lot of mistakes. For every drug they bring to market, there are a lot of drugs that don't come to market. They need the help. They need a return. God bless them. Give them a return. They are creating a product that makes us all live better and longer.

But we also said that rate of return, that patent, which is what the patent really is, can't be unlimited. And so we said, after a period of time, 20 years after the patent was filed, others could come and produce the drug. It worked. Innovation, from the date Hatch-Waxman passed to the present, in the field of pharmaceuticals has been unparalleled. Lives have been saved. The people are living longer and better and healthier. We see that in our parents and our grandparents. It is amazing.

In the last 5 years, I believe Hatch-Waxman has steered off course. In fact, the whole pharmaceutical industry has steered off course. For people who make a wonderful product, they are evolving into an industry that is despised and hated.

They could say to themselves: It is only because these drugs cost a lot, and we can't help it because it costs a lot to research them.

I would say it is not that simple. I wish it were. They have evolved because, in a headlong rush to keep their profitability as high as it has been in the past, they are desperately clinging to extend patents longer than Hatch-Waxman ever intended. They end up hiring not just the best researchers anymore but the best lawyers.

A drug company should go to Harvard Medical School, not Harvard Law School, as it continues its work. But they have been spending much of their time and effort in coming up with schemes—that is what they are—to extend the patent beyond the time it should be extended.

What does that mean to the average citizen? It means a drug, instead of costing $25 a month, is going to cost $100 a month—vital drugs. If anything, they have pushed it further and further because so many of these blockbuster drugs, these wonderful drugs, are coming off patent shortly.

I know my colleague from Utah has a lot invested in Hatch-Waxman. I very much appreciate it. The little changes that we make, Senator MCCAIN and I, in our bill, just build on it and readjust it. But I think the view that Hatch-Waxman is just fine as it was in 1984 is off base. The statistics will show it. That is why this bill has such great support. I am certainly open and willing and eager to hear whatever suggestions my colleagues from Utah and Tennessee will make. But I will tell them this: The view that we should just go back to the old way in 1984 doesn't work.

Mr. KENNEDY. Will the Senator yield?

Mr. SCHUMER. I am happy to yield.

Mr. KENNEDY. We have before us the author of the amendment. Since the Senator has the floor, I would like to ask him a question or two.

Isn't it true that HMOs use their bargaining power to lower costs of prescription drugs today? HMOs all over the country have been doing that.

Mr. SCHUMER. Yes, all over.

Mr. KENNEDY. Isn't it true that insurance companies use their leverage and powers to get the lowest cost possible?

Mr. SCHUMER. Yes, and they are proud of it. They brag about it.

Mr. KENNEDY. What could be the possible logic in denying the people of the States, particularly the smaller States—or large States, for that matter—what is the logic of denying them their bargaining power? If we are going to let the HMOs and insurance companies do it, why not the States?

I am sure we will hear that it is because the States are a governmental power and therefore this is price control. As I understand it, if the drug company doesn't want to sell to them, they don't have to, do they?

Mr. SCHUMER. My colleague is exactly right. By the way, our Federal Government does the same thing in Medicare. They bargain with the drug companies for a lower cost for Medicare. Why can't the States do it for their citizens who are not under Medicare and Medicaid? My colleague from Massachusetts is right on the money.

Mr. KENNEDY. It seems we will hear that somehow the States can't bargain because they are a governmental institution. But the concept is very much the same. For the insurance industry, it is fine—it is a free market system; and for an HMO, it is fine—it is the free market system. But somehow for the State, it is government. Even though the pharmaceutical company is free to say: We don't like these negotiations; therefore, we won't sell to you. If all the pharmaceutical companies did that, obviously, the State would have to bargain in good faith. There is no indication that they are not bargaining in good faith.

As the Senator pointed out, there is no indication that these industries have been suffering adversely. They are one of the most profitable industries—and Lord only knows they are paying the highest salaries to their executives as well. But I am not as interested in that as in the concept of what we are talking about here.

Finally, if the Senator would agree, I am perplexed: We are not talking about bargaining for high income people in the State; we are talking about bargaining for the lowest income, the poorest of the poor, many of whom would not be able to have access to the prescription drugs unless this were offered. Why is that PhRMA says: No no, you can't do it; we are going to squeeze the very last dollar out of them?

Mr. SCHUMER. The Senator is literally on the money. The bottom line is that the Senator is exactly right. There is no difference, from an economic point of view, in a State getting together and bargaining for its people and an insurance company or HMO doing it. In fact, you can argue that the State has more legitimacy, being an elected body and representing the will of the whole people of Michigan, Maine, Massachusetts, or New York, No. 1.

No. 2, what about over in Europe or in Canada? They put on a price control. The pharmaceutical company still ends up selling the drug. Do you know what ends up happening? It is the American citizen who ends up paying for all the research, which does good around the whole world, for, say, Celebrex or Vioxx. Who pays the whole thing? Us.

Why shouldn't the American taxpayer and citizen, through his and her State government, be allowed to say we should not bear that whole cost ourselves?

That is the thrust of the amendment of the Senator from Michigan. It is free market. There is no lock-in. Just as Germany said, you can sell Vioxx for 3 pfennigs, and that is not worth it. The company doesn't have to sell it. It is the same exact thing here.

Mr. KENNEDY. Well, the point is that the State is not even doing it for all the citizens; it is not even doing it for all of them. They are doing it for the poorest of the poor. That is whom they are trying to bargain for in these circumstances. The drug industry is contesting that.

Let me, finally, ask my friend, Senator STABENOW, if she has a viewpoint on this matter. As I understand, this is not a partisan issue in any respect. I read Governor Engler's very strong comments about this where he was actually talking about manipulating public policy. He was using the word manipulate, suggesting that we have to manipulate public policy. The drug companies are manipulating public policy in their patent policy and in the collusion with the generics, which is being addressed by the Schumer proposal.

So we have a Republican Governor talking about manipulating public policy. I was interested in the fact that this should not be a partisan issue. The silence in support from the other side of the aisle is deafening with regard to the Stabenow amendment. I am hopeful there will be voices on the other side that will rise in support of this. To their credit, they supported the Schumer proposal in the committee. Five Republicans did. I hope we will hear those voices again.

I just say to the Senator, this isn't really a Democratic or Republican, or liberal or conservative issue. I find there are liberals and conservatives, Republicans and Democrats, as well as Republican and Democratic Governors who share the view of the Senator from Michigan and the Senator from New York. If the Senators would comment on that, I would appreciate it because it is an important issue.

Mr. HATCH. Madam President, I have one simple question.

Mr. SCHUMER. I am happy to yield to the gracious Senator from Utah for that.

Mr. KENNEDY. If they can answer my question, then I will be seated.

Mr. HATCH. If I may ask, how much longer does the Senator need?

Mr. SCHUMER. No more than 5 minutes longer. I thank the Senator. I will yield to the Senator from Michigan to answer these very worthy questions.

Ms. STABENOW. I thank both of my friends and colleagues, who are such champions on this underlying issue—the entire issue of Medicare and prescription drug coverage and lowering prices. In fact, as our leader, the Senator from Massachusetts, indicated, this is a measure that is a bipartisan amendment. We have Governors—frankly, the majority of Governors—Republicans and Democrats, who are struggling with this question of lowering prices and making prescription drugs and lower prices available to their citizens. So as the National Governors Association is meeting right now, they have said their biggest challenge is the price of prescription drugs

and the explosion, in their budget, of Medicaid. They need to address these issues.

This amendment will support the Governors across the country. It is a bipartisan amendment. It is something supported across the country on a bipartisan basis. I am very hopeful that we will have colleagues' overwhelming vote on both sides of the aisle supporting the effort to say yes to this innovation of the States. This is not mandatory, it is purely based on States taking action on their own to decide if they would like to do this. If they do that through their State legislatures and the Governors on behalf of their people, this simply says that this is legal and that, hopefully, it will stop the suits PhRMA has been bringing against our State governments.

Mr. SCHUMER. I thank the Senator. She is on the money. It is voluntary. No State is forced to do this. But if the citizens of the States, through their elected representatives, both Republican and Democratic Governors, want to do this, they should be allowed. We should not be tied up in litigation for years while the prices go up and up and up.

I am fully supportive, again. To underline this, this is a free market policy. It is no different than what the insurance companies do, the HMOs, and God bless them. It is saying that people may aggregate. Are we going to have people opposing mergers of the big drug companies? No, we are not. They say they can do it better in a larger size. Why can't the average citizen do something in a larger size? That is what we are trying to do.

I am going to conclude with one little pitch today. I know my colleague from Utah has been patient, and I very much appreciate that. Whether it be the Schumer-McCain bill, generics, or this bill, these are reasonable and modest proposals. I say to my friends in the drug industry—again, I admire them; I think they have done a good job—please, you have become ''Dr. No.'' Whenever that comes up, you say no. No change. You are willing to change it with your lawyers to extend the patents, with all these new ways you find around what we think the original intent of the Hatch-Waxman law was. Do not be Dr. No. Get with it. Go back and innovate. Go back and form new wonderful drugs and get your patent on those, but when people want to get together to lower those prices in a fair negotiation, when this Congress says we ought to prevent the lawyers from changing the original intent of Hatch-Waxman and drawing it off course, do not stand in the way.

In fact, I challenge PhRMA to come up with one constructive proposal to help people with the cost of drugs, not just to keep doing it the same way when we know there is an outcry. They know best what helps with innovation. Come up with a proposal. Do not go the way of the cigarette companies and spend all your life being sued. Do not go the way of the cigarette companies and become the object of scorn and hatred.

You make a wonderful product. You do something good. Support the bill of the Senator from Michigan. Support our bill or come up with some constructive proposals.

I will make one other point, Madam President, and then yield the floor. I went to PhRMA a year and a half ago. The Senator from Utah knows this because I informed him of the negotiations. I said: Let's sit down and figure out something. Let's get the generic industry and brand industry together to come up with a compromise to deal with some of the problems.

They listened politely, but, frankly, I do not think they thought our legislation had much of a chance for passage, and they said no.

Now we are knocking at the door. We are almost there, and it is not too late. It is not too late to come up with some answers that will solve our problems—the problems that the Senator from Michigan deals with in her legislation, and the problems that Senator MCCAIN and I deal with in our legislation—and get something done. I think I speak for all of us that much rather than make speeches, much rather than win political victories, we want to get something done, and that is what we are here to do today.

In conclusion, I urge support for the Stabenow amendment to restore some bargaining power which is voluntary. Let a State's Governor, if they want, do this. Do not wait 5, 10 years until the litigation is finished—it will probably come out the same way—and give people a break. Let them be able to afford these wonderful medicines that we have and at the same time allow the drug companies to continue on their path of real innovation as opposed to false innovation of patents, pill sizes, colors of bottles, and different applications.

Madam President, I yield the floor and once again thank my colleague from Utah for his courtesy.

The PRESIDING OFFICER (Mrs. CLINTON). The Senator from Utah.

Mr. HATCH. Madam President, I rise to speak on the pending legislation, S. 812, the Greater Access to Pharmaceuticals Act. I did not realize the pioneer companies that have been referred to as PhRMA are as satanic as they have been represented to be on the floor today. One would think they are everything that is bad in this world and that they are the cause of all the high costs of drugs in our society; that they are not being fair to the generic companies that help bring drug prices down; that HMOs are the reason drug prices come down and that the States do not have the same type of market power. I heard all these things. I heard how terrible the research-based companies are. My goodness, I have never known that before. I am so happy to get this information.

I would like to cite a book called ''The System.'' This book was written by Haynes Johnson and David S. Broder, hardly a conservative set of authors, but very intelligent, and highly respected journalists and authors. The book is an excellent account of the infamous and failed Clinton health care plan. History has a way of repeating itself. You can hear a theme on the floor over the last several days that comes right out of the Clinton play book.

On page 90 of that book, it says, in speaking about the political tactics to garner public support, a group of the President's political advisers have the following discussion, which sounds familiar to the way the debate is going on the floor of the Senate and elsewhere:

> In the campaign period, Fried recalled, Clinton's political advisers focused mainly on the message that for ''the plain folks, it's greed—greedy hospitals, greedy doctors, greedy insurance companies. It was an us-versus-them issue, which Clinton was extremely good at exploiting.

That was Fried. Then they go on further, and I quote from the Broder and Johnson book:

> Clinton's political consultants—Carville, Begala, Grunwald, Greenberg—all thought ''there had to be villains.'' Anne Wexler——

Who, of course, is not known for her Republican politics——

> remembered, It was a very alarming prospect for those of us looking long term at how to deal with this issue. But at that point, the insurance companies and the pharmaceutical companies became the enemy.

All this sounds familiar.

That is what has been going on here on the floor. Frankly, I do not think it is right. My experience has been there is no one single group who should be blamed for the high costs of pharmaceuticals. I do not want to blame the FDA because it takes up to 15 years and 5,000 different compound experimentations to get an approval of a drug and at a cost, according to some of the top authorities, of up to $800 million. That is 15 years out of the patent life. Frankly, one wonders why, with the few remaining years they have on patent life, drugs cost so much. I am not going to blame the FDA because their job is to protect Americans, but on the other hand, that is a long time, and I may talk a little bit about that today.

I am not going to blame the generic companies. They provide a tremendous amount of support for American people who need help. I believe in the generic industry. By and large, those companies are doing a great service, as we intended in the Hatch-Waxman bill.

By the way, without the pharmaceutical companies, the pioneer companies, there would not be any drugs for the generic companies to copy and reduce prices. So there has to be a delicate balance between the two, and that is what Hatch-Waxman is all about.

This underlying bill, of course, which for some reason is being debated before the Federal Trade Commission comes out with its comprehensive study and

recommendations on the very issues addressed in the pending bill, which should occur before the end of next month—will change one of the most important consumer bills in history. I am not concerned just because it is my bill and Congressman WAXMAN's bill, but because without waiting for the FTC to give its recommendations, this underlying bill will change the Hatch-Waxman law before we have had a chance to hear from the FTC, FDA, other experts and interested parties. I do not think it is right to change the law until we have all the facts and understand better what this bill will do.

Hatch-Waxman, according to almost all authorities, has saved consumers $8 billion to $10 billion every year since 1984. It created the modern generic drug industry, but it also strengthened the PhRMA companies, the pioneer companies. Back then, they were spending about $3 billion a year on research and development. Today, it is over $30 billion a year. I think almost as satanic as they are portrayed on the floor by our friends on the other side, it seems to me they ought to be given a little bit of credit for some of the major therapeutical pharmaceuticals we have today.

Without them, we would not be where we are. We would not be the leaders in the world with pharmaceuticals, nor would we have the balance of trade surplus we get from the sale of American pharmaceuticals.

Let me comment on three aspects of the underlying legislation: Politics surrounding floor consideration; the process by which the bill moved to the floor; and finally, the substance of this bill.

At the outset of this debate, I congratulate and commend the original cosponsors of this legislation, our colleague from New York, my friend, Senator SCHUMER, and my colleague from Arizona, my friend, Senator MCCAIN. Even though I disagree with them on the way they resolved the key issues addressed in S. 812, and although the bill that emerged from the HELP Committee does not adhere to the original Schumer-McCain language in virtually every key policy area, they deserve recognition for their effort in highlighting issues, issues that are of concern to each of us to in this body: Access to prescription drug coverage and affordable prescription drug coverage.

As most of my colleagues know, I have a special interest in today's pending legislation. Throughout my career in the Senate, I have helped fashion a portfolio of legislation that facilitates our Nation's pharmaceutical research and development capacity. I am proud to have played a leadership role in crafting the law that the bill we are considering seeks to amend, the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman bill. A key partner in this effort was my good friend from the House, HENRY WAXMAN. That a liberal member like Mr. WAXMAN and a conservative like ORRIN HATCH got together to write this law is but one sign of the bipartisan consensus that developed with respect to the 1984 law and that should be developed today.

Incidentally, on the House side of the Capitol, this law is often referred to as Waxman-Hatch and in the Senate the names are often reversed. This shorthand is only used because it is so time consuming to keep repeating the Drug Price Competition and Patent Term Restoration Act of 1984.

I have a lot of complaints about the process we followed to bring S. 812 to the floor, and despite my grave dissatisfaction over the process, I do want to recognize the efforts of Senators EDWARDS, COLLINS, KENNEDY, GREGG, and FRIST to make improvements to the substance of the bill. To be fair, there have been improvements in some critical areas of the legislation. As a general matter, in moving away from some key provisions of McCain-Schumer, the HELP Committee substitute is headed in the right direction.

Now, I hasten to add, though, that some new provisions were added to the bill during the markup process to make it impossible for me to support a bill that is so important to me—a bill that amends the law carrying my name, a law that has been shown to benefit millions of Americans every day.

Let me talk about the politics and process. Before I discuss the merits of the committee substitute for S. 812, I want to make a few comments concerning the politics and process whereby we find ourselves discussing these issues at this time.

One of the things about which I am most apprehensive in the current debate is the way the Drug Price Competition and Patent Term Restoration Act of 1984, a painstakingly crafted bill that passed with overwhelming bipartisan support in both the Senate and the House, now finds itself at ground zero in one of the most controversial and potentially divisive issues of this year, that is the debate over the Medicare drug benefit.

The Medicare drug benefit is certainly an issue that deserves the Senate's attention, and I am in one of the original tripartisan groups that I believe has come up with a nonpartisan bill that would solve the drug benefit problems for the American people, especially the poor.

I commend our colleagues in the House for successfully passing a prescription drug bill that promises to make a major expansion of Medicare benefits by providing an outpatient drug benefit. I think it is now time for the Senate to debate this issue, pass a bill, conference with the House, and present a bill for the President to sign into law. I am also, like I say, proud to be the cosponsor of the so-called tripartisan Medicare prescription drug benefit bill. I think Senators BREAUX, JEFFORDS, GRASSLEY, SNOWE, and I have put together a strong bill that our colleagues should, and I think will in the end, support.

I had hoped the tripartisan bill could have been the subject of a Finance Committee markup, as it deserved. I think it would be approved by the Finance Committee, which more than likely explains why we are on the floor today with S. 812. So as we enter this debate, let us be clear that the way the Senate Democratic leadership has chosen to structure the floor vehicle, it is very possible the partisan fervor that often accompanies Medicare legislation will spill over into the heretofore bipartisan consensus surrounding the 1984 Waxman-Hatch law. I hope not.

One of the things we did back in the 98th Congress in 1983 and 1984 was to take the time and effort to build a broad, bipartisan coalition for the Hatch-Waxman law. I hate to see us lose support as this body becomes caught up in the unavoidable election year politics of Medicare. Frankly, it is almost amusing how the Democratic leadership has structured the debate on the Medicare drug benefit. A bill that involves hundreds of billions of dollars and over a trillion dollars in some of the proposals will be debated as an amendment to the more modestly sized S. 812. Talk about the tail wagging the dog.

I hope if, as is well possible, we cannot achieve consensus on the Medicare drug debate, the inevitable ill feelings and political posturing do not create a poisonous atmosphere in which the broken tail of Medicare crushes the dog of Hatch-Waxman. Conventional wisdom has it that a large part of what is at stake in the legislation we will debate over the next number of days has to do with jockeying for political positioning over who is left holding the bag with the voters in the fall if we fail to enact a Medicare drug benefit before the November elections. That is why I hasten to add that I hope my colleagues will look at the tripartisan bill, which is nonpartisan, which basically can solve these problems for especially the poor in our society with regard to drug benefits and the cost of drugs.

I firmly believe the best thing the Senate can do for the American public is to lay aside, as best we can, the political infighting and genuinely try to strike an acceptable compromise on the Medicare drug bill.

Make no mistake about the fact that although S. 812 may be nominally the pending business before the Senate, the real matter we will be debating is the Medicare drug benefit. I would have greatly preferred to debate Hatch-Waxman amendments as a stand-alone bill in a less charged atmosphere. If we had to debate amending Hatch-Waxman with other legislation, probably my last choice would have been to lump it together with the politically volatile Medicare drug bill.

Then we have the ill-advised drug reimportation bill, which has been added as an amendment to S. 812. This would have been my second to last choice to add to Hatch-Waxman. I laid out yesterday my concerns with that proposal.

Suffice it to say, the reimportation language was a bad idea in the year 2000, and it is an even worse idea today, given the threats of our post-September 11 world.

While the regrettable encore appearance of this feel-good but ultimately downright dangerous drug reimportation legislation is deeply troubling to me, it is doubly troubling to me that it will now be linked to the 1984 Hatch-Waxman law because of the way the majority has chosen to proceed.

I recognize part of the reality of being on the minority side of the aisle is that we have to go with the flow as the majority leader calls up legislation that he desires or his side desires, and I understand that. As a coauthor of the legislation that S. 812 seeks to amend, I take exception to calling up a bill that opens up Hatch-Waxman in order to create a legislative vehicle that promises to throw into play every conceivable way to punish one of the great American success stories in innovation and in the pharmaceutical industry.

This, ''everything but the kitchen sink,'' mentality, may be satisfying to some politically. But mark my words, it starts this body down a path that ultimately can only punish the American health care system. In my experience, delicate provisions and nuances of patent law, antitrust law, and FDA regulatory law are generally not best crafted in the elbows-flying, raw meat atmosphere of high-stakes election year politics such as we will have during the course of this debate, in addition to what I consider to be an unfavorable environment that will be created by the likely flood of major amendments not relevant to S. 812 or the underlying Waxman-Hatch law.

I must also raise objection to the manner in which the bill so hastily was reported from the HELP Committee. Frankly, I am deeply disappointed in the way the HELP Committee has acted, although I guess we should not be altogether surprised given the perceived political advantages my friends across the aisle believe they have and that they have gained by calling up S. 812 as the backdrop—or should I say backstop—to debate pharmaceutical issues.

It is true that S. 812 was referred to the HELP Committee. It is true that the committee held a hearing on this bill on May 8. I testified at that hearing. I stated my reservations about the way the McCain-Schumer legislation acts to distort the original premise of the Drug Price Competition and Patent Term Restoration Act of 1984.

While I am heartened by the fact that the HELP Committee version of S. 812 that is pending before the Senate today resembles more closely the perspective of my testimony than the original Schumer-McCain language, I am troubled by the fact that we basically have a bill emanating from the HELP Committee that centers on patent law, civil justice reform, and antitrust policy. I object to this outcome, and I want to take a few moments to comment that the way the Judiciary Committee was effectively cut out of the process is a matter of great concern to me.

Even if three members of the Judiciary Committee serve on the HELP Committee and are highly involved in this effort, I am concerned that the recent actions of the HELP Committee with respect to this bill will come at the expense of the jurisdiction of the Judiciary Committee both today and into the future. This is wrong. The Judiciary Committee has a role to play in overseeing and legislating with respect to pharmaceutical patents and competition in the pharmaceutical marketplace. The process and timing that are being pursued can only undermine the appropriate role of the Judiciary Committee, a balanced committee.

The fact is, last year we held a hearing on competition in the pharmaceutical marketplace and reported Chairman LEAHY's bill, S. 754, the Drug Competition Act, which I support. I cooperated with Senator LEAHY in the development and refinement of his bill, S. 754, the Drug Competition Act. I voted to report the bill out of committee even though I had some reservations about some of the language, and I remain prepared to work on those concerns.

The fact is, the HELP Committee bill contains patent forfeiture provisions, similar in many respects to the concept once under discussion as Chairman LEAHY and I worked to refine S. 754. I ask why the HELP Committee adopts a policy of patent forfeiture not on the outside of its jurisdiction but already rejected by members of the Judiciary Committee. I emphasize that this is not a matter of public health policy but a patent law and civil justice reform, and so is within the province of the Judiciary Committee, not the HELP Committee.

I am mindful of the fact it was referred to the HELP Committee, but this body has a history of committees working in tandem on issues of mutual interest. In 1998, although the tobacco bill was referred to the Commerce Committee, the Judiciary Committee held 10 hearings on aspects of the legislation that touched upon our jurisdiction. We all know the long-awaited FTC study of the pharmaceutical industry that focuses precisely on the provisions of the law that the HELP Committee seeks to change today will be completed in a few short weeks. Why not wait for that? Why not get the best advice of the Federal Trade Commission? They have done an extensive review.

Whether we agree or disagree with the final outcome of that, we at least ought to get it before we try to wholesale change the law that has been called the best consumer piece of legislation in the last 50 years.

It is clear, to me, that consideration of this legislation would be more informed if we had the information that is about to be presented by the FTC to Congress and the public. We should ask the experts at FTC, DOJ, the Patent and Trademark Office, and Health and Human Services if their perspectives on the changes in the law are advisable. It would have been preferable to hear what the experts think of the HELP Committee language before it was brought to the floor. Whatever happened to holding a hearing on the actual language of an important bill?

The reality is, in the course of the markup, the HELP Committee virtually rewrote the major components of S. 812. Unfortunately, this sprint to the floor cannot foster the careful type of review and analysis that the Senate conducted in 1983 and 1984 when we passed the Drug Price Competition and Patent Term Restoration Act.

Despite my disappointment about the committee process on consideration of the Medicare drug benefit in the Finance Committee and the way the Judiciary Committee was bypassed from playing a role in shaping S. 812 before it reached the floor, I want to take some time to make a few remarks about the spending bill, the underlying bill, and how it might affect the law it would amend; that is, the Drug Price Competition and Patent Term Restoration Act of 1984.

It is useful to think about the words in the title of the law because they remind us that we had two distinct goals in writing the law—goals, by the way, which have been met. Attempts to change the law must also reach the critical test of these two goals: First, to provide incentives for the development of innovative pharmaceuticals—if we don't have that, we don't have anything; second, to promote widespread distribution of generic drugs by permitting a shortcut to regulatory approval, which Hatch-Waxman did.

There is evidence to conclude that the 1984 law has met with success in accomplishing both of these ends, much to the benefit of the American public. The 1984 law contains the incentives with respect to the intellectual market that have brought hundreds of therapeutic new drugs to the American public.

To mention a few of the drugs, these include products such as Vioxx to treat arthritis; the cholesterol drug, Lipitor; new medications that help millions of diabetics; and as recorded from Barcelona last week, a family of drugs to treat HIV infection and the complications of AIDS, two areas in which both the distinguished Senator from Massachusetts and I have spent a lot of time working together.

Private sector investment by research-based pharmaceutical firms increased from $3.6 billion in 1984 to over $30 billion this year. This substantial level of private sector applied research funding, coupled with the $27 billion invested by the taxpayers in the National Institutes of Health budget next year, helps explain why the unique public-private partnership that forms the U.S.

Biomedical Research Enterprise has American scientists positioned to usher in a revolutionary new age of discovery in the biological sciences. We all should take pride in the fact that the United States leads the world in developing innovative medicines. Part of the reason for this leadership is the intellectual property protections contained in the 1984 statute.

The debate on the pending legislation centers on the price competition that occurs between generic and name brand drugs. But as we consider legislation that alters protection of the innovator firms' intellectual property, it is important not to lose sight of the importance of the fierce competition between the generic companies and the brand name companies. It is the competition for new drugs that creates advances in medicine and improves public health and ultimately provides blockbuster drugs for generics to copy and to put out at, hopefully, less cost.

As we debate how to see that the American public, particularly senior citizens, gains access to today's pharmaceutical products, during the golden eggs of our biomedical research establishment we must be mindful of the long-term health of the goose that produces these innovative drug products. Not only does the American public enjoy the benefits of the latest breakthrough medicines, but consumers also reap the savings associated with the use of generic drugs.

Since the 1984 Drug Price Competition and Patent Restoration Act, the share of the prescriptions written for generic drugs has more than doubled and has increased from somewhere less than 20 percent to almost 50 percent of all prescriptions written. And as we will hear in the debate that will take place over the next several days, everyone in Congress knows that senior citizens, particularly senior citizens, have a great interest in programs, such as the 1984 law that resulted in cutting the costs of drugs.

One undeniable bottom line measure of success of the Drug Price Competition and Patent Restoration Act of 1984 is the fact that according to the Congressional Budget Office, this law has contributed to annual consumer savings of $8 billion to $10 billion every year since 1984. I wish all our legislation would be as effective and as successful as this one.

It might prove useful to summarize briefly how the Drug Price Competition and Patent Term Restoration Act works. When you hear how the statute operates, you will understand that a central principle of this legislation is balance among the incentives of both the research-based firms, the pioneer firms, and the generic firms.

This balance is not on only a simple matter of fairness to both of these sectors of the pharmaceutical industry. Achieving a balance was critical to help ensure that both of these sectors would succeed because the bottom line of Hatch-Waxman is to help the American public receive both the latest in medical breakthroughs, and the more affordable generic drugs.

As we consider changes to Hatch-Waxman, we must be careful not to upset the balance because if we do, it is the American people who will suffer. Here is how the law works. In order for a drug to be marketed in the United States, a manufacturer must prove to the Food and Drug Administration that the drug is both safe and efficacious, effective. Drug discovery and development is an extremely time-consuming, expensive, and risky process.

As I have mentioned before, experts at the Tufts University Center for the Study of Drug Development have placed the costs of developing a major new drug at $800 million, when the opportunity costs of capital and the cost of failed drugs are factored into the rare, successful product.

During this debate, some will no doubt be tempted to characterize the drug industry as nothing more than a bunch of greedy, money-grubbing companies. In fact, for much of the last decade, it has been the most profitable sector of the U.S. Economy.

Nevertheless, as many analysts have noted, and was discussed by Senator WYDEN at the Commerce Committee hearing this past March, drug discovery is a highly speculative venture and there is currently an industry-wide slow down in the pipeline of products close to final FDA approval.

For every drug that succeeds in gaining FDA approval, more than 5000 compounds are screened and fall by the wayside during testing. Some of these compounds fall out in the lab; only about 250 of the original 5000 compounds will proceed to full-scale animal testing; and, of those 250 that enter animal testing, only 5 will make it to human clinical trials; and, finally, the great majority—4 out of the remaining 5 of drug product candidates—will fall out during the required 3 phases of human clinical testing.

The first phase of clinical testing usually entails about 30 patients. The goal of this phase is to assure that the compound under study is safe for human use. This is a very difficult hurdle as, for example, it can be expected that a compound that can eradicate cancerous cells will also likely be toxic to the surrounding healthy cells. It is no wonder that the pharmaceutical industry invests a higher percentage of its revenues into research than other industrial sectors. Are they given any credit for that on the floor over the last number of days? Give me a break. They certainly have not. In fact, they have been condemned in talk after talk as though they are the sole cause of the high cost of drugs.

In the second phase of clinical trials, efficacy is examined. This may involve several hundred patients and it may take several years to design, conduct, and analyze the trial.

If success is sustained through Phase II—and remember that experience teaches us that most of these costly trials will result in failure—an investigator may proceed to the third and final phase of human clinical testing in which the drug is administered to several hundred and sometimes several thousands of patients.

Phase III trials attempt to further evaluate safety and efficacy, fine tune dosing regimens, and uncover any propensity for adverse reactions among subgroups of the broad patient population taking the medicine.

Because they involve more patients and seek more precise information, Phase III trials are generally even more expensive and time consuming than the earlier phases of drug development. In order to gain FDA approval, the agency prefers to see two successful Phase III studies.

In addition to costing hundreds of millions of dollars to screen and test drug candidates, it also takes a great deal of time. It has been estimated by experts that it takes, on average, about 14 years to bring a drug from the lab through clinical testing and FDA review.

And all during this time the clock is ticking on the patents held on these drug candidates. For example, in the case of the anti-inflammatory drug, Daypro, the patent lapsed during the 21-year FDA review of the product.

While this case was clearly an outlier and FDA review time has improved somewhat over the last decade due to the user fee legislation, it remains true that the U.S. pharmaceutical industry is one of the most highly regulated sectors of the economy.

It is an expensive process, mainly an expensive regulatory process. If we could somehow find a way of cutting that down, then the cost of drugs would come down, too.

We passed a bill—it was another Hatch bill—called the FDA Revitalization Savings Act, in the early 1990s, that said we should create a central campus with state-of-the-art buildings and equipment and scientific facilities instead of the almost 40 different locations, some of them converted chicken coops, where they are conducting research today. The FDA has hardly hired a research scientist in the last 30 years. The reason is there is not the prestige in their eyes to work for the FDA for less money than they would get in the private sector.

NIH doesn't seem to have that problem because it is so prestigious to work there, even at the lesser salaries, that scientists flock to NIH. It is exciting, plus they have state-of-the-art buildings and equipment with which to work.

We need to do that. We need to stop blaming the pharmaceutical companies, the pioneer companies for all the problems here.

In recognition of the exacting and time-consuming nature of FDA review of safety and efficacy testing, the Drug Price Competition and Patent Term Restoration Act provided a number of

incentives designed to help research based pharmaceutical companies.

The statute provides for partial restoration of pharmaceutical patents, but only under limited rules:

First, the law allows one day of patent term restoration for each two days spent in the human clinical trial phase.

This is known as the IND Phase. IND stands for the investigational new drug and refers to the exemption that FDA grants to allow the human clinical trials to proceed.

The law also allows day-for-day patent term restoration when the drug is in the final stage of FDA review. This is called the NDA phase. The NDA, or new drug application, is the formal application that contains the data demonstrating safety and efficacy. I should point out that given that each NDA contains data and records on thousands of patients, the NDA literally contains hundreds of thousands of pages of information. In some cases those millions of pages of information would fill this whole Chamber—that's how complicated it is. Yet, we hear badmouthing of the pioneer companies every day here on the floor. There are fair criticisms, but I don't think all the criticism has been fair.

There are two further limitations on the partial patent term restoration. First, when the one-for-two rule in the IND Phase is applied with the day-for-day rule during the final review of the new drug application, no patent may be restored more than 5 years. You should keep in mind that, as I said earlier, it takes about 14-years to bring a drug through pre-clinical studies through FDA approval.

Finally, even after this 5-year limitation kicks in there is another rule that prevents any patent from being restored such that it will have an effective patent life beyond 14 years.

The 5-year and 14-year limitation rules are sometimes referred to as the Hatch-Waxman caps.

So I just want to point out that you will hear a lot of talk during this debate about patent extensions, but what we are talking about is partial patent term restoration to offset part, and a relatively small part at that, of the time lost during the rigorous FDA review of safety and efficacy. You don't hear many comments about that from the critics the fact of the matter is, this is a long, arduous expensive time consuming, costly process. To blame the pharmaceutical companies for everything that is wrong is just not fair.

It is worth noting that the 14-year cap on effective patent life contained in the Waxman-Hatch Act stands in contrast to how other types of patents are treated with respect to administrative delays at the Patent and Trademark Office.

This is a somewhat complicated story but I think it bears discussion in order to place the Hatch-Waxman policies into context with subsequently enacted changes to the patent code.

Basically the GATT trade treaty required implementing legislation that mandated the United States to change its patent system from 17-years, measured from the date of approval to a new system of 20-years, measured from the of date of application with the Patent and Trademark Office.

There was concern by many intellectual property owners that this change in the law could actually decrease effective patent life due to administrative delays at PTO. As a result, a provision was included in the 1999 American Inventors Protection Act—a bill that passed with broad bipartisan support—that allowed patent term to be restored up to 17 years in cases where there was undue delay at the PTO.

The 17-year patent term floor in the American Inventors Protection Act extends to all types of patents and should be contrasted with the 14-year patent term ceiling contained in the Waxman-Hatch for pharmaceutical patents. Moreover, most patent applications are reviewed by PTO in one and one-half to two years, so that the effective patent life for most products is actually 18 to 18.5 years. When all is said and done, most patents run appreciably longer than patents related to drugs due to the 14-year Waxman-Hatch cap.

In addition to the partial patent term restoration provisions of the 1984 law, the statute provides that each FDA-approved new drug that consists of a new chemical entity receives 5 years of marketing exclusivity—not 18 years, which other manufacturers get, but 5 years of marketing exclusivity. In other words, we want to treat them at least somewhat fairly.

This 5-year marketing exclusivity provision means that FDA may not approve any generic drug for that time 5-year period regardless of whether the drug is protected by any patent.

The last major incentive on the R&D side of the ledger that I will discuss is the provision that entitles a pioneer drug firm that successfully undertakes a clinical trial yielding data that significantly improves, or modifies the use of an existing drug compound, to 3 years of marketing exclusivity.

As you can see, this is complex. But it works, and it has worked amazingly well. Our country has benefited from it. And it was bipartisan. Actually, you would have to say it was nonpartisan. That is what I would like to see in a full Medicare prescription drug bill. This 3-year incentive helps encourage incremental, but often vitally important improvements, to existing drugs and does not bar generic competition from the original approved uses of the drug once any patent or marketing exclusivity has expired.

I hope my colleagues can see that the 1984 law contains a powerful set of intellectual property incentives that help foster the necessary private sector investment in pharmaceutical R&D.

That is one reason our pharmaceutical companies have done so well. That is why we have such a good balance of trade. They have been among the most successful companies in our society up until now, and they are about to be stratified where they won't have the money to go through this $800 million and 5,000 misses to get one single drug, if they are lucky and then have just a few years of patent life. You wonder why drugs cost so much through that market exclusivity.

In parallel with the incentives I have just described for innovator firms, the Drug Price Competition and Patent Term Restoration Act provided the necessary regulatory regime that created the modern generic drug industry. Rather than unnecessarily squander societal resources by requiring the duplication of the expensive and time consuming process by which safety and efficacy is established for pioneer products, the law provided a shortcut through the FDA regulatory process.

That was one of the generic aspects of the law. The 1984 law, in essence, allows generic competitors to rely upon the proprietary safety and efficacy data generated by the pioneer firm and requires that the generic drug merely be shown to contain the same active ingredient and be absorbed by the human body in a bioequivalent fashion. This simple provision of law allowed generic firm to bring on high quality copies of the pioneer drugs for a fraction of the cost and, most importantly, to pass these savings onto consumers.

Their cost is less than 1 percent to put the drugs in the marketplace. I want it that way. We wanted it that way when we did the Hatch-Waxman bill.

Another key feature of the law is a unique change in the patent code designed to allow generic product to enter the market literally the day after the patents on a pioneer drug expire.

Upon first consideration this may not sound like a dramatic development in the law but it is. Here's why.

Let us start with the Constitutional basis for patent protection. Article I, Section 8 of the United States Constitution provides: ''Congress shall have the power . . . to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.''

It is said that Thomas Jefferson had his hand in the drafting of the first patent statute enacted by Congress back in 1790 and that in his capacity of Secretary of State actually issued and signed some of the first patents issued by the United States federal government.

In areas such as pharmaceuticals, where it is relatively easy to copy pioneer products that require enormous R&D expenditures—I mentioned $800 million to find one drug—it is critical to have strong laws prohibiting the infringement of patents.

I should also like to add that a patent right is a negative right and does not automatically confer monopoly power; a patent only allows the patent

owner the right to exclude others from utilizing the patented invention or process.

Section 271(a) of title 35 of the United States code contains the general rule against patent infringement. It says: '' . . . whoever without authority makes, uses, offers to sell, or sells any patented invention . . . during the term of the patent . . . infringes the patent.''

This is a tough provision and a good provision because it protects the rights of inventors, inventors of all products used, manufactured or sold in each of our states, who have made substantial investment in research and development.

In order to allow generic drug firms to enter the market the day the patent expired, the general rule of section 271(a) had to be modified. This is so because in order to get the drug through the truncated FDA review process and gear up production the generic firm has to make and use the patented drug, and this is important, while the pioneer drug is under patent protection.

I should also add that under the common law there is a research exception to the general rule against patent infringement so that academic researchers could be free to explore new areas of scientific inquiry.

During the course of the negotiations over the Waxman-Hatch law, a question arose in the courts with respect to whether this research exemption might carry over to the type of research activities necessary to develop a generic drug.

And right in the middle of these negotiations we got the answer when the precursor court to the Federal Circuit Court of Appeals issued its opinion in the case of Roche v. Bolar. The court held that the research exception did not extend to commercialization activities such as those necessary to prove bioequivalence.

The result was that the Drug Price Competition and Patent Term Restoration Act contains a legislative override of the court case. This provision, the so-called Bolar Amendment, creates a unique provision in patent law. Section 271(e) of title 35 contains the Bolar Amendment. Section 271(e)(1) says: ''It shall not be an act of infringement to make [or] use . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.''

When considering the pending legislation, it is important to understand that in preparing an abbreviated new drug application, or an ANDA as they are called, the generic firm gets a head start over virtually all other types of generic manufacturers in that they are permitted to make and use—and thus violate—pioneer firms drug patents while these patents are still in effect.

That is a major change in patent law that we put into Hatch-Waxman to get the generic industry really going. And it helped to create the modern generic drug industry.

(Mr. EDWARDS assumed the Chair.)

Mr. HATCH. In the interest of accuracy, I must add a footnote. In the 1990 Supreme Court decision of Lilly v. Medtronic, the Court held in an opinion written by Justice Scalia that the Bolar amendment also applies to some other FDA-regulated industries such as medical devices. While you need to read the opinion for yourself to see how this not-so-obvious result was accomplished, as coauthor of the bill, I did take note of Justice Scalia's observation that:

No interpretation we have been able to imagine can transform section 271(e)(1) into an elegant piece of statutory craftsmanship.

Mr. President, ouch!

But the Medtronic decision has only limited significance and it is still fair to say that the generic drug industry enjoys a head start that virtually no other type of generic manufacturers could even imagine—the ability to make and use on-patent products for commercial purposes. The head start granted to generic drug firms by the Bolar amendment was an integral part of the balance of the 1984 law and must be kept in mind when I next discuss the closely related patent challenge provisions of the bill.

But before I discuss these provisions, I want to first emphasize that the central feature of the Hatch-Waxman law thankfully remains unscathed by the pending legislation.

This is the policy tradeoff whereby part of the patent term lost by innovator drug firms during the extensive FDA review is restored while, at the same time, generic drug firms were permitted to rely upon the proprietary safety and efficacy data of innovator drug firms and enter the marketplace upon a showing that the generic copy of the drug is delivered to the patient in a bioequivalent manner.

And from the summary I have just provided, I think you get the idea that the Drug Price Competition and Patent Term Restoration Act of 1984 law is a complex piece of legislation. It took us 2 solid weeks, 18 hours a day, in my office. I was there every minute of those negotiations to get this negotiated between the PhRMA companies and the generic companies. I will also concede, as Justice Scalia has noted, that the statute does not read like a novel.

The 1984 law has been instrumental in delivering both new drugs and more affordable drugs, but this is not to say that such a complex piece of legislation cannot be improved to address unanticipated or unintended consequences as well as changes in the marketplace and science.

Before I discuss my views on the pending legislation, the HELP Committee substitute to S. 812, I would like to complete my summary of the Drug Price Competition and Patent Term Restoration Act by describing the patent challenge features of the statute. Perhaps no feature of Waxman-Hatch has generated as much controversy as the provisions relating to patent challenges. These are the least understood and, indeed, least appreciated provisions of the law. The guts of the HELP Committee substitute focus on these provisions.

I hope that everyone agrees that patents are critical to the drug development process because absent patent protection it would be relatively easy to copy virtually any drug. The challenge of drug development is not in the chemistry of manufacturing, but in conducting the extensive and expensive preclinical and clinical research that demonstrates safety and efficacy.

While patents are integral to drug development, consumers can benefit greatly from earlier price competition if it were determined that, for whatever reason, the underlying patents on a drug were invalid or not infringed.

At any rate, during the negotiations over the bill in 1984, a policy question arose regarding how best to guarantee that drug patents would be challenged and what to do in cases in which a challenge was successful.

We ultimately decided that a generic firm which successfully attacked the patents on a new drug would receive a period of 180-days of marketing exclusivity during which no other generic competitor could be approved by FDA.

The 1984 law contains an elaborate set of rules surrounding patent challenges. Here is how the system works.

From my earlier discussion, you will recall that all new chemical entities—even and especially drugs without any patent protection—receive a 5-year period of marketing exclusivity during which the generic drug firm may not rely upon the safety and efficacy data generated by pioneer drug firms.

And keep in mind that there may be no other industry in which generic competitors can rely upon pioneer manufacturers' proprietary information submitted for Federal approval purposes.

In any event, the law allows the generic drug firm to submit an abbreviated new drug application after 4 of the 5 year marketing exclusivity period has lapsed. When the generic drug application is submitted, the generic firm has to make one of four certifications with respect to each patent related to the drug listed in the official FDA records called the Orange Book.

This chart sets out these choices.

First, that such patent information has not been filed.

Second, that such patent has expired.

Third, the date on which such patent will expire.

And fourth, and finally, that such patent is invalid or will not be infringed by the manufacturer's use or sale of the new drug for which the application is submitted.

It is the last certification, the so-called paragraph IV certification, that is the chief cause of the major problems the bill pending on the floor seeks to address.

As I have said many times over a number of years, by the way, and will say again here today, I acknowledge there are some problems with paragraph IV patent challenges.

These need to be corrected. I would like to shape legislation to correct them.

But it is also no secret that my preference was to address these problems in the course of a comprehensive review of the Drug Price Competition and Patent Term Restoration Act.

In fact, in the good old days when I was still chairman of the Senate Judiciary Committee and my friend from Vermont, Senator JEFFORDS, was the chairman of the HELP Committee, we were working together to conduct such a review.

But times have changed. What should not change is that this body should resist the pile-on mentality which villianizes an industry which is doing more to help millions and millions of Americans daily than any other industry we could imagine.

Before I close my remarks today, I will outline the types of issues that ought to be considered a more thorough review of the 1984 law than the pending bill contemplates.

In any event, to return to the paragraph IV litigation procedures, the filing of a generic drug application triggers a 45-day period during which the pioneer drug company or firm could initiate a lawsuit to determine whether its patents were valid or infringed. In order to give a court adequate time to familiarize itself with, and hopefully dispose of on the merits, the almost always complex issues attendant to patent litigation, the Waxman-Hatch law provides a statutory 30-month stay.

During this 30-month period FDA may not approve the generic drug application in dispute unless a court resolves the matter.

It is also true that this is a unique provision not available to other types of patent holders. However, this unique 30-month stay provision that benefits patent holders must be understood in context of the overall system of balances contained in the 1984 law, and, in particular, in connection with the operation of the Bolar amendment.

The Bolar provision, you will recall, has the laudable public purpose of trying to get the generic drug product onto the market the very day the patent expires.

As I explained earlier, in order to achieve this pro-consumer end, the patent code was amended to allow the generic firms to infringe patents.

But we must recognize that the reality of the Bolar amendment is that it takes away the customary rights of a patent holder to bring a patent infringement action the moment a generic drug manufacturer makes or uses a patented product. In this case, the commercial purpose consists of seeking FDA approval and gearing up production. It cannot be disputed that section 271(e) of the patent code—the Bolar amendment—places pharmaceutical patent holders in a disadvantageous position from which to defend themselves against challenges to its patents by generic drug challengers.

This is so because a second prong of the Bolar amendment, codified at section 271(e)(2) of the patent code, treats the somewhat artificial act of filing a generic drug application as an act of patent infringement, and it is at that point, and not before that point, that the patent holders can assert their normal patent rights through the courts.

It seems only fair to recognize the unique head start that the Bolar amendment allows to generic firms on the front end of the generic drug development by making available to pioneer firm patent holders the 30-month stay that allows the courts adequate time to delve into the merits of the challenged patents. Absent the Bolar amendment—and don't forget that this provision reversed the Federal Circuit Court of Appeals decision that decided against generic drug firms on the matter of patent infringement—the case for the 30-month stay would not be as strong.

In any event, during the course of the 30-month stay, it is hoped that an adjudication on the merits of the patent challenge will be completed. If at the end of the litigation the pioneer firm prevails, the generic drug applicant must wait until the patents expire before the FDA can approve its application and the generic product can be marketed. On the other hand, if the courts determine that the patents are invalid or the generic drug firm has successfully invented a way around the patents, the 1984 law grants an award of 180-days of marketing exclusivity. As I said earlier, this is to encourage vigorous patent challenges so that consumers can benefit from earlier access to cost-saving generic drugs.

I thought then, and think now, that it is sound public policy to contain an incentive to assure legal attacks on pioneer drug patents, and we all must recognize that such litigation is risky, complex, time-consuming, and costly.

Now that I have laid a foundation by discussing the basic provisions and policies of the Drug Price Competition and Patent Term Restoration Act, I want to add to the debate that was initiated yesterday by briefly describing the key problems that have been observed in recent years with respect to the 1984 law.

I first remind the Senate that in the next few weeks the Federal Trade Commission is expected to issue a comprehensive report that centers on what many believe are the two most important abuses of the current system: First, the manipulation of the patent system for the purpose of triggering multiple overlapping or late-in-the-process 30-month stays; and, second, collusive arrangements between pioneer and generic firms to game the Paragraph IV litigation in order to preclude the triggering of the 180-day marketing exclusivity clock so that no generic can reach the market in a timely fashion.

I am frustrated by the fact that the tactical choices of my colleagues across the aisle preclude us from debating this important legislation without the benefit of the FTC report.

I await with great interest the final version of the forthcoming comprehensive FTC report on the drug industry so we may get a more accurate picture of the number of instances in which drug firms have tried to game the system by listing a late-issued patents into the FDA Orange Book.

While my staff and the staffs of a few other Members have been briefed on the general findings of the FTC study, it was under the condition of confidentiality and with the understanding that the commissioners had not evaluated the data and given us their interpretations, conclusions, and recommendations.

Along the same lines, I would like to add that the FDA Chief Counsel, Dan Troy, convened a meeting in February of representatives of both the generic and pioneer drug firms.

Mr. Troy elicited information and debate on several maters, including a full and frank discussion of both the 30-month stay and the 180-day marketing exclusivity provisions of the 1984 law.

One of the many down sides of rushing this bill to the floor in this fashion was that it precluded members of several committees, including the Judiciary Committee, Commerce Committee, as well as HELP Committee, from first reviewing the comprehensive FTC study on the very issues that the pending legislation seeks to address.

We may have also missed out on a meaningful opportunity to have the usual give and take of a public hearing with the FTC and the FDA on these issues. We could have—and should have—taken the more routine and orderly path to legislation by holding a hearing to solicit the administration's detailed advice in crafting language, including soliciting their views on the language that arose just last Tuesday in the HELP Committee.

Yesterday, Senator GREGG read from the first, but no doubt not the last, missive from the administration commenting on this new language.

In any event, let me turn to the 30-month stay provision. It is my understanding that the FTC report will reveal that there have been several—perhaps about 10—cases of either multiple, consecutive 30-month stays or later-issued patents that resulted in surprise 30-month stays.

The facts matter.

We need to learn about these cases. We also have to keep matters in perspective. Although some in this debate suggest that there has been, and will continue to be, an epidemic of unjustified triggering of the 30-month stay, I am not sure that the evidence will support this charge.

We must take care not to overcorrect any problems based on anecdotal information.

But I will say this: the now famous case of the drug Buspar convinces me and many others that Congress should take action to address the problems associated with late-issued patents triggering new 30-month stays.

This was the case in which a patent on the metabolite of a drug was listed in the Orange Book just as the original patents on the drug were set to expire and generic were literally on the loading dock ready to be shipped.

I do, however, want to note for the record that in the case of Buspar the courts stepped in and the stay lasted only 4 months, not 30-months.

The HELP Committee bill would freeze those patents eligible for the 30-month stay to those patents filed with FDA within 30-days of approval of the New Drug Application. All other subsequently issued patents would be eligible for injunctive relief but would not be entitled to the longstanding protection afforded by the 30-month stay.

First, I commend Senators EDWARDS and COLLINS for overturning the McCain-Schumer language that completely—and unjustifiably—eliminated the 30-month stay. The Edwards-Collins amendment also is a great improvement over the language that Chairman KENNEDY circulated in the days before the markup.

The Kennedy language would have arbitrarily limited the types of patents eligible for the 30-month stay to drug substance patents and method of use patents.

By treating some patents as inferior to others, the Kennedy draft would have reversed a longstanding principle of Hatch-Waxman not to discriminate among types of patents.

The very purpose of the 30-month stay is to give the courts an adequate period of time to make an informed analysis of the complete patent portfolio surrounding a drug product.

The 30-month stay allows the time necessary to make fact-based determinations of the validity of the challenged patents as well as to determine if the generic challenger has successfully navigated the field of valid patents and produced a non-infringing version of the drug.

I know that Senator GREGG was working on a language that would have retained the 30-month stay for each patent recorded in the Orange Book prior to a generic drug challenger filed a marketing application with the FDA. I think that there is great merit in this approach.

The Hatch-Waxman law does not even allow generic drug applicants to file a generic drug application until four full years have elapsed after the NDA has been approved for a new chemical entity.

That is because, as I stated earlier, under the 1984 law, drugs consisting of new chemical entities—and these are likely to be the breakthrough products—automatically receive five years of marketing exclusivity before FDA can approve a generic copy of the drug. It seems reasonable to conclude that, at a minimum, all patents filed before a generic can first challenge a pioneer drug, that is, after four years have elapsed, should be accorded the protection of the 30-month rule.

For example, consider the hypothetical but not unrealistic case of an approved intravenous drug covered by pre-NDA issued patents on the compound and the method of use. In addition, assume the drug sponsor has applied for, but does not receive, a patent on the intravenous formulation until two years after the NDA is approved. While the Edwards-Collins language is barely one week old and I am still studying its implications, upon first consideration, I find it difficult to justify treating the post-NDA-issued formulation patent differently than the earlier two patents. After all, a generic challenger—although free to infringe the patent under the Bolar amendment for the purpose of providing bioequivalence data and to prepare for full-scale production—cannot even contest any of the three patents for 2 years after the third patent issues.

That is because the filing of the generic drug application creates the artificial act of patent infringement required by the Bolar amendment that allows the Paragraph IV litigation to commence.

I emphasize the fact that the lawsuit may not begin at least until the four year statutory bar on submitting a generic drug application expires.

And if it makes sense to include all patents issued within the first four years during which no ANDA application and Paragraph IV challenge can be made, one can argue, as Senator GREGG has, and I suggested in my testimony before the HELP Committee in May, that it makes sense to freeze the patents listed in the Orange Book for the purpose of the 30-month stay on the day that any particular ANDA is submitted, whether or not it is filed on the first day of ANDA filing eligibility, or years later.

The McCain-Schumer proposal to do away with the 30-month stay altogether is dead.

The Kennedy proposal to allow only some types of patents to qualify for the 30-month stay is dead. Perhaps the governing principle should be one bite, and one bite only, of the 30-month apple and all we are debating is when, not whether, to cut off the availability of the stay. As I said last night, in some respects the Edwards-Collins language is a step in the right direction and this is one of those improvements.

We know that it currently takes, on average, about 18 months for FDA to complete its review of generic drug applications. I understand that it takes, on average, about two years to reach a district court decision in Paragraph IV patent challenge case. We also know that the generic have argued—and the Edwards-Collins amendment embraces—that it would be unfair to start the 180-marketing exclusivity clock—a matter that I will discuss latter in my remarks—until a final decision has been reached by an appellate court. This appellate review takes about another year, so the total litigation period of Paragraph IV cases is about 36 months.

I can understand why generic Paragraph IV challengers want to wait—the prospects of treble damages seems to me like a good reason for them to exercise caution—until an appellate court decides the merits of the patent challenge. Given the risk adverse behavior engendered by the threat of treble damages, I don't see why it is so absolutely critical in the first place to bifurcate the application of the 30-month rule at the time a new drug application is approved.

Perhaps the FTC study will unveil a pattern of cases in which courts have ultimately determined that frivolous, or at least invalid, patents were filed between the approval of the NDA and the first ANDA submissions. Perhaps not, only time will tell.

But frankly, this is an area where the actual data that presumably will be forthcoming in the FTC study will be extremely helpful. I will be greatly interested to know how the patent challenge cases would have broken down if the Edwards-Collins NDA-plus 30 day rule were applied retroactively. Stated another way, are there any significant differences in the outcome Paragraph IV challenge litigation between Orange Book patents listed before, and those patents listed after, 30-days after the NDA has been issued? It will be beneficial to get a sense on whether there is a pattern with respect to when invalid patents and patents that have been circumnavigated tend to be listed.

And as I said earlier, I think we would have all been better served if the Committees of jurisdiction had been afforded the opportunity to conduct hearings with the purpose of analyzing the actual language of the Edwards-Collins Substitute and with the hindsight provided by the FTC report, together with the expert advice and analysis of the FTC, other federal agencies, and other experts and interested parties.

We should all recognize that patent litigation is often, as in the case of pharmaceutical patents, inherently technical and complex.

For example, The Legal Times recently reported that the Federal Circuit has a reversal rate of 40 percent in certain patent cases. I am concerned that to the extent we adopt a policy that relies too heavily on simply throwing the matter of injunctive relief to federal district courts absent a period to allow the court to sufficiently familiarize itself with the issues at hand not only disrupts a justified internal check and balance of Waxman-Hatch, but also may have the effect of creating uncertainty as the district courts wrestle with arcane matters of patent law.

While I can see how some enterprising generic firms and their attorneys might be able to turn this new and potentially unpredictable environment into leverage for settling patent challenges, I am not sure that this instability is either fair to pioneer drug firms or in the long run interests of the American public.

For now, I will listen carefully to the debate on this matter but, from what I now know, I am inclined to conclude that the Gregg proposal is preferable to the NDA-plus 30-day standard contained in the HELP-reported version of S. 812.

Moreover, as I stated earlier, I think a case can be made for making the 30-month stay available to all patents listed within four years after the NDA has been approved since no patent litigation can commence under the 1984 law until that time.

In short, while I am open to further debate and discussion on the matter, at this point I question whether the Edwards-Collins language unnecessarily cuts off the 30-month stay too early in the process?

I welcome the understandable and justified attempt to address the problem of late or even multiple 30-month stays that can occur when later-issued patents are entered into the Orange Book. As I said in my testimony in May, if there is a compelling case to keep the current policy of universal availability of the 30-month stay for all patent whenever listed, let's hear the arguments.

Once again, let me commend Senators EDWARDS and COLLINS for moving the Committee away from the these negative aspects of the McCain-Schumer and Kennedy proposals.

I am pleased that there appears to be something of a consensus on the importance of retaining the 30-month stay even though, for the reasons I have just described, I think we need further discussion of when the stay should be available and when it should not be operative.

Having addressed the general issue of the wisdom of retaining the 30-month stay, I would be remiss if I did not comment upon some aspects of the Edwards-Collins substitute that would also drastically affect patent litigation under the 1984 Waxman-Hatch law.

Mr. President, I speak now of the what I will call the file-it-or-lose-it and sue-on-it-or-lose-it provisions of the HELP Committee Substitute.

Mr. President this is a case of the HELP Committee trying to rewrite patent law and doing an absolutely horrible job at it to boot.

There are three very similar and very disturbing provisions that essentially say a pharmaceutical patent holder can effectively forfeit their rights by not filing patent information or a patent infringement action at a certain time.

The first of these provisions is found in Section 3 (a)(1) ''(2)(F)'' of the bill. This provision requires manufacturers of innovative new drugs to file certain patent-related information in the FDA Orange Book upon penalty of—and here's the rub—forfeiture of their patent enforcement rights.

A second provision of the bill, contained in Section 3(a)(2)(B) of the bill makes this filing requirement applicable to drugs approved prior to enactment of S. 812.

This provision says, in effect, that upon enactment of S. 812, every holder of a pre-enactment approved new drug application has 30 days to file all specified patent-related information in the FDA Orange Book or lose forever their rights to sue for patent infringement.

Talk about Draconian remedies for failing to file information with the government. This takes the cake! I should also point out that section (a)(1) ''(2)(C)'' of the bill significantly expands the type of patent information that must be filed, including requiring very precise claim by claim certifications of what each particular patent covers. I am concerned about the policy and potential effects of this language.

Given that forfeiture of patent rights is the penalty for the two file-it-or-lose-it provisions I just described, you should not be surprised to learn that the patent right forfeiture trifecta is completed in section 4(a)(2)(C) which contains a sue-on-it-or lose-it provision that appears to say that failure to defend against any Paragraph IV challenge waives your patent rights against all challengers for all time.

I was relieved to hear Senator KENNEDY state on the floor yesterday that this last provision was not intended to require forfeiture of patent rights as against all potential infringers. I take him at his word that this language will be clarified. But, once again, I must ask why we find ourselves on the floor with a poorly drafted patent provision that has not been vetted by the Judiciary Committee, the PTO, the White House or the patent bar or any number of other experts?

Nevertheless, I find these three provisions so troubling I hardly know where to start my criticism. Under the current law, failure to defend against a Paragraph IV challenge does not result in automatic forfeiture of patent rights.

Mr. President, my colleagues should know that under current law the penalty for not promptly defending against a Paragraph IV litigation challenge is waiver of the 30-month stay, not forfeiture of any patent rights.

It seems to me that the current law waiver of the 30-month stay against the particular litigant bringing a particular paragraph IV challenge is a proportionate response to the failure to defend against a particular lawsuit.

I think that both of the two file-it-or-lose-it provisions and the sue-on-it-or-lose provision simply go too far. I am not aware of any analogous provision in title 35, or in case law, but I am the first to admit that because this language is only a week old my study is not complete. I must question embracing the principle that if a patent holder, for whatever reason, fails to file information with the FDA that those rights should be automatically surrendered against any would-be patent infringers.

It seems to me that these provisions should be subjected to careful scrutiny under the takings clause before they are adopted. As well, the disadvantageous treatment accorded pharmaceutical patents under these three positions should be examined from the perspective of the TRIPS provisions of the GATT Treaty. That involves the Finance Committee as well.

We must not lose sight of the fact that patents are presumptively valid. We must not lose sight of the fact that the reason we have laws to protect intellectual property is because society benefits from advances in the arts and sciences, as the Constitution asserts.

If we expect to have breakthrough medicines, we better protect patents.

Why would we ever support a system in which the failure of a mail room clerk, even if underpaid and overworked, or the U.S. Postal Service could result in the forfeiture of rights stemming from literally hundreds of millions of dollars and precious human capital invested in cutting edge biomedical research?

Just this week, because of the anthrax problem, I received some Christmas presents. One can imagine what can happen on some of these patent cases.

Why shouldn't pharmaceutical product patent owners retain the same time-honored rights exercised by all other patent owners to decide how and when to respond to patent challenge litigation?

Mr. President, I must tell my friends on the HELP Committee that this member of the Judiciary Committee—the committee charged with overseeing the patent law, antitrust law, and the administration of civil justice—that I do not support the manner in which they have resolved significant matters of patent law, civil justice and antitrust policy.

In fact, when Judiciary Committee Chairman LEAHY and I were negotiating over the provisions of his bill, S. 754, the Drug Competition Act, at one point a Leahy staff draft contained a provision in some ways similar to the pending bill's file-it-or-lose-it and sue-on-it-or-lose-it provisions. Ultimately, that approach was rejected. And for good reason.

As many of my colleagues know, S. 754 requires the prompt reporting of any potentially anticompetitive agreements between brand name and generic drug firms to DOJ and FTC.

Basically, the Leahy staff proposal—I cannot say whether Chairman LEAHY was aware of all of the details of this particular provision—was that a drug company would surrender its patent rights if it did not promptly report to

FTC and DOJ any potentially anti-competitive agreement with a generic drug firm.

Let me read the Leahy staff draft that was circulated to my staff last July.

It was contained in the enforcement section of the bill, and it said:

Contract and Patent Enforceability—if any person, or any officer, director, partner, agent, or employee thereof, fails to comply with the notification requirement under section 5 of this Act, such failure shall render permanently unenforceable any agree which was not filed with the Commission—[referring to the FTC] and the Attorney General, and [here comes the relevant language] shall also render permanently unenforceable any patent of the generic drug manufacturer or the brand name drug manufacturer that is the subject of the agreement.

I must give Senator LEAHY's staff a great deal of credit. One of them is Ed Barron, the deputy chief counsel of the Judiciary Committee Democratic staff. Ed is a level-headed, gifted lawyer and has been an asset to the Senate and the Judiciary Committee for many years.

As well, Susan Davies, a former Supreme Court clerk, is an extremely talented lawyer.

When they consulted with experts in the field and further studied the matter, they properly concluded that patent forfeiture was an improper response for a mere reporting failure—even if that unreported agreement was ultimately found to be violative of the Federal antitrust laws.

How does a patent law provision with civil justice reform implications aimed at an antitrust problem find its way in three places in a HELP Committee-reported bill, one year after the chairman and ranking Republican member of the Judiciary Committee considered and rejected the same basic policy in a bill that covers the same concerns as the pending legislation?

Mr. President, I am afraid that yet another casualty of the truncated process observed by the HELP Committee in its consideration of S. 812 can be seen in the last minute inclusion of the ''file-it-or-lose-it'' and ''sue-on-it-or-lose-it'' provisions of the pending bill. But this is exactly the kind of negative outcome that can occur when there is a markup on a Wednesday and untested language appears the day before.

The truth of the matter is that is exactly what took place last week in the HELP Committee.

While I have commended Senators EDWARDS and COLLINS for rejecting the key provisions of the McCain-Schumer bill, in the case of the ''file-it-or-lose-it'' and the ''sue-on-it-or lose-it'' provisions, I must commend Senator MCCAIN and Senator SCHUMER for not including such troublesome language in the first place.

I urge all of my colleagues to think carefully about the precedent this body would be setting for patent and copyright owners if we follow the lead of the HELP Committee and retain this language.

At a minimum, I hope the Judiciary Committee will have a chance to hold a hearing on this novel language.

If the press of election year politics precludes the Senate Judiciary Committee from holding such a hearing, I would hope that the House Judiciary Committee will step up to the plate and fully vet this issue.

We need to hear from PTO and the patent bar on this issue.

We need to hear from the American Intellectual Property Law Association and the intellectual property groups on this issue.

This matter is far too important to be brushed aside in the rush of the HELP Committee to report a virtually complete substitute to S. 812—a substitute that suddenly springs forward last Tuesday, a day before the markup—a substitute that is then hastily plucked off the Senate calendar before, I believe, a committee report is even filed, and then rockets its way onto the floor as a straw man for the Medicare prescription drug debate.

I am dubious of the language in the bill that creates, I am told, perhaps for the first time in the Federal Food, Drug, and Cosmetic Act, a private right of action.

I am speaking of the provision in the Section 3(a) ''(2)(E)'' of the bill that creates what appears to be a new cause of action to attack patent listings.

Aside from setting an unwelcome foothold for trial lawyers to reach into the FDC Act, one must wonder how a provision that seems to create a parallel course of litigation to the well-established Paragraph IV patent contests simplifies or adds any measure of certainty to the patent challenge system? As the debate unfolds, I may have more to say on this matter and urge my colleagues to act to strike this language.

The last major area on which I wish to comment with respect to the pending legislation relates to the collusive agreements that have occurred in connection with the 180-day marketing exclusivity incentive of the 1984 law.

Mr. President, in closing, I have just discussed why I believe the pending bill's treatment of the 30-month stay is an improvement over the McCain-Schumer bill. For the reasons I have just discussed, I think the NDA plus 30-day rule goes too far. I come here today to give you my views on the 30-month stay issue and to see how the sponsors of the pending legislation respond to my arguments. If they say this is a nonnegotiable matter, that is one thing. If they are willing to modify the language, I will be willing to work with them on this. I would like to hear from them on this issue.

I have a number of other issues I will raise, but I want first to see whether there is a willingness to work with me in correcting what I consider to be inflexible language and to work with me in providing the flexibility to work on the 30-month stay, the file-it-or-lose-it or the sue-on-it-or-lose-it provisions, and the private right of action.

I have worked on many occasions with the Senator from Massachusetts. I have worked against him. I have worked with him. I know sometimes he adopts the no amendment strategy. The minute we yield the floor, I am raising the question of whether the sponsors are totally locked in on the language, and then I would like to hear what they have to say about the arguments I have made. This is too important an issue to play politics. We are talking about the health of the American public. I am willing to work to improve the bill. The language has improved as it has moved further away from the original Schumer-McCain language, but for the reasons I have described I think the language still needs some work.

I have a lot more to say, but I will end by rereading first an administration policy from the Executive Office of the President and then rereading a paragraph from this book.

In the Statement of Administration Policy, it says:

However, the administration opposes S. 812 in its current form because it will not provide lower drug prices. S. 812 would unnecessarily encourage litigation around the initial approval of new drugs and would complicate the process of filing and protecting patents on new drugs. The resulting higher costs and delays in making new drugs available will reduce access to new breakthrough drugs. Moreover, this new cause of action is not necessary to address patent process abuses. Clearly, the bill would benefit from consideration by the Senate's experts on Hatch-Waxman law on the Judiciary Committee, the proper committee of jurisdiction for this bill.

Let me finally conclude where I began, and that was the book written by Haynes Johnson and David Broder, highly respected journalists, certainly not conservative journalists but journalists I respect, and they said this on page 90:

In the campaign period, Fried recalled, Clinton's political advisers focused mainly on the message that for ''the plain folks, it's greed—greedy hospitals, greedy doctors, greedy insurance companies. It was an us-versus-them issue, which Clinton was extremely good at exploiting.'' Clinton's political consultants—Carville, Begala, Grunwald, Greenberg—all thought ''there had to be villains.'' Anne Wexler remembered—

Who is one of the leading Democrats in this town, one of the leading lobbyists in this town. I respect her greatly. She said—

It was a very alarming prospect for those of us looking long term at how to deal with this issue. But at that point, the insurance companies and the pharmaceutical companies became the enemy.

All I ask in this debate is that we get rid of some of this rhetoric that the large pharmaceutical companies are a bunch of criminals and bad people who have run up the costs of drugs and who really do not play much of an important role in our society, and who literally are the reason we cannot get low-cost, affordable drugs to the American people.

During those 18 days or so, whatever it was, that we debated in my office and came up with the Hatch-Waxman

Act, we had almost fist fights between the PhRMA companies, the pioneering companies, and the generic companies, but in the end we were able to bring them together. Neither side was totally happy, but I believe both sides have been totally happy with the Hatch-Waxman results over the last 18 years. To be honest, before we change something that has been so doggone effective and efficacious, I might add, to use an FDA term, it seems to me we ought to at least make sure we are doing it the right way.

I have a lot more to say, but I have spoken for a long time. I understand that. I apologize to my colleagues, but I will be back to discuss other issues such as the 180-day rule which is at the center of what are considered to be collusive deals between the generics and the pharmaceutical firms.

To me, these issues are important. I want to apologize to my colleagues for going on so long, but this is a very complex bill. There is no way it can be explained in a matter of a few minutes. I have only covered a small part of it, but I have covered some very important parts, and I think, and I hope, my colleagues will realize I have made a case that they really ought to give consideration to.

I do not have any political axes to grind. I like both sides of this business. I like the pharmaceutical companies that have done so much to come up with lifesaving drugs, and I love the generic firms that have done so much to duplicate those drugs at an almost nonexistent cost, compared to the $800 million to create those products, but that have gotten them out there in bioequivalent ways for the benefit of the American people.

They both deserve a great deal of credit. Neither one of them deserves to be torn down in the Senate. I think we can fix Hatch-Waxman in ways that will continue to give both of them the incentives to continue to provide a pipeline of very wonderful drugs, lifesaving drugs, for us, and at affordable prices ultimately. I hope my colleagues will listen to what I have to say. I do not have any desire to malign anybody, but I really believe what I have had to say today is important and that Hatch-Waxman is an important bill. I do not want to see it fouled up because we are unwilling to pay the price to do it right.

I yield the floor.

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

Mr. FRIST. Mr. President, I rise to extend in many ways the comments made by the Senator from Utah. At the outset, I not only express my respect and admiration for his eloquent remarks, but also for the tremendous commitment he has shown on this particular issue over the last 20 years, especially with the Hatch-Waxman law which for the last 18 years has achieved so much for the benefit of the American people. The Senator from Utah has shown a commitment and has shown real foresight, in sponsoring and authoring—along with other colleagues in this body—the original Hatch-Waxman bill in his eloquent analysis of the legislation before us, as has been modified and improved markedly in the Health, Education, Labor, and Pensions Committee. He has also provided an excellent analysis of the underlying McCain-Schumer bill and some of the deficiencies he sees within this legislation.

After listening to his remarks, I think the underlying message was the real beauty in this legislation and in the original Hatch-Waxman legislation in achieving a sense of balance between the brand pharmaceutical companies and what they achieve through research and development, creativity and innovation, that balance with the growth and the appropriate incentives given to the generic community, where we know that cost-effectiveness has been demonstrated and needs to continue to be demonstrated as we move forward. We need to keep this in mind especially in this world with skyrocketing drug costs, which are putting the cost of pharmaceuticals out of the reach of seniors, of everyday Americans, and of individuals with disabilities.

Much of the discussion over the last 3 days has been on how best to provide seniors and individuals with disabilities in Medicare access to prescription drugs, and that debate will continue into next week.

Throughout this entire discussion is the whole issue of cost—what we need to do responsibly that can be sustained long term in terms of cost to make sure the cost of drugs are appropriate, reasonable, and not beyond the reach of Americans. The Hatch-Waxman law has had 18 years of balance, and now is the time to go back and readjust and make sure that balance is well situated for the next 5, 10, 15, or 20 years.

I heard the distinguished Senator from Utah say the legislation, as currently written—and recall he commended the various amendment processes in the HELP Committee to improve the bill—goes too far in correcting what is out of kilter today. That balance needs to be readjusted. The underlying legislation has many deficiencies that he believes, and I agree, should be addressed. I will walk through several of those from the perspective of having served on the Health, Education, Labor, and Pensions Committee.

The issue of cost is one that disturbs everyone. It is at the heart of the discussion on health care and on extending prescription drugs in an affordable way, in a bipartisan way, to seniors and individuals with disabilities. The cost is not just in the public sector but the private sector as well. The skyrocketing cost is driving people to the ranks of the uninsured.

As we look at the overall skyrocketing cost of health care, the cost of prescription drugs is increasing in a way that cannot be sustained over time. In the name of cost savings and in the name of reaching out and rallying support for particular pieces of legislation or amendments focusing on cost savings, never should we threaten public health, which we talked about yesterday. Furthermore, never should we threaten the research and innovation that has made us the envy of the world in terms of health care—the great breakthrough drugs, the investment in research and delivery, which eventually will deliver a cure for things which are not curable today, such as HIV/AIDS. That virus will kill somewhere around 60 million people over the next 20 years. We do not currently have a cure, however, I am confident a cure will be found by research and development from our pharmaceutical companies.

The Hatch-Waxman Act has served us very well. As the distinguished Senator from Utah said, generic drugs represented only about 20 percent of the market in 1984. Yet today, half of all drugs in this country are generic which, again, is a huge advance. At the same time, we have been able to see this rise in the generic industry, which I advocate because of the cost-effectiveness that is demonstrated there because of the balance we have. The brand name pharmaceutical companies have continued to invest in research and development. Over that same period of time since 1984, that research and development by the brand name pharmaceutical companies have increased not twofold, threefold or fivefold but have increased ninefold since 1984.

We have seen dramatic breakthroughs in pharmaceutical treatments for such areas as mental health, cancer, and heart disease. Costs have put drugs out of reach for too many Americans today, and we must address that. Over time, both the generic industry and the brand name pharmaceutical companies have, unfortunately, circumvented the intentions of Hatch-Waxman. That circumvention is clearly an abuse because it ultimately drives up the cost of health care, and it must be addressed. Adjustments are in order. What concerns me and what clearly concerns the original author of the Hatch-Waxman legislation, the Senator from Utah, is that this underlying legislation goes too far.

I will comment on several of the areas. First, I restate the legislation in the Senate today is currently much improved over the original Schumer-McCain legislation introduced last May. The original version of S. 812 took a heavy-handed approach to this very real problem. It would have dealt a serious blow to pharmaceutical research and innovation, which we all depend on as we look for potential cures and potential therapies in the future.

My colleagues, Senators EDWARDS, COLLINS, GREGG, HUTCHINSON and others should be commended for working

with the chairman of the Health, Education, Labor, and Pensions Committee. Senators MCCAIN and SCHUMER also worked to approve the legislation. Nevertheless, the bill before us has significant flaws. Let me briefly outline several of my concerns.

First, we are focused most importantly on cost savings, the driving force. Everyone knows the costs are too high. It is important for our colleagues to understand there has been no demonstration that the underlying legislation will actually save money, lower the overall burden of prescription drugs and generic drugs in the aggregate to either consumers or in the aggregate in terms of the overall health care dollar.

The intent of the authors has been clear—the goal of the legislation is to improve competition. If improving competition is achieved, and I have real questions about whether competition will be improved as written, I believe costs will decrease. It will speed cheaper generic drugs to the market, which is the intent of the authors of this legislation.

Part of the legislation discussed today is clearly being promoted because of the intent, or what the proponents say it would do, and that is to lower costs. The real question is, Does it? Is there any evidence that it will do so?

The Congressional Budget Office, to the best of my knowledge, has not scored this piece of legislation. By score, I mean it has not estimated the cost of this legislation. Neither this legislation nor the original bill introduced by Senators SCHUMER and MCCAIN has been analyzed by the CBO.

As you listened to Senator HATCH's eloquent comments earlier and you listened to the complexities of this bill, I ask, Does this increased complexity and new cause of action actually contribute to increasing costs?

Lastly, I am not aware of any other estimates of potential savings by independent, nonpartisan experts that members of the Senate will have a chance to review before we go forward.

My second point refers to how best to curb abuses. The whole idea of curbing abuses is a common goal that we share in the underlying legislation, in the amendment process, and in the H.E.L.P. Committee. As Senator HATCH again spelled out in his comments, the Federal Trade Commission is currently conducting an extensive study of potential abuses in this area. As we discussed in the hearing several days ago and as Senator HATCH requested, the FTC is preparing a report regarding this area. It would be nice to have an objective body like the Federal Trade Commission present its data before we potentially complicate legislation over the next several days and weeks.

Unfortunately, we are not going to have that opportunity. It is too bad because as I understand it, the real problem is being made in terms of the Federal Trade Commission's ongoing study.

Current law, as we look at the 180-day exclusivity provision, provides an incentive for the first generic that challenges an innovator's original patent. It awards that generic company 180 days, or about 6 months, during which other generics may not be approved. The bill before the Senate, which is quite different than the original legislation, provides that if one generic loses that 180 days of exclusive rights, it can pass on to the next generic.

I am told the 180-day exclusivity rule has been the most frequently litigated area of the Hatch-Waxman legislation over the last several years.

I am concerned and again this understates the concern of Senator HATCH. The provisions in the proposed bill are overly complex and they might actually encourage even more litigation and promote even greater confusion in this area.

As Senator HATCH mentioned, during the Health, Education, Labor, and Pensions Committee's evaluation, we reached out to understand the language in this particular bill. I have to admit that the new bill's language was confusing to me, but at the end of our discussion, my interpretation as we listened to the proponents of the bill is that the 180-day exclusivity period would allow, theoretically, a rollover indefinitely.

If that is a correct interpretation, it could actually take longer for cheaper generic drugs to get to the market. While a generic drug would be cheaper during this 180-day period than a brand name drug, it certainly would be more inexpensive during the 60-day or 180-day exclusivity period, where it had absolutely no generic competition.

Last May, Senator HATCH and others were highly critical of a concept of rolling exclusivity when they testified before the Health, Education, Labor, and Pensions Committee. In fact, Senator HATCH testified and quoted former Acting Director of FDA's Office of Generic Drugs, Gary Buehler, as follows:

> We believe that rolling exclusivity would actually be an impediment to generic competition.

Senator HATCH further stated:

> If our goal is to maximize consumer savings . . . it is difficult to see how rolling exclusivity achieves this goal.

In fact, many experts believe and have expressed that the 180-day exclusivity period is no longer necessary today, and that if it were abolished, even more significant cost-savings could be achieved. Moreover, eliminating the 180-day provision altogether, in my opinion, could be the best way to curb abuses currently being investigated by the FTC—where brand companies and generic companies have allegedly entered into collusive and potentially anti-competitive agreements to prevent cheaper generic drugs from coming to market and benefitting consumers.

My main point is if we are going to act in the absence of the FTC report, which examines this very issue and their findings, we clearly should not add confusion to this area. We should not add provisions which would increase litigation or increase costs, and we should not add provisions that could exacerbate incentives for anti-competitive behavior by both generic and brand name drug companies. This is the area we need to fix.

If we are not ready to eliminate this 180-day rule or wait for the FTC report to help guide us on how we can make that ultimate decision and act responsibly, I believe what is called a ''use it or lose it'' policy would better discourage anti-competitive behavior. This so-called ''use it or lose it'' policy would take away incentives for generic companies to make their own potentially anti-competitive arrangements.

Senator GREGG initially proposed this ''use it or lose it'' policy during the Health, Education, Labor, and Pensions Committee consideration of this legislation. I believe this policy would clearly benefit consumers more than any form of ''rolling'' exclusivity. If we are going to act in the absence of the full report of the FTC, we ought to at least to do so in a straightforward way that promotes competition and that clearly helps consumers.

The third issue I would like to raise is the issue of bioequivalence. This is a particular issue that I introduced in the Health, Education, Labor, and Pensions Committee and spoke a little about on the floor two days ago. Again, it is an issue I want to put out to my colleagues for their consideration. The unintended consequence, in the way this legislation is written, is potentially harmful in a way that I will delineate.

The Hatch-Waxman law allows generic companies to market off-patent drugs if they are able to demonstrate this so-called bioequivalence. Bioequivalence simply means the active ingredient in a generic pharmaceutical or a generic drug is absorbed at the same rate and to the same extent as the brand drug.

The bill before us—and this is the key point—could significantly weaken this important patient protection by giving the Food and Drug Administration broad authority to significantly relax, to loosen, the statutory Hatch-Waxman bioequivalency standard. My concern is this potential loosening of the standards.

We all have agreed—at least in the Health, Education, Labor and Pension Committee discussions, including the proponents of the legislation—that the FDA has broad authority with regard to bioequivalence and that there has not been a successful challenge to the FDA bioequivalence standards as they exist today.

Based on existing statutory language the FDA has developed through the process of notice and comment—rulemaking specific bioequivalence test methods to address a range of products have been established over time. They

have not been successfully challenged. As we discussed this in committee, the FDA has been uniformly successful in defending its bioequivalence methodology and its findings. In fact, we agreed in committee that the FDA's authority in this area has been repeatedly upheld. There has not been a reported case challenging the FDA's bioequivalence standards since the case was decided in FDA's favor back in 1997, five years ago.

Therefore, as we look at bioequivalence, I think it is unnecessary, imprudent, and unwise to include any bioequivalence language in this legislation. Nonetheless, the bill before us would deem FDA's regulations to be authorized under relevant provisions of the Food, Drug, and Cosmetic Act.

Again, my concern is that it could insulate the FDA from any potential challenge in this area.

The reason I keep bringing it to the floor and talking to my colleagues about this issue is because I hear a lot about it from the medical community, the scientific community, and the biological research and development community. Given the importance of the bioequivalence requirement in assuring the safety of generic drugs, I believe any loosening of standards is in the disinterest of the American people. Why? Because, once again, it goes back to safety and public health. Instead of moving forward, it is moving backwards.

There are many examples, but a typical example would be taking a blood thinner such as Coumadin. Coumadin is used all over the country. It is a tremendous drug and a very powerful drug. It is well known that one generic of Coumadin versus another versus yet another behaves in a different way, even if you prescribe the same dose in milligrams. The bioequivalence can be variable and might be tiny, 3 percent, 5 percent, 8 percent. But when the goal is thinning of the blood so you do not have another stroke or heart attack, when you go from one drug to another drug for whatever reason—it might be the pharmacy telling you to do it, it might be your health plan, it might be you who has chosen to do it—your blood might be thin one day and not thin the other, and you think you are taking the same drug.

That is what bioequivalency is—where there might be loosening of the current standard. The reason I say there might be loosening is because people who are a lot smarter than I who study the language tell me the language as written looks to be loosening.

Mr. GREGG. Mr. President, will the Senator yield for a question?

Mr. FRIST. I am happy to yield for the question.

Mr. GREGG. The Senator from Tennessee understands the issue better than anybody else, and certainly the points he makes are excellently made.

It was my understanding on this specific point of bioequivalency that the Senator had a commitment from a primary Democratic sponsor of the bill, Senator EDWARDS, that this would be worked out or straightened out before the bill came to the floor. Am I correct?

Mr. FRIST. Mr. President, in response to my distinguished colleague, this issue of having a general agreement that we would work out technical language, and then after 48 hours or 72 hours have the bill come to the floor without the opportunity, in a bipartisan way, to be able to access experts in the field, is what concerns me most. You can take an initial bill and improve it a little bit, and then you can leave something out and not reach bioequivalency. In response to the question is a particular instance where during the discussion, the mark-up, we said let's get together and make absolutely sure that we address it in a way so that standards are not being loosened; yet, the bill that comes to the floor does not have that guarantee in it.

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

Mr. FRIST. Mr. President, let me continue. Let me answer one question, and then return to my comments. I would be happy to yield for a question.

Mr. DURBIN. The Senator from Tennessee is the expert. He is a cardiac heart surgeon who is recognized for what he has done before he came to the Senate. I will certainly bow to his educational and professional experience.

Talking about bioequivalency, is it not true that when it comes to the efficacy of a drug that we should also take that into consideration when we are dealing with women, children, or pregnant women? It is my understanding that all of these are relevant to the efficacy of drugs—bioequivalency.

Is it not correct that were it not for the congressional pressure and mandating the same pharmaceutical companies the Senator is speaking of they would not be engaged in clinical trials sufficient to make certain that the efficacy of drugs would be the same for women and men, and dosages for children?

The point I am making is the industry, itself, had to be pushed into a position to find exactly what was better for people in usual circumstances of life. Is that not a fact?

Mr. FRIST. Mr. President, I agree with my distinguished colleague that we need to do a much better job in pushing the pharmaceutical industry to make sure that when it comes to testing of drugs or investigating drugs that they are adequate, especially as you look at bioequivalency in a varied population.

In fact, in the HELP Committee, as my colleague knows, we have passed legislation and we will continue to work on legislation that says we need to do more in terms of testing to see what the bioequivalent standard is. What is called in my profession of medicine a ''dose response'' relationship is in populations—whether it varies by race, age, or gender—we need to do a lot more. We need to keep pushing there.

My concern with bioequivalence—we will agree, whichever population it is or whether clinical trials are being conducted—the way this language is written today allows a significant loophole for a lessening of the bioequivalent standards that we as the American people deserve. That is my concern.

As the Senator from New Hampshire addressed in his question to me, we are reaching out. Clearly, we are in the minority. We are not going to have the votes. But I am going to continue to reach out. And I think you will see that our side will continue to reach out in the interest of cost savings. We do not want to push so hard that we lower the standards for the safety of the American people who take these drugs. I do not care if the cost savings is $100, $50, or $5. If that drug is not bioequivalent—if the dose is too strong, then your blood will not clot properly and you can get a stroke from bleeding in the brain, or, if the dose is too weak, then your blood clots too easily and you can get a stroke from having a blood clot go to your brain—you have done a disservice to the American people.

As the Senator from New Hampshire just mentioned, I will continue to reach out on this particular issue of bioequivalence.

You heard Senator HATCH from Utah stress that we need to slow down a bit to make sure that your intent in having cost savings does not hurt the American people. That is really the issue.

I am not the expert. Of course, I have dealt with a lot of these drugs, and I know what it is like being told by a managed-care organization that you have to switch drugs. The fear I have is that the drug has not been tested in a certain population effectively. Again, it could be by race or gender or age. That concerns me. Therefore, I do not want any lowering of those standards by our Government.

The Biotechnology Industry Organization sent a letter to Senator KENNEDY dated July 15.

I ask unanimous consent that it be printed in the RECORD.

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

BIOTECHNOLOGY INDUSTRY ORGANIZATION,
*July 15, 2002.*

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

DEAR SENATOR KENNEDY: This letter protests proposed legislation (the Edwards-Collins substitute) to alter the Hatch-Waxman Act of facilitate generic drug approvals. The substitute's proposed changes raise serious concerns for members of the Biotechnology Industry Organization (BIO). We urge you to reconsider these amendments and to work on a more considered basis on any effort to revise the carefully-balanced Hatch-Waxman system.

As you know, the Drug Price Competition and Patent Term Restoration Act of 1984 (the ''Hatch-Waxman'' Act) strikes a balance between promoting access to generic drugs and fairly protecting the legitimate rights of the patent holder. It proves an expedited path to market for generic drugs, while ensuring that innovators receive an adequate term of patent life to stimulate new drug development.

The initial purposes of proposed amendments to Hatch-Waxman were to prevent abuses and facilitate efficient market entry of generic products. The reported bill goes far beyond these purposes. Among other things, the reported bill would completely abolish patent rights if litigation is not initiated within 45 days of notice by a generic that it intends to challenge a patent, or if a new drug applicant failed to list its patent with the FDA within 30 days. It creates a private right or action for generic manufacturers to attempt to ''correct'' patent information filed on a listed drug. At least prior to committee consideration, the bill provided the FDA with broad authority to define and apply standards governing bioequivalence—the critical determination of safety and efficacy of a generic drug—without challenge (or even comment) from affected members of the public. If enacted, these proposals would significantly erode the measures included in Hatch-Waxman to ensure an effective patent incentive for new drug development, and would create undesirable precedents for sound science-based regulations of drug products in the United States.

Our specific concerns follow:

When it enacted the Hatch-Waxman Act, Congress recognized that patent disputes over drugs regulated by the abbreviated new drug procedure were inevitable. The abbreviated new drug system thus provides procedures to permit generic and pioneer manufacturers to resolve these disputes before the FDA grants marketing approval to a generic producer. Under its procedures, the FDA will not immediately approve an abbreviated new drug application if the ANDA applicant challenges a patent that has been identified as covering the drug (a so-called paragraph IV patent certification). Instead, the patent challenge triggers, by statute, an opportunity for the patent owner to initiate a legal proceeding to resolve the patent dispute. The initiation of a patent suit in response to the paragraph IV certification will trigger a 30-month stay of action by the FDA on the abbreviated new drug application. The patent challenge procedures and the stay of approval ensures that products that would clearly infringe the patent rights of the innovator will not enter the market.

The amendments approved by the HELP Committee convert these procedures—which were designed to enhance the ability of a patent owner to enforce its rights—into an all or nothing system that can eliminate the patent rights of our companies. Under the legislation, a patent owner who for any reason fails to initiate litigation against a generic drug applicant within 45 days of receiving notice under the ANDA procedure will be barred from enforcing patent rights in any forum against either the ANDA applicant or any party that manufactures, uses, sells or offers for sale the approved drug product. In addition, a new drug applicant—who may not even be the patent owner—who fails to list a patent with the FDA within 30 days of approval of a new drug application, or within 30 days of the grant of a patent if that occurs after the NDA is approved, is similarly barred from enforcement of patent rights on the drug against a generic manufacturer. Either of these events will completely abolish patent rights in new drugs or related technology.

The legislation also creates new opportunities for generic drug makers to harass our companies through unnecessary and pointless litigation. As proposed, our companies and their drug marketing partners would be required to list patents that pertain to an approved new drug. Failure to list patents would render our patent rights void. Notwithstanding this mandatory listing process, the legislation would create a private right of action to permit a generic manufacturer to challenge these mandatory patent listings. The legislation also would allow generic drug applicants to initiate this litigation regardless of whether our companies or their partners intend to assert their patent rights in the ANDA process. Plainly, the motivation to prevent improper listings of patents has been turned onto its head by these procedures.

Members of BIO thus unquestionably will be harmed by the Edward-Collins substitute. Many of our companies focus on improving currently marketed drugs regulated under the new drug and abbreviated new drug approval system. These innovations of our companies create new and better medicines for patients that are more effective, easier to administer and open up new opportunities for treating unmet medical needs. These technologies frequently—often by commercial necessity—are licensed to multiple drug manufacturers who have the resources to bring new drug products that use these technologies to market. Perversely, under the legislation approved by the HELP committee, if our companies elect to not aggressively enforce their patent rights by immediately suing every generic drug applicant, or if one of the marketing partners makes administrative errors in listing patents with the FDA, the patent rights of our companies will be forfeited. This forfeiture will occur without compensation, without a right of appeal and without any recourse. This provision is probably unconstitutional, and in any event is totally unconscionable.

Finally, as you know, as originally drafted, Section 8 of the bill would selectively codify certain regulations governing ''bioequivalence'' requirements and would legislatively shield the FDA from challenges to its actions in setting approval standards. We understand the purposes of Section 8 to be limited: to confirm the authority of the Food and Drug Administration to use testing methods other than those specifically set forth in current law to establish the bioavailability and bioequivalence of a generic drug, when the methods specified cannot be applied. Types of generic drugs to which alternative testing methods would be applied would include drugs intended to deliver the active moiety locally, such as topical preparations for the skin or oral dosage forms not intended to be absorbed.

As pointed out by Senator Frist during markup, section 8 as currently drafted goes far beyond the intended purposes of the provision. The draft proposal presented during markup would codify fifteen pages of FDA regulations governing ''bioequivalence'' requirements on both new drugs and generics and would legislatively shield the FDA from challenges to its actions in setting approval standards. In essence, the proposed changes would make it impossible for drug manufacturers, whether pioneer or generic, or members of the public, to challenge improper standards enacted by the agency on key approval criteria, or to challenge improper decisions made under valid authority. Moreover, the current regulations include several provisions in which FDA provides to itself unfettered discretion to create or define at will any standard ''deemed adequate by FDA.'' This makes an otherwise legitimate challenge to an agency decision virtually impossible to sustain. Shielding the agency from actions to challenge its proper authority simply makes no sense, particularly when the consequences involve potential risks to patients and to public health.

We were assured by your staff that this provision would be narrowed to its intended scope, in consultation with BIO, prior to floor consideration, and we provided alternate language to your staff that would accomplish the intended purpose of section 8. We have been presented with another draft that would continue to codify all of FDA's bioequivalence regulations (including the ability to define at will any standard it deems adequate) but only preserves ''existing'' legislative authority to regulate biologics under the Federal Food, Drug and Cosmetic Act. This is simply unacceptable to BIO. At this stage we can only ask that the entire section 8 be deleted. We point out that FDA's authority to establish different standards for non-systemic drugs has been confirmed by the courts. See *Schering Corp.* v. *Food and Drug Administration*, 51 F. 3d 390 (3rd Cir., 1995).

Provisions in the draft that served as the basis for committee discussion were made available to the biotechnology industry less than two days prior to markup. These provisions would have an enormously negative impact on the property rights of the emerging biotechnology industry and completely upset the delicate balance between the interests of pioneer and generic companies crafted by the Hatch-Waxman law. They go far beyond the provisions of McCain-Schumer, which served as the basis for the Edwards-Kennedy redraft; the late release of the redraft made meaningful legal review and comment impossible.

We urge you not to rush this bill to the Senate floor. The implications of the changes being proposed by the Edwards-Collins substitute are far reaching and will significantly and adversely impact biotechnology companies. They would severely diminish the incentives of the patent system for our industry to develop newer, safer, easier to administer and more effective drugs that could help patients lead better lives. The changes being proposed, simply stated, will not yield better results for patients or the biotechnology industry.

Sincerely,

CARL B. FELDBAUM,
*President.*

Mr. FRIST. Mr. President, I also ask unanimous consent to have a similar letter from the Massachusetts Biotechnology Council be printed in the RECORD.

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

MASSACHUSETTS BIOTECHNOLOGY COUNCIL,
*Cambridge, MA, July 16, 2002.*

Hon. EDWARD M. KENNEDY,
*Russell Senate Building,*
*Washington, DC.*

DEAR SENATOR KENNEDY, I request that you oppose S. 812, legislation to alter the Hatch-Waxman Act. The bill raises serious concerns for our Massachusetts Biotechnology Council membership. I urge you to work on a more considered basis on any effort to revise the carefully-balanced Hatch-Waxman system.

I understand that under the reported bill, a patent owner who for any reason fails to initiate litigation against a generic drug applicant within 45 days of receiving notice under the ANDA procedure will be barred from enforcing patent rights in any forum against either the ANDA applicant or any party that

manufactures, uses, sells or offers for sale the approved drug product. In addition, a new drug applicant—who may not even be the patent owner—who fails to list a patent with the FDA within 30 days of approval of a new drug application, or within 30 days of the grant of a patent if that occurs after the NDA is approved, is similarly barred from enforcement of patent rights on the drug against a generic manufacturer. Either of these events will completely abolish patent rights in new drugs or related technology.

The legislation also creates new opportunities for generic drug makers to harass biotech companies through unnecessary and pointless litigation. The reported bill would create a private right of action to permit a generic manufacturer to challenge these mandatory patent listings. The legislation also would allow generic drug applicants to initiate this litigation regardless of whether our companies or their partners intend to assert their patent rights in the ANDA process.

The proposal would codify fifteen pages of FDA regulations governing ''bioequivalence'' requirements on both new drugs and generics and would legislatively shield the FDA from challenges to its actions in setting approval standards. In essence, the proposed changes would make it impossible for drug manufacturers, whether pioneer or generic, or members of the public to challenge improper standards enacted by the agency on key approval criteria, or to challenge improper decisions made under valid authority. Moreover, the current regulations include several provisions in which FDA provides to itself unfettered discretion to create or define at will any standard ''deemed adequate by FDA.'' This makes an otherwise legitimate challenge to an agency decision virtually impossible to sustain. Shielding the agency from actions to challenge its proper authority simply makes no sense, particularly when the consequences involve potential risks to patients and to public health.

I urge you to oppose S. 812. The implications of the changes being proposed are far reaching and will significantly and adversely impact biotechnology companies. They would severely diminish the incentives of the patent system for our industry to develop newer, safer, easier to administer and more effective drugs that could help patients lead better lives. The changes, simply stated, will not yield better results for patients or the biotechnology industry.

Sincerely,

STEPHEN MULLONEY,
*Director of Government Relations and Communications, Massachusetts Biotechnology Council.*

Mr. FRIST. Mr. President, the Biotechnology Organization represents over 1,000 biotechnology companies and their members all over the country and in every State. California, Massachusetts, and Maryland have the highest concentration of biocompanies in the United States.

I think what people understand and what my colleagues understand is that the biofield is a fairly new field. When I was in medical school, these biotech companies were not out there. The drugs they are looking at today were nonexistent. For the most part, they are in their infancy today. Fifty years from now and looking back, we will see on the curve an increase that right now we are at the beginning of.

Of the 130 biotech drugs approved by the FDA, all were produced by fewer than 100 companies. As I just said, there are over 1,000 biotechnology companies that exist today. What that means is, if you have ten companies working at the early research stage to figure out what drug is going to cure HIV/AIDS, or reverse a certain case of emphysema or reverse that blood clot just about ready to cause a stroke in your brain, one company will ultimately produce an effective product. Many of these companies are small, emerging companies.

Look at Senator KENNEDY's language on bioequivalence. That is the language that will ultimately go into the bill.

These letters make clear the concerns raised by myself in committee and others during the Health, Education and Labor Committee markup. The bioequivalent language in the underlying bill has not been addressed.

You heard Senator HATCH's plea. Even if this bill sails through, please listen to us and allow us to participate in changing that language.

Let me just say that I also share the concerns of others about the codification in this bill.

Let me quote from their letter only three sentences. This is from the biocommunity.

> . . . section 8 as currently drafted goes well beyond the intended purpose of the provision. In essence, the proposed changes would make it impossible for drug manufacturers, whether pioneer or generic, or members of the public, to challenge improper standards enacted by the agency on key approval criteria, or to challenge improper decisions made under valid authority. Moreover, the current regulations include several provisions in which FDA provides to itself unfettered discretion to create or define at will any standard ''deemed adequate by FDA.'' This makes an otherwise legitimate challenge to an agency decision virtually impossible to sustain. Shielding the agency from actions to challenge its proper authority simply makes no sense, particularly when the consequences involve potential risks to patients and to public health.

Bioequivalence—again, that is probably the last time I will be able to address this issue on the floor. It is a plea that we work together and come to an agreement so we do not accomplish a loosening of these standards.

The Senator from Utah also mentioned the 30-month stay provisions.

Let me just say that this 30-month stay provision has served a very important purpose. If you look back at the legislation, which is consistent with remarks from the Senator from Utah, you will see that the 30-month stay is part of the balancing act between the brand name pharmaceutical companies, which are heavily invested in R&D, and the cost-effective generic companies to achieve that balance, which we have seen is so important.

As I have said, it has been the magic over the last 16 to 18 years. We need to be very careful when we start tinkering with that and whether or not that goes too far in upsetting that balance.

I know and my colleagues know that there have been huge abuses by some brand name companies versus the generic companies in our discussions. They have filed what are late patents. They file late patents that may not represent significant medical advances. Their purpose is because they saw the law written this way as simply to extend that 30-month stay protection period. And they are protected. When you have that sort of protection, obviously, it affects prices throughout.

The legislation before us would treat patents, listed after a new drug application is approved, differently than patents listed when a new drug application is approved. Providing lower protections to patents at any point in time will have real implications in terms of innovation, in terms of incentives to innovate as you develop new formulations and new aspects of drugs.

There are a whole slew of examples where these patents that are issued, not early on but later, could involve an important innovation. I will not go through the examples here today, but we have talked about them in our Health, Education, Labor, Pension Committee.

So if you have a new drug here, a patent here, and you can improve on that drug later in the life cycle, that improvement needs to be protected in some way. Furthermore, you need to give a pharmaceutical company an incentive, which is what this patent protection is. That is what patents are all about: an incentive to look at a new formulation of that drug that could be important.

There was a question, a few minutes ago, about certain populations. For example, this applies very specifically to the pediatric population. If you have a drug that can either be injected or be applied intravenously inside a vein, and you have a patent on that drug, it would be nice to give somebody an incentive to make sure you can use that same drug in a liquid formulation, to give them some incentive to develop that liquid formulation. And it may come later in the cycle of that drug.

In fact, two weeks ago Dr. Tony Fauci of NIH was quoted in the New York Times about the importance of developing an oral formulation of a drug that was discovered as an injectable drug to treat HIV/AIDS. Forty million people in the world today with HIV/AIDS are struggling in countries, such as in Africa, where two out of three of these cases are today. Many of my colleagues, on both sides of aisle, are trying to figure out how we can link prevention, care, and treatment. The problem is, treatment today is just so expensive. So we want to incentivize people to take an injectable drug, which is very difficult to administer throughout Africa, and develop an oral formulation of that particular drug.

Dr. Tony Fauci talked about the importance of developing and patenting an oral formulation of this drug. Unfortunately, that is the kind of new patent, on a previously discovered drug,

that would be afforded less protection under this bill. When you afford something with less protection, it is true that fewer companies, fewer people, are going to be interested in investing and figuring out that new formulation.

Again, because the distinguished Senator from Illinois mentioned the pediatric population, it brings to mind the fact that we worked very hard on what is called a pediatric exclusivity bill. We unanimously passed it in the Senate. It provides a market incentive for brand-name drug companies to test certain drugs in the pediatric population. Many of us were cosponsors of that bill, and it unanimously passed in this body. It provides a market incentive for brand-name drug companies to test certain drugs for pediatric use for which the FDA issues a written request.

We gave certain protections. Now, all of a sudden, we are saying: Well, maybe or maybe not in the pediatric population. Let's lower the protections that we are giving instead of increasing the protections—which was the intent of this body—and give less legal protection just because of the timing in which a patent was filed.

The issue is complex, as Senator HATCH has said. People say, you are being critical of it. You illustrate the problems. Are there better approaches? The answer is, yes, there are better approaches, to my mind, that I hope we will have the opportunity to debate.

One approach would be to not allow brand companies to automatically extend the 30-month stay for patents issued after the filing of what is called an abbreviated new drug application—what is called an ANDA—by a generic company.

Another alternative would be to allow an additional 30-month stay only for patents that were filed but not approved by the Patent and Trademark Office at the time of the NDA.

The impact of this would be to reduce incentives for brand companies to ''game'' the system, something that all of us want to avoid—companies coming in and trying to take advantage of whatever structure we set up.

The fifth point that I want to bring up, in the hopes that we will be able to come back in some form to be able to address these issues, is the broad bar on patent lawsuits. Senator HATCH also raised this point, for the record.

I am troubled by provisions in the bill that cause patent holders to lose their rights to sue for infringement of a patent if the patent holder does not meet certain requirements, including these timing requirements.

For example, a patent holder would lose its right to sue for infringement if it does not submit appropriate patent information to FDA within the specified deadline, or if it does not bring an infringement lawsuit within 45 days of receiving notice from the generic applicant that its patents are being challenged.

I believe this fundamental change, of which the Senator from Utah spoke, to the Hatch-Waxman law will force companies to bring more litigation, not less litigation. In our hearing, we kept saying that we want to see less litigation. It will force more companies to bring more litigation to avoid the risk that otherwise they will waive their rights for all time.

If they do not sue, they are going to waive those rights for the future. That is a concern to me, especially as we are looking to decrease the number of lawsuits and decrease overall cost.

In fact, as I understand it, this provision alters basic rights that go with a patent, rights that give brand-name drug companies the incentives, as I mentioned earlier, to improve upon existing products.

I have to ask: What happens if a patent owner does not have a good-faith basis to sue at some point in time, but later learns something that would give him reason to sue for infringement? The answer is that that patent holder is simply out of luck.

America's research institutions and academic medical centers would clearly suffer under the ''list-it-or-lose it'' or ''sue-or-suffer'' provisions of this bill. Under these provisions, NDA holders are required to file patents that meet listing criteria whether or not they own or have a license under those patents. Under the bill, patent owners will be lose their rights to enforce their patents if the NDA holder fails to list, and the patent owners can do nothing about that (only NDA holders, not patent owners, have the ability to list patents).

For example, suppose Harvard University owns a patent on a drug substance discovered by one of its academic researchers. Normally Harvard would license that patent to a brand name pharmaceutical company that would develop the drug and submit an application for approval to the FDA. Under the bill before us, if that brand name company failed to list the patent within the arbitrary 30 day period, Harvard, the patent owner, would irreparably forfeit its ability to enforce its valuable patent rights against any generic drug applicant forever.

This is true even if a company completely unrelated to Harvard develops a drug that might potentially be claimed in a Harvard patent. Under this approach, Harvard, which has not control over the timing of the listing, would suffer a complete loss of its patents rights against generics without any recourse or ability to remedy the situation. That is both arbitrary and punitive.

While we are acting, in large part, over these next several days out of concerns over health care costs, as I mentioned before, the Senate has no formal cost estimate from the Congressional Budget Office, the Office of Management and Budget, or really any other credible source.

I mention that only because the overall assumption—and what we would all like—is that whatever we pass here will ultimately bring costs down. But we do not have any outside independent evaluation of that.

While we are acting aggressively to curb past abuses, we do not have the benefit, as you have heard from Senator HATCH and myself today, of the ongoing information that is being compiled by the Federal Trade Commission. The FTC has been specifically charged with the investigation of potential abuses by brands and generics. I believe and I am confident this report will provide crucial additional information. As Senator HATCH has said: We just simply don't have the facts.

I look forward to working with my colleagues on these issues. Again, Senator HATCH and I have spent a long time outlining our concerns, in large part, because I do not think we are going to be in the climate—I know we are going to other very important amendments about extending prescription drug coverage to seniors—that each of these very technical issues are going to be able to be adequately debated, but also to write in language that would fulfill the intentions on the floor, and that we are going to reach out and hopefully have that opportunity to work together on these.

I will likely end up, for the reasons I have outlined, voting against this underlying base legislation, despite the good work and the incremental advantages that have been added to this bill by Senators COLLINS—and I mentioned most of them—EDWARDS, GREGG, HUTCHINSON, and many of my colleagues.

The bottom line is, the balance is critical. Balance has been achieved to a very successful degree, much better than I would think anybody would have anticipated in 1984 from the Hatch-Waxman legislation. It is the magic as to why it has worked. It is why we have seen this proliferation of generic drugs and, at the same time, preserving the innovation and research.

What I am afraid is that in the legislation as written, we have gone too far. Going too far could indeed have a detrimental impact on research and innovation and the public good, without providing the cost savings promised by its supporters.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Illinois.

Mr. DURBIN. Mr. President, I ask unanimous consent that before I am recognized to speak, the Senator from Missouri be recognized for 5 minutes.

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

The Senator from Missouri.

Mrs. CARNAHAN. I thank the Senator from Illinois.

Mr. President, over the next 2 weeks, the Senate will address an issue that Americans have come to understand far too well—the high price of prescription drugs. We need to do all we can to lower the price of prescription drugs for consumers.

Senator STABENOW's amendment is one example of a concrete action the Senate can take. Her amendment would give the State the flexibility to negotiate Medicaid drug discounts for non-Medicaid-eligible individuals. This amendment would help lower prices for all consumers. I am a cosponsor of the amendment and encourage my colleagues to support it.

We need to do much more. We need to pass the underlying Schumer-McCain legislation. Today, pharmaceutical companies are making historic profits while average Americans are paying historic prices. Let's look at those profits.

Earlier this year, Fortune magazine did a comparison of U.S. industries to see how profitable they were in the past year. The pharmaceutical industry ranked No. 1 in all three of Fortune's profitability measures. Almost 20 percent of its revenues were profits.

But now let's look at the prices. In 2001, the prices of the 50 prescription drugs used most often by seniors increased on the average by nearly three times the rate of inflation. For example, Lipitor, which is used to treat high cholesterol, rose 13.5 percent, more than five times the rate of inflation. Paxil, which is used to treat depression, rose 11.6 percent. And Celebrex, used to treat arthritis, rose 10.4 percent. For seniors who are living on a fixed income, the high price of prescription drugs means making tough choices every day between lifesaving medication and food and rent and heat.

The No. 1 issue which I hear about in Missouri from our seniors is prescription drugs. Whether people live in urban or rural or suburban areas, they are all feeling the pain of high prices.

Recently, I visited the Terrace Retirement Community in Columbia, MO. While I was there, I led a roundtable on the topic of prescription drugs. If you could have heard some of those stories. They were definitely heart wrenching.

One of the women I met that day in Columbia was Annie Gardner. She is an impressive 63-year-old mother of five children, but she suffers from diabetes and high blood pressure. Her hardship began after taking a buyout from her employer. In this transaction she lost her health insurance and was not able to afford insurance on the private market. This left her unable to afford her prescriptions. Often she had to ration them by taking half the prescribed amount so it would last longer.

Ms. Gardner knows how dangerous this can be because she is a licensed practical nurse and has been for 40 years. Later, she had to quit purchasing the drugs entirely because of other expenses, such as fixing her car and paying increased taxes on her home. Ms. Gardner and thousands like her make these tough life-threatening decisions every day. But no one should have to make those kinds of decisions.

Seniors are not the only ones who have been hit hard. For far too many families, the cost of prescription drugs is a budget buster. Working families without health insurance are paying the highest price of all because they do not get the benefits of the negotiated discounts. This issue also hits employers. They absorb the cost of high prescription drug prices in the health benefit packages they provide to their employees.

For example, last year General Motors spent $1.3 billion for prescription drugs for its employees and retirees. This problem has reached such a crisis that companies, including General Motors, have joined the Governors to form the Business for Affordable Medicine Coalition. Their key issue is the one we are debating today—closing the loopholes in the current law so that generic drugs can compete fairly with brand name drugs.

I am pleased that the Senate is considering ways to close these loopholes with the Greater Access to Affordable Pharmaceuticals Act. I applaud Senators SCHUMER and MCCAIN for authorizing this legislation. I, too, am proud to be a cosponsor of that bill.

It is imperative that we close these loopholes in current law that prevents generics from coming on the market. Generics cost on the average one-third the price of brand name drugs. Generics bring competition into the market and lowers the price for drugs for all Americans.

When a brand name drug is under patent, its manufacturer enjoys a monopoly. One company sells the drug; one company sets the prices. Now I support patents for drugs. Patents are there for a legitimate reason—to allow companies to recoup the cost of research and development that they invest in creating the drugs. But drug companies are abusing loopholes under the current law and extending their monopoly on prices sometimes for years at a time.

A 1-year delay in a generic coming to market can translate into hundreds of millions of dollars in profit for the brand name company. In 1984, Congress passed the Hatch-Waxman act. This act was intended to strike a balance, a balance between brand name drug companies being compensated for their investments and generic companies eventually having access to the market. But the original purpose of the law has been distorted.

The law is now being used to extend patent protections far beyond what Congress intended. Balance needs to be restored. American taxpayers deserve better than what they are getting.

Over the next 5 years, a remarkable 26.7 percent of the entire 2001 pharmaceutical market is scheduled to face exposure to generic competition. If generics are allowed to come on the market, it would mean more choices and lower prices.

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

Mr. DURBIN. Mr. President, I yield 5 additional minutes to the Senator from Missouri with the consent of the Senate.

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

Mrs. CARNAHAN. Generics can save consumers over 60 percent per prescription. Here are some examples of brand name drugs whose patents are supposed to expire in the next few years. Listen to the numbers on what consumers should be expected to save.

The patent on Claritin, an allergy medication, is scheduled to expire in December. Annual savings after the generic becomes available are expected to be over $500 million. The patent on Zocor, a cholesterol-lowering drug, is scheduled to expire in December 2005. The annual savings after the generic becomes available is expected to be about $735 million. The patent on Zoloft, a drug for depression, is scheduled to expire in December 2005. The annual savings after the generic becomes available is expected to be $577 million.

However, given the amount of money that is at stake, pharmaceutical companies have a lot of incentive to delay generics from coming on the market. Unfortunately, current law allows them to do this.

If we in this Congress have the courage to act, American consumers will save billions of dollars. If we don't, the money will go directly from the pocketbooks of American families and on to the profit statements of the drug companies.

Congress must move on yet another front. We will soon be considering a historic addition to the Medicare Program, a prescription drug benefit. The legislation I am supporting would create an affordable and accessible benefit administered through the Medicare Program.

This Senate plan is simple. Assistance begins with the first prescriptions. There are no gaps or limits on coverage, and seniors will pay $10 for generic drugs and $40 for brand name drugs. There is certainty and there is stability.

The House bill is the complete opposite. It is complicated. There is a $250 deductible before seniors get relief. There are months where seniors have to pay a premium, but they would not get assistance with their drug costs. Under the House plan, seniors will pay approximately a $35-a-month premium but still pay the full price at the drugstore.

The House Republican plan would require seniors to use drug HMOs to get their benefit. However, there are no guarantees that private plans would provide a benefit in all geographic areas, or that a plan would even stay in business.

Look at what has happened with Medicare+Choice, Medicare's HMO. Since 1998, nationwide, 2.2 million Medicare enrollees have lost Medicare+Choice as an option because of plans withdrawn from the market. In Missouri, from 1998 to 2001, eight health plans stopped providing Medicare+Choice options in the State.

Furthermore, some options are available in only urban centers and not in rural areas.

Why would we rely on this same type of system to give prescription drug coverage to rural areas?

To me, what the House passed is unacceptable. It is an incomplete benefit with absolutely no effort to lower drug prices. It is unacceptable for Missouri's seniors and unacceptable for American seniors. We must do better in the Senate.

I yield the floor.

The PRESIDING OFFICER. The Senator from Illinois is recognized.

Mr. DURBIN. Madam President, I thank my colleague from Missouri. The Senator spelled out in amazing detail what this debate is about. We come to this floor understanding that a miracle has taken place in terms of health care in America within the lifetime of most of us. When this Senate considered the Medicare bill back in the 1960s, there was a very limited formula, a limited number of prescription drugs that were available, and they did not include in Medicare the coverage of prescription drugs.

Look at what has happened since then. There has been a massive investment by the Government, the taxpayers, and by private industry, and we have seen emerging from that brandnew pharmaceuticals that give us the hope of conquering diseases that have plagued mankind forever. This new formulary, ever-expanding, has created a new demand. Of course, it is a demand brought on by people who want to save their own lives as well as those of their family members. It is a demand that is monitored by doctors; a doctor will decide whether this particular drug is right for this patient at this moment.

But at the same time that this miraculous evolution was taking place, the cost of these pharmaceuticals was also rising geometrically, to the point that today many average Americans cannot afford the very prescription that their doctor believes will keep them healthy and out of the hospital. So many of them put off filling a prescription and maybe take half of what they are supposed to take or they have to make a sacrifice—whether it is food, shelter, or paying a utility bill—in order to pay for their drugs.

There has been a demand growing in America for the Congress to respond and to expand the Medicare Program again so we would include prescription drugs. That is something that is worthy and is supported by Democrats and Republicans and Independents.

When you come down to the specific challenge of making it work, one of the biggest problems you face is price. If the cost of prescription drugs continues to grow, as it has in the past, there is no way any of us in the Senate or in the House can devise a Government program to pay for it and to keep up with that cost. Last year, the cost of prescription drugs across America went up some 18 percent. You cannot create a Government program and fund it properly that will keep up with that kind of geometric growth in price.

So there are various ways we can address it. To the north of us, Canada has addressed it with a national health system. We can argue back and forth about whether doctors or hospitals should be Government employees, but when it comes to prescription drugs, what Canada said to the drug companies in America is: If you want to sell your product in Canada, we will bargain with you as to how much you will be paid. The American drug companies said: Fine, let's start the bargaining process. As a result of that bargaining process, there are dramatic differences in the price of drugs between the United States and Canada.

If you look at this chart and go through the drug names, you will recognize some of them. These are the drugs that you find advertised on television, on radio, in newspapers, and in magazines almost on a daily basis. Celebrex, for arthritis, goes for $135 for 90 doses in the United States. In Canada, the same drug, same dosage, and the same company, it is $83. Lipitor, for cholesterol, is $266 in the United States and $179 in Canada. Nexium, for ulcers—the little purple pill, I think it is—is $344 in the United States and $219 in Canada. Paxil, which we have seen ads for, is for depression and anxiety; it is $236 in the United States and $152 in Canada. The list goes on. There is Premarin, Prevacid, Vioxx, Zocor, Zoloft—all the names we are familiar with because of advertising.

The lesson to be learned is that when the Canadian Government said they were going to bargain for the good of people living in Canada, they started saving money for their people and their health system. What is missing in this picture? There is nobody in the U.S. who is bargaining for the American consumer.

Yesterday, on the floor of the Senate, my colleague from Pennsylvania, Senator SANTORUM, argued that is just a price Americans have to pay. It is our responsibility, as he argues, to subsidize the profitability and growth of American drug companies. The fact that these same drugs are costing a fraction—the exact same drugs—in countries around Europe, Canada, and Mexico, he believes is just part of their socialized Government-controlled system.

I can tell you from the U.S. consumer's point of view, it is cold comfort to be told that for a drug you have to pay 40, 50 percent more than someone living a few miles over the border in Canada because it is your burden to subsidize American pharmaceutical companies. But that is the argument being made by those who are opposing many of the issues before us today.

Now, Canada isn't the only entity bargaining with American drug countries. Mexico and a lot of European countries bargain and say: If you want to come into our health system and sell your drug in our country, we are going to reach an agreement as to what you can charge; otherwise, you are not welcome. Well, the companies, by and large, have all agreed to do exactly that—enter into this agreement and reduce drug costs in every country but the United States.

In the United States, there are certain elements within our society that have bargaining power with the drug companies. A couple of examples come to mind immediately. The Veterans Administration, on behalf of America's veterans and hospitals, bargain with drug companies to bring down the cost of drugs. I am glad. The veterans benefit from it. Indian Health Service, the same story; Public Health Service, the same story. Many States, through Medicaid, bargain in terms of bringing down the cost of drugs. When you look at it, private insurance companies reach these same bargains. They say to a drug company: If you want to have an eligible drug for the people we insure, we are going to bargain on a price that we think is acceptable. That bargaining takes place to the benefit of another group of Americans.

If you look at the population of this country, who is being left out in the cold? I will tell you. The first group you will notice is Medicare recipients, people over the age of 65. No one is bargaining for them. These people, retired and on fixed incomes, are paying the highest prices, not only in America but in the world, for drugs that are being made in the United States. High prices, of course, apply to many other families as well.

There are several ways we can approach this. We can decide that, as a society and as a government, we are going to negotiate on behalf of American consumers, the same way it is done in other countries around the world. Well, we have not quite reached that decision. Instead, we are trying to inch toward more competition and price justice. I salute the Schumer-McCain bill—the underlying bill—because this bill says we are going to try to make certain that generic drugs continue to play a major role in terms of providing the kinds of protections that Americans need.

Generic drugs have come a long way in America. We have seen, in a very short period of time, that they have become a substantial part of serving America's health needs. Almost 40 percent of the drugs today are generic drugs.

What is the difference between a brand named drug and a generic drug? Well, by classic definition, a brand name drug is under patent protection exclusivity. Only one company can make that drug. But when the patent runs out, expires, other companies can move in and use the exact same formula, make the same drug, and the price drops dramatically.

I will give you an illustration of how it works. I doubt there is a person in

America who hasn't heard of Claritin, made by the Scherling-Plough drug company. The ad shows people skipping through a field of wildflowers saying, I am not sneezing, so go to the doctor and tell him you need Claritin. Scherling-Plough spent more money advertising that drug than Pepsi-Cola spent advertising Pepsi in a given year or Anheuser-Busch spent advertising Budweiser. They wanted the Americans to develop an appetite for this drug Claritin. Then they got panicky because the patent was running out because then someone else could make a Claritin generic drug at a fraction of the cost. So they would come to Congress and try to find, at the midnight hour, a way to slip in an amendment to extend their patent another few months or years. We fought them back time and again.

And Scherling-Plough wasn't the only group trying to do that. What we have seen happen now is Claritin is coming off patent and the generic drugs are going to compete. Scherling-Plough is thinking: What are we going to do?

What did they do? They tweaked a molecule in Claritin and created a new allergy drug called Clarinex. Have you seen it on TV? It will soon be coming to a television near and dear to you. Now they want to create this appetite for Clarinex because it is back at the price they used to charge for Claritin. The odd thing is, if you had asked, many doctors from the start would have told you that over-the-counter drugs are as effective as Claritin or Clarinex will be ever be for most Americans.

The point I am making is, when you are talking about generic drugs, you are talking about affordable drugs for Americans. You are talking about giving them the same type of drugs, bioequivalent, as those under brand name and patents, and making certain they save money in the process. Senator SCHUMER and Senator MCCAIN are trying to eliminate some of the abuses as drugs come off patent and move toward generic so consumers can enjoy that benefit.

Yesterday, on the floor of the Senate, by a vote of 69 to 30, we adopted an amendment by Senator DORGAN. Senator DORGAN of North Dakota said he finds it strange that in Canada, the exact same drug made by the same American company subject to the same inspection sells for a fraction of the cost, and why shouldn't we be allowed to reimport these drugs from Canada for the benefit of American consumers?

They came here on behalf of the pharmaceutical industry and said it is an invitation to terrorism; you are going to bring in counterfeit drugs. One of my colleagues said he had a formula he was holding up that was made out of highway paint. I could not follow the debate very closely, but the suggestion is that drug that moved across the border is, all of a sudden, suspect when it comes back.

I wanted to ask the critics of the Dorgan amendment why, if we have busload after busload of Americans going into Canada buying these drugs, if there is such a danger, why have we not heard some scandalous report about people dropping dead on the buses or as soon as they got home? It has not happened. It will not happen.

In the Senate, by a vote of 69 to 30, we decided to create another opportunity, beyond generic drugs, for reimportation of drugs from Canada, with the approval of the Secretary of Health and Human Services in terms of their safety and the fact they save us money. That was a step forward.

Today, I am happy to be a cosponsor of an amendment presently before the Senate which, frankly, has not been discussed for about 3 hours. I have listened to the debate on the floor, and no one has discussed this amendment by Senator STABENOW.

The last two speakers on the Republican side, Senator HATCH and Senator FRIST, spoke to the generic drug part of the bill, but they are not addressing this bill which I think is a good one by Senator STABENOW.

What this bill says is that States across the Nation, such as Maine, Vermont, even the State of Illinois, can decide they want to try to bargain with the drug companies to bring down prices for everyone living in the State. What is wrong with that? If we are letting it be done in Canada and Mexico, the Veterans' Administration, private insurance companies, the Indian Health Service, why shouldn't a State try to find drug prices more affordable for the people living there? That is what the amendment says. It is as simple and straightforward as that. It is another opportunity for us to put some competition in drug pricing and to give consumers a break when it comes to paying for the pharmaceuticals they need to survive.

I think this amendment moves us in the right direction. It is sad that, once again, we are looking for another alternative to national action. That is what we need in this situation. We can think of a dozen different ways to reduce prices—by where you live, what State, whether you happen to be a veteran, whether you happen to have access to Canada. But shouldn't we as a nation address this in a straightforward fashion, understanding that the drug companies are in business to make a profit?

I will concede that point, but for the last 10 years, when one takes a look at the profitability of drug companies, one finds that it is about 19 percent a year on average. The median income and profitability of Fortune 500 companies during the same period of time is 3.3 percent. Drug companies are extremely profitable, and they are selling more and more drugs at higher prices and driving up that profitability.

We also believe that you should have enough money at a drug company to put money back into research—capital investment in research for new drugs. It is obvious. It is not only a question of making a profit, it is a question of finding that next generation of drugs to improve the lives of Americans. I think that is a very valid thing to do.

Senator STABENOW will not be offering the amendment I cosponsored with her that said those companies that are spending more money on advertising than they are on research ought to be held to only deducting the amount of money equivalent to what they spent on research for their advertising. I think that is reasonable, too. It calls the bluff of a lot of companies that say: We need to be more profitable for research. They need to be more profitable for more advertising, advertising creating many times a false appetite.

I stand today in support of this legislation on generic drugs. I believe it is a step in the right direction. The average price paid for a prescription for a brand name drug is about three times the amount of that paid for generics. The average consumer pays 238 percent more for brand name drugs, an average of $45.96.

Last year, 47 percent of all prescriptions were filled with generic drugs. Remember, the doctor makes the ultimate decision. If the doctor happens to believe a brand name drug is better for you or your family because of some situation, some peculiarity, that is the doctor's call, but having generic drugs available gives that doctor a choice and gives you a chance to find an affordable alternative for safe and efficacious treatment.

The underlying bill on generics is sound. I supported the reimportation amendment and stand in strong support of flexibility for States to act, which Senator STABENOW has submitted and which I am happy to cosponsor. Let us give to the States the opportunity to reduce prices so people can benefit from this competition and bargaining and still remain healthy.

Mr. SCHUMER. Will the Senator yield?

Mr. GRASSLEY addressed the Chair.

The PRESIDING OFFICER. The Senator from Illinois may yield for a question.

Mr. DURBIN. I believe I have the floor, and I have agreed to yield to the Senator from New York.

The PRESIDING OFFICER. The Senator may yield for a question.

Mr. SCHUMER. Mr. President, I know the Senator from Iowa is in a hurry. Maybe I can ask unanimous consent I be recognized immediately after he finishes instead of yielding.

Mr. DURBIN. If the Senator from New York does not have a question, I will be happy to yield the floor.

The PRESIDING OFFICER (Mr. MILLER). Is there objection to the unanimous consent request?

Mr. REID. Mr. President, what was the unanimous consent request?

The PRESIDING OFFICER. The Senator from New York wishes to speak for 5 minutes immediately following the remarks of the Senator from Iowa.

Is there objection? Without objection, it is so ordered. The Senator from Iowa.

Mr. GRASSLEY. Mr. President, I am so glad we are in a position where we are able to discuss these very important prescription drug issues, including a prescription drug program for senior citizens as part of Medicare.

I am also glad that we are in a position on the floor of the Senate where we are divided in a traditional way, and in that traditional way, I do not mean just Republican and Democrat because too often that is overplayed.

We are divided between a group of Senators. First of all, I think we may not have 100 Senators who favor a prescription drug program for senior citizens, but I surely believe that we have 85 Senators who believe that we should have a prescription drug program for senior citizens as part of the modernization of Medicare.

Within that 85, I suggest we have some traditional division—division between those who have only confidence in the Government running the program and those, including myself, who have some confidence in the Government but not enough to believe that drug prices are going to be kept minimal through Government control so that we have confidence in the competition of the marketplace to reduce the price of drugs.

We are going to find over the next several days, as we continue to debate this legislation and hopefully bring it to culmination and pass a bill so we answer the concerns of our senior citizens who sometimes have to choose between food or medicine—and they should not have to make that choice—that we will have a prescription drug program as part of Medicare.

During that debate, I hope the American public listening will consider, do they have confidence in the Government running a program or in the private sector and the competition of the private sector keeping down prices?

Quite frankly, I believe when the Government is involved, we are going to run up the price of drugs. I think I can give evidence from the Congressional Budget Office, the nonpartisan scoring arm of the Congress, to that effect. I can also give evidence that if we have a program for senior citizens that has competition in it—in other words different organizations competing for membership of seniors and, in turn, competing for the lowest possible price with the pharmaceuticals—we are going to bring down the price of pharmaceutical medicines.

Since 1965, the Medicare Program has provided lifesaving health care services to our Nation's seniors and disabled populations. Hundreds of millions of Americans have had their quality of life improved and their health protected because of this Medicare Program. So we must ensure that Medicare continues the exemplary service it has provided beneficiaries since its inception in 1965, and through these program changes, including prescription drugs, improve it vastly.

Unfortunately, we have a situation that this is necessary because Medicare has not kept up with the advances in medical treatment. Medical advances in delivering health care have moved us light-years beyond 1965, but the Medicare Program has not changed to reflect those health care advances. So in order to ensure that Medicare is meeting the needs of today's and tomorrow's seniors, the program needs to be brought into the 21st century.

Very few people drive 1965 automobiles today, but every senior citizen is using a 1965 model of Medicare. So that is why, after a year of work, I introduced, with Senators SNOWE, BREAUX, JEFFORDS, and HATCH, a bipartisan bill—or if you look at the political backgrounds of all five, a tripartisan bill. Our 21st Century Medicare Act, as we have named it, is designed to bring Medicare up to date by adding a comprehensive prescription drug program and by making other improvements in the program as well. The Congressional Budget Office has estimated our bill will cost $370 billion over 10 years.

Now there are other proposals. Senator DASCHLE, from the other side of the aisle, has a bill. As I understand it, it has not yet been scored by the Congressional Budget Office. How much does it cost? I have heard figures from introducers of that legislation, maybe $450 billion, maybe $600 billion. We need to know what these programs are going to cost before we vote for them.

I want to take a moment and walk my colleagues through the elements of the 21st Century Medicare Act. First, the prescription drug benefit adds a comprehensive, voluntary, and permanent drug benefit to Medicare. Our monthly premium is $24. It is the lowest premium of any comprehensive proposal before the Congress, as the authors of those proposals have expressed what their premium is. Our drug benefit is focused on providing money where it is needed most—to the low-income senior citizen who has to choose in some instances between food and medicine. They will no longer have to make that choice.

It also targets those who have very high out-of-pocket expenses. Some people might refer to that as catastrophic coverage. We have other names for it, but I think we know that we are trying to protect people where the sky is falling in on them because of the need for prescription drugs.

I will describe for seniors with low incomes what this would do, starting with those below 135 percent of poverty. That would be about a $12,000 yearly income individually, about $16,000 a year income for a couple. Medicare will first pay the entire amount of their monthly drug premiums, no out-of-pocket expenses for them buying into the program.

Secondly, Medicare will assist them in paying for drugs at every level of spending. They will pay only $1 to $2 for their prescriptions. On average, this group of low-income, older people will see a 98 percent reduction in their total drug costs, another example of one not having to choose between food or medicine because they are low-income.

Next we would look at seniors with incomes above 135 percent of poverty but below 150 percent of poverty. This includes individuals with income a little bit over $13,000 and couples with income of almost $18,000. These enrollees will receive Medicare assistance on a sliding scale based upon their income to help pay their monthly premium to get into the program, and also Medicare will assist them in paying for drugs at every level of expenditure. There is no gap for these beneficiaries below 150 percent poverty.

Let us look at those with incomes above 150 percent of poverty, which is above $18,000 for a couple. They will pay an average monthly premium of $24 for their immediate care drug benefit—again, the lowest of any premiums that have been announced by other authors that we know about. They will pay a $250 deductible, and after they have reached the deductible, Medicare will cover 50 percent of their drug costs up to the benefit level of $3,450 in total drug spending. Furthermore, Medicare will cover 90 percent of all drug costs after beneficiaries have paid $3,700 out of their pocket for drugs.

Let me say a bit more about our drug benefit for Medicare beneficiaries above 150 percent of poverty. That is the group I just described. First, I wish we did not have a gap in coverage between $3,450 and $3,700, but the problem is that we are working within a limited amount of money—$370 billion—which is about halfway between the President's program for seniors and, let us say, the other prominent plan before the Senate, the Democrat plan. We are about in the middle. We have adopted a policy of using funds to benefit the largest possible number of Medicare beneficiaries, particularly those with low incomes, as I have demonstrated.

So helping low-income people as opposed to doing more with incomes a little bit higher, it requires some sort of a trade-off, and we have opted to help lower income and to help less the further up the line one goes. It is important to point out and to stress that even with these trade-offs, fully 80 percent of all Medicare beneficiaries will spend less than the initial benefit limit or will have access to low-income protections and therefore will have no gap in the coverage. The percentage, again, is 80 percent.

In the jargon of Washington, DC—and I know our constituents get tired of hearing Washington talk; we need to talk Iowa talk, but for my colleagues, that means 80 percent of the seniors in America under our plan will not be touched by what we call the doughnut hole. For the 20 percent of enrollees exposed to this gap in coverage, our bill

requires that Medicare drug plans pass negotiated drug discounts along to Medicare enrollees all the time. All of those enrollees will be able to purchase drugs at a reduced price.

Everyone is going to benefit from this legislation. Our bill may include this small doughnut hole, but proposals from the other side of the aisle seem to me to include a black hole since this drug benefit ends in 2010, leaving Medicare enrollees without any drug benefit whatever.

Again, when we talk about legislation, if it comes to an end, we say that is a sunset. It is my understanding that the proposal from the other side has a sunset; in other words, a time when the benefit will end unless Congress reenacts it. Seniors are not going to sunset. Seniors are going to continue to need prescription drugs after this other proposal sunsets.

One of the disputes is lack of understanding of our benefit delivery system. I heard my colleagues describe how we arrived at the approach to delivering drugs, as the tripartisan bill does. That reminds me, I want to say another thing because I think we forget how things get done. No Republican plan can get through the Senate. No Democratic plan can get through the Senate. A Republican plan can get through the House of Representatives because that is the way that system runs and the majority party rules with an iron hand. There is a Republican plan that got through the House. There is a Democrat plan in the House that obviously did not pass the House. We got the President's program that is obviously a Republican program because we have a Republican President. We have a Senate Democrat plan. We do not have a Senate Republican plan, but we have a Senate bipartisan plan. That is the only way we will get anything through the Senate, and that is a bipartisan approach.

Getting back to how did we settle upon our delivery system for the prescription drug program for Medicare, we have been working for several months, to my chagrin, too many months, with the CBO to work through policy and what a certain policy would cost and changing policy—not basic policy but fine-tuning our policy from time to time to fit the realities of what CBO says.

The CBO is important in this process. It is an independent, nonpartisan congressional staff office that analyzes legislative proposals for costs on the one hand and workability on the other hand. The CBO does not have any ax to grind. And they had better not. And we in Congress rely on that. They are the bible for a lot of decisions made, particularly budget decisions.

According to CBO, spending on drugs for seniors over the next decade will grow at an astronomical rate. Over the next 10 years, there will be a steep rise in the price of pharmaceuticals. The CBO said the only way to contain the cost of a drug benefit is to ensure that drugs are delivered efficiently. In turn, the CBO says the only way to have drugs delivered efficiently is to have true competition, two or more organizations competing with the drug prices to get the prices down, as opposed to the other program I am talking about that relies on a government-run program. I quote the CBO that a government-run program will not bring down the price of drugs but one where there is true competition. We have a delivery system based on true competition.

According to CBO, this requires that we must use private plans that assume a reasonable degree of risk; in other words, some risk on the organization to make sure it is efficiently run, to see there is competition, as opposed to a government-run program where risk in pricing of drugs is assumed by the government. What I mean by risk is, if they are efficient, they will make money and, if not, they will lose money. If they drive hard bargains with drug manufacturers, they will make money. If not, they will lose money.

A limited degree of risk is all the tripartisan bill requires. People will ask, What sort of risk do you have if there is going to be a 75-percent subsidy for the Medicare prescription drug plans in our program? Because the Federal Government is protecting that 75 percent. We are told by CBO that at 25-percent risk we will be assured this level of risk is high enough to promote sufficient drug coverage and low enough to assure that plans participate in a stable, reliable drug system. It is the optimal level of risk.

Insurers who are so unhappy with the House bill in 2000 have indicated they can live with the level of risk in our bill. They would be crazy not to participate.

Our opponents are saying if the Federal Government lays $340 billion on the table, by far the largest entitlement expansion ever, plans will not participate. Where do our opponents get that? Flatout, according to the CBO, they are wrong. CBO says the insurers themselves say they are wrong. Most importantly, common sense says they are wrong. Unfortunately for our opponents, no one has invented a prescription drug that gives you common sense.

We need to make the dollars we have go as far as we can. Whatever our individual thoughts, the CBO in this case is an arbiter, and they tell us our bill, the 21st Century Act, does that; in other words, it keeps the cost of medicine down, guarantees the participation of those agencies to deliver the drugs.

Now, I know the Presiding Officer is from a rural State. I will address the question of whether the system the bill will establish will work in rural areas. Even if you are from Atlanta, there are a lot of rural areas in Georgia, so you ought to be asking, will we take care of rural areas? If you are in Montana or North Dakota, it is probably even more of a concern. I represent a rural State—maybe not the most rural State—and I would not support a Medicare drug bill that would put the rural parts of our Nation in jeopardy of not receiving equal access to prescription drugs under the same conditions as people in New York City.

Our bill guarantees that every Medicare enrollee will have a choice of at least two Medicare drug plans, a minimum of two. The Government will establish service areas for plans to offer Medicare drug benefits. These service areas must be the size of a State at a minimum. They can be multistate but at least the size of a State.

I stress that because you hear from the other side that plans will cherry-pick. You are not going to cherry-pick in the State of Iowa. You have to serve Des Moines just as you have to serve Armstrong, IA.

Another point I want to make concerns pharmacists. Pharmacists play a very important role in prescription drug programs for seniors. Not only that, but as we have increasing use of drugs, and seniors taking multiple prescriptions, and the interaction of those, pharmacists are going to play an even more important role. They are going to be needed to protect—I don't know whether the word ''protect'' is right—but oversee, to some extent, when prescription drugs are given, how they interact. Maybe a doctor won't be on top of that. You might have a person who gets a prescription from two different doctors. Are they going to interact? The focal point for that determination might be the pharmacist—ought to be the pharmacist, and will be. So there is going to be an increasing need for pharmacists.

Another thing I want to point out about the legislation is our assurance that Medicare beneficiaries will have convenient access to a brick-and-mortar pharmacy. The standards outlining what is convenient will be determined by our Department of HHS. Furthermore, in developing convenient access standards, our Department is explicitly required to take into account Medicare beneficiaries in rural areas.

We ought to consider consumer protection, so I will address that as our bill does. Our drug benefit proposal puts into place important consumer protections for our Medicare enrollees.

By the way, one of the things I didn't say that the CBO said about ours, we will have 99 percent of the seniors taking advantage of this program. That is how high the enrollment is going to be.

First, in regard to consumer protections, all Medicare drug plans will be put through a comprehensive approval process to ensure they will deliver quality drug benefits to seniors. The new Medicare competitive agency in the Federal Department of Health and Human Services will have to review and approve the application of the plan before that plan can participate in the program.

Standardized information on each drug plan will be sent by Health and

Human Services to all Medicare enrollees. If a Medicare drug plan wants to advertise for enrollees, all marketing material will have to be approved by HHS. All seniors will have access to necessary prescription drugs. Health and Human Services will determine therapeutic classes of drugs. Medicare drug plans will be required to offer drugs in all therapeutic classes.

If Medicare drug plans use formularies, they must establish a pharmacy and therapeutic committee to develop and review the formulary. Physicians and pharmacists must be represented on that committee. The P and T Committee shall base formulary decisions on scientific evidence and on standards of practice.

What I have outlined is a few ways in which our bill differs from Senator DASCHLE's bill. I would like to add a few more ways in which our bill differs as well.

First, Senator DASCHLE's plan is overly bureaucratic and I think extravagant, therefore it does nothing to curtail or even slow skyrocketing prescription drug costs. Why pass a bill if we are not going to do something to put the damper on the rapidly rising increases in the cost of drugs?

That is why it is essential that any new prescription drug benefit contain proper cost management controls that moderate growth in price while ensuring Medicare enrollees' access to prescription drugs.

While guaranteeing prescription drug coverage for all seniors, our proposal imposes reasonable cost-sharing obligations on beneficiaries and does promote competition among prescription drug plans which, as I have said so many times, will lead to a better overall effect on drug prices. That is a benefit to Medicare beneficiaries and to all Americans who are not even yet eligible for the Medicare Program because of age.

We have flexibility in Medicare drug benefits that we do not want to overlook because under Senator DASCHLE's plan, seniors face fixed copayments that, in many instances, mean they will actually pay more for drugs than they would under a system such as the one we propose, that gives prescription drug plans more flexibility to offer lower cost copayments.

I suggest that before the plan is finally put before the Senate by the other side—I will bet they will have that fixed because they have looked at our plan and they know we are more fair, particularly to low-income seniors, with our flexible drug benefit than what their fixed costs are.

Senator DASCHLE also writes into law the monthly premium seniors will pay for a drug benefit. But what happens if a plan has been efficient and wants to attract more Medicare enrollees by lowering their premium below that of other plans? Under Senator DASCHLE's approach, Congress would have to pass legislation for the plan to lower the premium. If you look at most of the problems we have with Medicare developing over the last 35 years, probably those coming directly from reimbursement of various health care providers, you will find that micromanagement of the Medicare Program by the Congress has led to most of the problems we have. So to the extent that we can have the marketplace be the disciplinarian in premium prices, copayments, in deductibles where catastrophic kicks in, et cetera, et cetera, we ought to allow that to happen.

We ought to look at what has benefited us as Senators and 10 million Federal employees or retirees or their families. You will see that competition among several of the Federal employee health benefits plans—they have, I don't know how many dozens of plans, but at least a couple of dozen plans, with competition among those plans, flexibility in those plans, the tailoring in those plans for particular interest groups of people in Federal employment, including Senators, they have been able to keep down the price of our Federal programs. That is directly related to the flexibility in the plans and the competition.

Why would you want to write into your plan a certain monthly premium?

Our plan then gives the freedom to offer premiums, copayments, and deductibles that are flexible, saving seniors money, or gives them more money.

We also have an enhanced Medicare fee-for-service option that is an improved and strengthened Medicare option—not one that seniors would have to take. If they are satisfied with the 1965 model, they can keep it with or without prescription drugs. If they would like to have a new and improved 21st century Medicare Program with or without prescription drugs—because prescription drugs are optional on all of these plans—we would give them the opportunity to do that. I will explain that.

None of the other proposals on the table do any of this. It creates the enhanced option. It is within the Medicare Program. It is a fee-for-service program. Let me be clear about the fact that it is delivered by the Federal Government just like Medicare. There has been some confusion on that point. It ought to be easily understood.

We think it is an option that many beneficiaries might find attractive. But the beauty of it is that we are not going to make that choice for them. It is voluntary. It is their choice.

Here is the bottom line. Beneficiaries, such as Medicare, have a right to keep it—keep it until you die. It is their choice. In fact, even future beneficiaries will always have this same choice under our plan—20–50. If you are 65 years old and you want the 1965 model of Medicare, choose it. But if it is 20–50, you are 65 years old and you want a 21st century model of Medicare, then you can choose the enhanced option.

I want to make it very clear that there is no sunset of the existing Medicare benefit package in our bill—like Senator DASCHLE's sunset in his drug benefit. We know on our side that senior citizens aren't going to sunset. They are going to be around forever.

In addition, Medicare enrollees can enroll in the Medicare drug benefit, whether they are in traditional Medicare fee-for-service, enhanced Medicare fee-for-service, or the Medicare+Choice.

Here is the choice that our bill offers seniors, if they want to take it.

Existing Medicare Part A and Part B focus on the coverage of routine, predictable medical expenses. But the enhanced option, which we are going to call Part E, focuses on preventive care and protection against devastating costs of serious illness. If beneficiaries prefer what they have now, for the third time, I say they can keep it. But if they like the idea of a better prevention and better insurance when they need it, then, for the third time, I say they can have the new, enhanced version.

On the subject of prevention, I would like to explain that we put a lot of emphasis on prevention. Medicare's current policy makes beneficiaries reluctant to seek out preventive services that may identify health problems and prevent more expensive care later. Part of that is because they have to pay a deductible.

Unlike many private health plans, Medicare today subjects people in this Part B to usually a 20-percent deductible.

For those who would elect the new, enhanced option, preventive benefits would not be subject to any deductible, or to any coinsurance.

That is an example of moving Medicare from 1965 to the 21st century.

I would like to highlight another improvement of enhanced option.

Medicare today has no limit on a beneficiary's expenses in a year, creating the potential for crippling costs in the event of a serious illness and maybe impoverishing some families. The bill would limit beneficiaries' exposure then to out-of-pocket costs for Medicare coverage services other than drugs to $6,000 per year. Beyond that amount, Medicare would pay 100 percent of any costs incurred by the beneficiaries.

In a given year, it is estimated that 2 to 3 percent of beneficiaries may have costs that reach above that level. Of course, if one looks at beneficiaries over multiple years, the likelihood of such expenses increases accordingly. If beneficiaries want the peace of mind that comes from such protection against serious illnesses, then for a fourth time, I say they have that choice.

Another issue our enhanced option addresses is the Medicare deductible structure. Under current law, the Part A deductible will be extremely high in the year 2005—$920 every time you go to the hospital—while the Part B deductible is going to stay at $100 per

year. The enhanced option includes a unified deductible of $300 per year for all services.

Medicare's irrational two-deductible system is unheard of in the private insurance industry today. Beneficiaries are used to single deductibles from their prior employer-based plan. If they like what they had while they were working, then they have the option, as I say for the fifth time, of taking the enhanced option within Medicare.

Here is another benefit from the enhanced option. Because Medicare benefits have so many holes in contrast to private insurance, most beneficiaries are forced to carry supplemental coverage to fill in the gap. We call that Medigap. Reducing those gaps will make such supplemental coverage less necessary, but, more importantly, if they want to have it more affordable for the beneficiaries, our bill establishes such new more affordable Medigap plans.

By the way, those employers who offer supplemental coverage will also find it less costly to do so under the enhanced option since it will have fewer holes to fill.

Is the enhanced option a better deal? From an actuarial standpoint, the answer is definitely yes.

The Congressional Budget Office tells us it is a more valuable benefit, largely because of the serious illness protections that it offers our seniors. But not all seniors are actuaries. So we are leaving it up to the seniors to decide which of the two plans is a better deal.

We make a few changes also in Medicare+Choice improvement. Starting in 2005, our bill takes modest steps to improve the Medicare+Choice Program. Medicare+Choice has been a big disappointment in my home State of Iowa. Only 1 county out of 99 has it. But seniors elsewhere—particularly in the larger cities and in the Sun Belt—rely on it.

Our proposal keeps that option alive without throwing money at the program as we have so much in the past. Instead, we create a competitive bidding system under which Medicare+Choice plans will compete with each other but not with the Medicare fee-for-service programs for beneficiaries.

I want to emphasize that no one in the fee-for-service Medicare will be affected by this change. We have made this change because today's bureaucratic pricing system sets arbitrary and inaccurate rates, and that discourages Medicare+Choice plans from participating. Our approach to Medicare+Choice is based on a bipartisan model embraced by the Clinton administration, and will result in fairer and more accurate payments to Medicare+Choice.

Before I give up the floor, I would like to comment for a short period of time on some statements that were made yesterday regarding our tripartisan 21st Century Medicare Act by people on the other side of the aisle. I think in some ways the facts were not given straight. I would like to correct the RECORD for the benefit of my colleagues.

Yesterday, there was reference made to an assets test as if there is something wrong with it. There is nothing wrong with it. Public policy for low-income Medicare populations has included assets tests since 1987. Our policy here in the Congress for low-income Medicare populations has included an assets test since 1987.

I said it twice so people know that it is not something new being thrown out there.

Specifically, assets test policies were first included in Federal policy in the Omnibus Budget Reconciliation Act of 1986, which passed the Senate by a vote of 88 to 7 with help from people who, yesterday, were denigrating our plan, and voted for the 1986 plan.

Our bill includes an assets test similar to the 1999 President Clinton—remember he was a Democrat—Medicare bill.

Under current law, States have the flexibility to waive this assets test. Nine States and the District of Columbia have chosen to waive the test.

Our proposal allows assets test flexibility, found in current law, to be retained in the Medicare drug benefit program. The assets test ensures that seniors who need assistance the most are provided the most protection.

Also, let me clarify that current law specifically excludes from the assets test a person's home and the land the home is on, household goods, personal effects, including automobiles, the value of any burial space, and other essential property.

The people attacking our plan also attacked our plan yesterday because of the flexibility we have in it. So I want to respond to that.

Medicare enrollees deserve a quality drug benefit that meets their individual needs. The Daschle-Graham proposal does not allow any variation in cost sharing or premiums and is a one-size-fits-all plan which will fail to adapt to the needs of seniors, as we are now so far behind with the 1965 plan that was adopted in 1965.

It is also important that Medicare enrollees get quality drug benefits at the lowest possible price. The tripartisan plan strikes the right balance to ensure Medicare enrollees have access to prescription drugs they need at the best possible price.

Anyone wanting to offer a Medicare drug benefit will be required to receive the approval of Health and Human Services. This is not a checkoff approval process. There will be intensive interaction between any plan and the Government to ensure that Medicare enrollees are getting what they are paying for.

There are five separate places in our bill where the administrator is required to certify that a plan meets strict standards of actuarial equivalence. The plans will not be determining what is the equivalent standard benefit. The U.S. Government is going to make that determination. If a plan is not equivalent to the standard benefit, it is obvious the bid will be rejected, and should be.

In fact, the Congressional Budget Office has told us our standards of equivalence are strict enough that Medicare drug plans will have little room varying in premiums or cost sharing. In their words, that little room to vary is critical to the success of a Medicare prescription drug benefit and indicates how the tripartisan bill has found the right policy in Government assumption of risk—just enough—to make sure there is competition out there, to make sure plans are run efficiently, to make sure there is competition to drive down drug prices.

While the Democrat plan claims to include competition, I do not understand how Medicare plans will compete if they are required to offer identical premiums and identical cost sharing. If drug plans wanted to lower their cost sharing or lower their premiums in order to attract Medicare enrollees, the only way it could be done is for Congress to pass more legislation.

The tripartisan bill ensures the innovations of the private sector are not stifled by micromanagement, one-size-fits-all, Government-run drug benefits.

There is guaranteed access to the plan. We have had Members of the other side apparently unaware that the tripartisan bill guarantees access provisions. The tripartisan bill guarantees two Medicare prescription drug plans to every Medicare enrollee.

If the enrollee lives in an area where there is Medicare+Choice, the Medicare+Choice plans will not count towards the two-plan minimum.

The Medicare plans are not determining their own service areas. The Government will determine service areas, and the service areas must be at a minimum the size of a State.

The Government will be covering 75 percent of the value of the Medicare drug benefits, equalling $340 billion over the next 10 years. So anyone who says the plans will not participate is simply not operating with any common sense—$340 billion of encouragement to participate. This is a clear attempt, and a failing attempt, I believe, to paint the tripartisan bill not as what it is—something that five Senators have worked on for a year—but to paint it, instead, as the House Republican bill, which it is not.

Lastly, we have been attacked from the other side about the tripartisan's policy toward employers. The tripartisan bill gives employers a 100-percent subsidy to offer drug benefits to their retirees, as long as the retiree plan is, at a minimum, as generous as the standard Medicare benefit.

In contrast to the tripartisan plan, the Democrat plan only gives employers a two-thirds subsidy to retain their retiree prescription drug plan.

Listen, from the other side you heard that our plan does not take into consideration protecting retirees who already have a corporate retirement plan with health benefits in it, when we pay 100 percent of that. And what does the other side pay? Sixty-seven percent. The other side's plan forces a standard benefit on all Medicare beneficiaries. Will employers be forced to change their entire drug benefit structure in order to obtain the two-thirds subsidy? This could result in employers being forced to charge higher drug expenses for their retirees in order to receive the subsidy.

Mr. KENNEDY. Is the Senator willing to yield for a question?

Mr. GRASSLEY. I will try to answer your question.

Mr. KENNEDY. I was just wondering about the time that the Senator will use. We have several Senators indicating——

Mr. GRASSLEY. I will be done in 2 minutes.

Mr. KENNEDY. I thank the Senator.

Mr. GRASSLEY. Currently, employers receive no assistance whatsoever in paying the drug costs for their retirees. Our 100-percent subsidy plan will allow employers who are offering a drug benefit at least as generous as the standard benefit to receive the full value of the standard benefit.

Again, our policy targets dollars where they might do the most good. And an employer subsidy recognizes the value of employer-sponsored retiree drug benefits.

In closing, I will simply say something I said when I started. In the next 3 or 4 days, there will be a lot of debate on this subject. It is very important to have a lot of debate on this subject.

You are going to find strong advocates for plans where the advocates have great faith in Government-run price programs versus whether or not you ought to have competition from the private sector. Remember, CBO says that a Government-run program is going to raise the price of prescription drugs. The alternative is to have competition. The Congressional Budget Office says that is going to reduce the price of prescription drugs.

We should be in the business of having public policy that is going to give seniors the best medical care, including prescription drugs, based on the least cost to the Government, as well as the least cost to the senior citizen.

I yield the floor and I thank my colleagues.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized

Mr. KENNEDY. Mr. President, I know we have not had an agreement with regard to time, but we have had the opportunity to hear from that side of the aisle for about 2 hours 40 minutes of the last 3 hours. So I was going to see if we could recognize the Senator from New York. And although our leaders here don't frown on allocating the time and indicating individuals, the Senator from New Hampshire has been willing to agree to this proposal: The Senator from New York would go for 10 minutes, the Senator from Georgia 10 minutes, the Senator from New Jersey 10 minutes, and I need 20 minutes.

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

The Senator from New York.

Mr. SCHUMER. Mr. President, I have been waiting here patiently to speak for a particular reason. Earlier this afternoon, the administration came out with its Statement of Administration Policy on S. 812, the Greater Access to Affordable Pharmaceuticals Act sponsored by myself, Senator MCCAIN, and 10 others.

I have rarely seen a piece of paper so far from reality and so far from the truth. Let me quote from it:

. . . the Administration opposes S. 812 in its current form because it will not provide lower drug prices.

What planet are they on? What are they smoking? Generic drugs will not lower the cost of drugs? If you want to oppose the bill for one reason or another, fine. Here are some costs: Claritin, brand name $86; generic $33; Cipro, brand name $89; generic, $35; Zocor, high cholesterol, $116; generic, $45; Zoloft, $69; generic, $27; brand of Singulair, $84; generic, $32.

That doesn't lower costs? It has been estimated it will save the American people $70 billion. It has been estimated it will save our State governments hundreds of millions of dollars. And they say it doesn't lower cost. What kind of argument is that? We all know it will lower cost. If they want to come clean and say they don't want to alienate the pharmaceutical industry, fine. If they want to say there is a better plan and better scheme, fine. If they want to say, keep things status quo, fine. But it won't lower costs?

I think they have a lot of disagreement even from people normally on their side. Here are some of the groups that think it will lower costs: General Motors, Ford, Chrysler, UAW, AFL–CIO, Verizon, Wal-Mart, Kodak, Motorola, Caterpillar, Kmart, Georgia Pacific, Albertson's, UPS, Kellogg, Sysco. The list goes on and on. These companies are not usually supporters of the kind of legislation we are talking about. They are all for this. They are for it for one reason: lower cost. Their own health care plan costs are going through the roof. I am utterly amazed. I ask the administration to retract this statement or prove why they believe that moving to generic drugs is not going to lower cost.

They say a few other things, too, which shows you that they really don't know what the bill is. They say in their statement that this bill would encourage litigation around the initial approval of new drugs. The legislation does not allow litigation for the approval of new drugs. They don't know what the bill does.

Will it prevent unnecessary litigation when someone files a patent in the Orange Book that is frivolous? Yes. That is not about a new drug. In fact, when it comes to a new drug, that is one of the few places where, of course, the patent can be contested by our legislation. What our bill does is simply force them to play by the rules.

The administration says the bill would complicate the process of filing patents. Of course, our initial legislation was clean. There was an amendment to change it, mainly to get support from members of their party. But if what the administration means is that it will complicate the process, if that means it makes brand companies comply with the FDA's current rules, you bet it will complicate the process.

The FDA requires that brand companies only list patents in the Orange Book that cover the drug or cover that approved use of the drug. Now the FDA does not enforce this, so the brand companies don't play by the rules. Our bill requires them to do it.

I had hoped that when Senator MCCAIN and I introduced this legislation—and my hopes were heightened when the legislation passed 16 to 5 and got half the members of the HELP committee from the Republican side—that we could have a debate and come to an agreement. The Senator from Utah, understandably, has pride of authorship. He may want to make some changes. But to just so baldly oppose a bill on specious grounds makes one wonder where the administration is coming from. Are they so afraid to offend PhRMA that they have to put out a statement that is just patently wrong?

We saw in the area of corporate litigation that the administration, which likes the American people to think it is moderate, is to the right of the Business Roundtable. We are finding the same thing here. We are finding that the administration, on the issue of drugs and the high price of prescription drugs, is to the right of much of corporate America.

Please, Mr. OMB Chairman, Mr. Vice President, work with us. We are not going to agree on everything, but work with us. This is a serious problem. If this memo is an indication that all we are going to get on the issue of reducing the cost of drugs and increasing the access of drugs is stonewalling, then it is a sad day for the American people.

We are going to fight hard for this legislation. The American people need this legislation. It needs to go beyond the original bill. That is why I have supported other amendments, and I hope the prescription drug plan offered by the Senators from Florida, Georgia, and Massachusetts prevails. But if even in this modest bipartisan step we get such stonewalling and such failure to grapple with the truth, then all those Americans who are paying such high prices for drugs are in trouble.

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

Mr. SCHUMER. I am happy to yield for a question.

Mr. GREGG. The Senator is probably not aware of this because this information has just been forwarded to me. I will actually have a paper on it. But there have been a lot of different representations as to how much the underlying bill would save. I have seen numbers that ran from $20 billion to $60 billion, and I believe the Senator mentioned it is actually a higher number.

We have just been advised by CBO that the underlying bill, the Edwards-Collins bill, will have $8 billion savings assigned to it by CBO. So as we debate this issue—I know some people are planning to use that savings to assist the major movement on the overall drug benefit—this is going to change the dynamics around here a little bit. But just so we are all playing off the same song sheet on savings, this bill is now scored by CBO as an $8 billion savings.

Mr. SCHUMER. If I could answer the question, which I know was meant to be a question, of the Senator from New Hampshire—the junior Senator from New Hampshire to correct the error of my ways—first, the $8 billion is the CBO estimate—I guess; I haven't heard it yet—but that is just for Medicare. The administration is saying it will not provide lower drug prices. The estimates are pretty widespread and pretty accepted that when you take not just the Medicare savings but the savings to every consumer who goes and buys the drug, the savings to all these companies that have their own health care plans, the savings to the States, it is going to be much more than that.

I am not debating how much right now. I don't know if that estimate is correct. It seems low to me. But let's assume it is. It is in direct contradiction to the Statement of Administration Policy that came out this morning which says: ''will not provide lower drug prices,'' period—not ''will not lower them enough,'' not ''will not lower them for everybody.'' It says, unequivocally, no lower drug prices.

So I would like to thank my colleague from New Hampshire because even though he is making a different point, he makes mine. The administration seems so hardheaded against anything to change the status quo, even though the vast majority of Americans are unhappy with the status quo, that it leads them to make statements that are patently absurd on their face.

The PRESIDING OFFICER (Mr. KENNEDY). The Senator's time has expired.

The Chair recognizes the Senator from Georgia.

Mr. MILLER. Mr. President, I rise to urge the Senate to let us try to come together on a prescription drug bill in these next 2 weeks for the sake of America's seniors.

Our seniors are up against a rich and powerful drug industry—an industry that, obviously, will fight tooth and nail against anyone who seeks to meddle with its obscene profit margin or its astonishing salaries for its CEOs or its TV media blitz.

Our seniors cannot fight this battle alone. Goliath is too big. Congress must step in immediately and help America's elderly in their day-to-day life and death struggle with prescription drugs.

This Senate has already taken a very big step toward helping seniors get their medicine at lower prices by passing the reimportation amendment. Now it is time to give some more help. It is time to add a prescription drug benefit to Medicare.

I was very glad to hear this week that the Nation's largest advocacy group for seniors, AARP, has declared the Graham-Miller-Kennedy bill as the one that, in their opinion, offers the very best value for seniors.

Let me take just a few minutes to tell you why they think and why I think this bill is better than the rest.

First, we use a system that is now in place—a system that is now in place for most working Americans, a system that the Federal Government and most employers use right now for their own workers. This new benefit is too important to risk using an untried, experimental delivery system; but the competing bills do just that.

Under our bill, every beneficiary will know how much their premium will cost each month and how much they will have to pay for each drug they buy. We guarantee seniors an affordable premium, while the Republican bill allows private insurers to set the premium cost. That means insurers would be free to charge seniors whatever premium they want, whenever they want.

It is simply a fact that seniors who live in rural America are often older, often sicker. Under the Republican bill, insurers would be able to charge them even higher premiums than those who live in urban areas. That would hurt the very people I call my friends and neighbors back home, and that is unacceptable.

The private insurers that are the centerpiece of the Republican bill will make profits based on managing drug care for beneficiaries, just as HMOs make their profits on managing care. That would result—it could not help but result—in fewer drugs being available to our seniors. That is not the kind of benefit our seniors need. That is not the kind of benefit they deserve.

Our bill uses a system that is already up and running in every ZIP Code in the United States. We guarantee that services will be available to seniors 24 hours a day, 7 days a week, for any emergency that arises. The competing bills offer no such protection.

The Graham-Miller-Kennedy bill is also the best plan out there because it has no gaps in coverage. That is very important to me, and to AARP, and to every senior in this country. We help seniors pay for the very first drug they buy each year. That coverage continues with no interruption through the last day of each year. No other bill makes the same guarantee.

There are two gaps in the competing bills. First, under the House Republican plan, all seniors would have to pay a $250 deductible. That means they would pay premiums but would get no coverage for the first $250 of their drug bills. Then, once drug costs reached $2,000, coverage would be cut off altogether. Seniors would get no help from the program until their out-of-pocket spending hit the $4,800 mark.

During this huge gap in coverage, seniors would still be required to pay their monthly premium even though they were not receiving a single penny of benefits from the program. And every beneficiary would experience that first gap in coverage because every senior would have to spend $250 before they saw the first dollar of benefit.

Then, almost half of all the beneficiaries would fall into the second coverage gap. Sixty percent of them would never climb back out of that gap to receive coverage again. Let me say that again. Nearly two-thirds of seniors who ran up drug bills of $2,000 would never see another penny in benefits for the rest of the year.

Because of these gaps, the typical beneficiary—let's say an elderly woman whose prescriptions run $2,400 each year—would still have to cover 71 percent of her drug bill each year.

Beneficiaries with higher drug bills are even worse off. Take an elderly man whose drug expenses run $400 a month, or $4,800 each year. He would have to pay 85 percent of his drug costs each year under the Republican bill. That is not much of a lifesaver to be throwing a drowning man.

Once again, there are no gaps of any kind in the Graham-Miller-Kennedy bill. Coverage continues every day, every week, every month, all year long, regardless of how high a senior's drug bill is.

Once drug costs have reached $4,000, the Graham-Miller-Kennedy bill says that we will pick up the entire bill for the rest of the year. It is what our seniors need. It is the least they deserve.

Mr. President, the time has come. It is just like back in 49 B.C. when Caesar had to ask himself a question: ''Do we cross this Rubicon?'' Do we make the commitment? Do we take this risk? You know, we throw around the term ''It's a matter of life or death'' pretty lightly. Seldom is that really the case. But this time it really is.

Many seniors—our mothers, fathers, grandparents, and other loved ones—will live or they will die because of this vote. Are we going to pass a meaningful prescription drug benefit as we have been promising and talking about for years? Are we going to go home and face the seniors of this Nation without doing diddly squat?

We have had a lot of sound and fury in this Chamber. Will it signify nothing, just a big fat zero? It isn't enough to have just good intentions, Mr. President. The road to hell is paved with good intentions. It isn't enough to promise good deeds. We must do them.

Thank you, Mr. President. I yield the floor.

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

Mr. TORRICELLI. Mr. President, the Senate is engaged in probably the most important health care debate in a generation. If we succeed in establishing a pharmaceutical benefit for the American people, it will be the greatest contribution to health care since Medicare.

We are engaged in this debate in the middle of an economic and corporate crisis. It would not be honest or even productive to pretend that one event is taking place without the backdrop of the other.

It is an extraordinary time to be redesigning the delivery system of an industry while corporate America is going through a series of tumultuous events.

I have an amendment prepared that I will offer to this legislation that is the nexus between the two problems because the pharmaceutical industry requires a transparency and a proper accounting of itself in the delivery and pricing of its products, just as certainly a variety of other American industries have suffered from their failure to do the same.

I address specifically two persistent problems. First, when an American family goes to a pharmacy to buy a prescription product, they operate under the assumption that they are getting sound medical advice, that the prescription that is being offered to them is suited for their problem, their malady, it is priced properly, and a medical judgment is being made on the merits. That is the assumption of every American family. It may not always be sound.

Through the years, marketing techniques from sporting events and theater productions to expensive vacations and gifts have become part of the routine of marketing pharmaceutical products. American families and senior citizens are left not knowing whether a product is being prescribed because it is the best for their health or because the doctor is indebted to a marketer or a corporation.

The same could be true of a pharmacy. Of all the corporate governance issues in America that deserve transparency, nothing could be more fundamental than the relationship between an individual American family and the delivery of their health care. People want to know, people have a right to know, is a gift an incentive, part of the prescribing of a prescription drug, or is it the quality of the product? Has a doctor been convinced this is the right drug for your child, for your family, for your health, or is this simply part of a relationship with an undisclosed incentive?

Under the amendment that I will offer, any corporation providing a gift to a doctor or health care provider as part of marketing a pharmaceutical product will need to disclose it. The incentive can be provided, the gift can be provided, you can offer the vacation, but at least people have a right to know whether the sales of products are related to price, science, the merits, or the financial incentive to consume them.

Some will argue that such techniques are common in industry. It may be true, but it is one thing if a retailer is getting an incentive to sell you a shirt or an automobile manufacturer is getting a secret or private incentive to an automobile dealer. That might be business. It may or may not interfere with the right judgment of the proper pricing, but that is marketing.

It is something else when it interferes with the judgment of a doctor and the confidence in health care delivery upon which people have come to rely, a judgment that involves not simply price but the intangible of trust in a health care provider.

Second, the amendment expands to deal with pharmaceutical benefit managers, otherwise known as PBMs. PBMs are essentially health maintenance organizations designed to deal with the delivery of pharmaceutical products. They are the middlemen who have placed themselves between drug manufacturers, health plans, and pharmacies. If they operate properly, they negotiate better prices, provide service and delivery at a superior cost to a beneficiary. For most of the last 25 years, that is exactly how they have operated.

A problem has developed, much like the gift, the vacation offered for selling a pharmaceutical product, except it happens on a much larger scale.

Pharmaceutical benefit managers have an obligation to their clients, the people who have contracted with them to buy the best product at the best price. The best product is to be based on a medical judgment. The best price is what can be negotiated. But the law has allowed a practice that is as morally wrong as it is reprehensible.

Pharmaceutical benefit managers who allegedly represent their clients go to pharmaceutical companies and ask for rebates. That is a polite word for a kickback. The client, the senior citizen, the working person is left believing they are buying a pharmaceutical product represented to them because it will deal with their illness and has the best science and is at the best price.

What they do not know is the pharmaceutical benefit manager may be offering that product because they are getting hundreds of thousands of dollars or millions of dollars in a rebate. Indeed, nothing else would explain what has emerged.

Pharmaceutical benefit managers are far less inclined to ever recommend generic drugs. Indeed, at the moment, brand name drugs are offered only 46 percent of the time compared with 54 percent of the time by a local pharmacist. The cost of a brand name drug offered by a pharmaceutical benefit manager can be $47 compared with $37 at a local pharmacy. So people who believe they are in a benefit plan to negotiate a better price are paying more, and they are not only paying more, they may be directed to products that are offered not based on a medical judgment or on a cost basis but because of a secret rebate.

The chart on my left illustrates exactly the problem, in what is now a four-tiered system from manufacturer to senior citizen. The manufacturer may offer a rebate with the belief that it could lower price and make their product more available through pharmacies to senior citizens, and many of these rebates may be offered by pharmaceutical manufacturers with the belief that like the rebate from an automobile manufacturer to an auto dealer, it is making the product more available, but here is the problem. The law allows the pharmaceutical benefit manager to keep the money. It does not go to the pharmacy. It never reaches the senior citizen. It stays here. The pharmaceutical benefit managers are in a contractual relationship supposedly representing the senior citizen. They are supposed to be their advocate, getting their price. Instead, they are keeping the money.

The PRESIDING OFFICER (Mr. CORZINE). The Senator's time has expired.

Mr. TORRICELLI. Mr. President, I ask unanimous consent for 1 additional minute to conclude.

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

Mr. TORRICELLI. Under the amendment I am going to offer to this legislation in the coming days, as certainly as pharmaceutical companies will have to disclose any gifts they are giving, any incentives they are giving to doctors to influence their medical judgments, so, too, pharmaceutical manufacturers will have to disclose any rebates given to PBMs so the clients of the PBMs know what they are getting and can demand that those rebates be handed down to senior citizens at a lower price.

It is simply transparency. It is what every American is asking of every American corporation. We have a free enterprise system for people to price their products, but we do demand truth and honesty. This is a minimum of transparency that we can bring to the pharmaceutical industry in America.

I yield the floor.

The PRESIDING OFFICER. The Senator from Nevada.

Mr. REID. Mr. President, I appreciate very much the Senator from Massachusetts withholding. The Republican leader is present, and I have a unanimous consent request that I would like to propound.

I ask unanimous consent that following the statement of the Senator from Massachusetts—he has 20 minutes. The Senator from Oklahoma, Mr. NICKLES, will speak for probably 20 minutes. Following that, Senator GREGG will speak for probably 5 or 10

minutes. Following those statements, we would vote on——

Mr. GREGG. Senator STABENOW would then have the right to close.

Mr. REID. I am going to do that before the vote. Following that, we would have a vote on or in relation to Senator STABENOW's amendment; that prior to the vote on Senator STABENOW's amendment, we would have 2 minutes for her to speak on behalf of her amendment, and Senator GREGG or his designee would speak 2 minutes in opposition to that amendment.

Mr. GREGG. Senator STABENOW would close?

Mr. REID. Yes. That upon disposition of Senator STABENOW's amendment No. 4305, Senator DORGAN's amendment No. 4299 be temporarily laid aside, and Senator GRAHAM be recognized to offer his prescription drug amendment; that immediately upon the reporting of his amendment, it be laid aside and Senator GRASSLEY, or his designee, be recognized to offer his prescription drug amendment; that the two amendments be debated concurrently; that no other amendments or motions be in order during the pendency of these amendments, except motions to waive as listed below; that on Tuesday, July 23, at 2:15 there be 30 minutes equally divided between Senators GRAHAM and GRASSLEY; that at 2:45 on that Tuesday, July 23, the Senate vote on waiving the Budget Act with respect to Senator GRAHAM's amendment; that immediately following that vote, the Senate vote on waiving the Budget Act for Senator GRASSLEY's amendment; that if either amendment successfully waives the Budget Act, it be further debatable and amendable; that if either fails to waive the Budget Act, it then be withdrawn; and that the preceding all occur without any intervening action or debate.

I further ask unanimous consent that when the Senate resumes consideration of Senator DORGAN's amendment that Senator GREGG or his designee be authorized to offer a second-degree amendment thereto and that upon disposition of Senator GREGG's amendment, Senator ROCKEFELLER be recognized to offer a second-degree amendment to Senator DORGAN's amendment.

The PRESIDING OFFICER. Is there objection?

The Senator from Massachusetts.

Mr. KENNEDY. Reserving the right to object, and I will not, will the Senator include that the allocation of time be equally divided on Monday and then Tuesday morning?

Mr. REID. That certainly is fair. We will equally divide the time.

Mr. NICKLES. Will the Senator yield?

Mr. REID. I would be happy to yield.

Mr. NICKLES. Is it correct there would be a budget point of order that would lie against both the Graham and Grassley amendments?

Mr. REID. The Senator is correct.

I ask that the request be amended so the time be designated, Senator KENNEDY, Senator GREGG, even though the amendments are those of other Senators. They are the managers of the bill and that is the way it should be.

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

The Senator from Mississippi.

Mr. LOTT. Mr. President, while I object to the process under which this is being considered—I think we should have had this prescription drug issue go through the Finance Committee. We should have a normal debate, markup, and report out what would normally have been a bipartisan bill and probably a tripartisan bill. That is the way we should do business, and I predict right now that eventually the only way we are ever really going to get a real prescription drug result is we are going to have to go back and do that.

Having said that, the bill before us everybody understood was going to be a vehicle to which Senator DASCHLE and others would be able to add prescription drug amendments or bills. That is what has happened.

I think we will have sufficient time for debate later on tonight, on Friday, on Monday, on Tuesday morning, I presume, with the votes to occur one after the other on Tuesday afternoon. I think that is a fair way to proceed.

Right up until the last few moments, we are getting people inquiring about what happens then. Well, of course, if one of them does get 60 votes, as is in the agreement, we could go back and have additional debate and amendments, or if they do not, then other options are available, other amendments to the pending issue that is being set aside or other proposals with regard to a different approach to the prescription drug issue.

I know Senators HAGEL, ENSIGN, SMITH, ALLARD and GRAHAM are interested in the Hagel amendment, and perhaps other amendments on this side.

We also retain the right to move to commit this whole issue to the Finance Committee with instructions, and at some point it might wind up being the most reasonable and popular thing to do. But this is not cutting off other amendments, not cutting off this issue, just setting it aside. It is not blocking other options from being considered. The truth is, both sides have been working for the last couple of days to try to get to this point. So I think it is the fair way to proceed. Everybody will be heard. We will have a vote and then see where we are.

Mr. REID. I want to express the appreciation of the Democratic Senators to the two leaders. It was not easy to get where we are right now, and the reason I appreciate that—I think everyone does on this side; I am sure on their side—we have two big issues that will be debated for several days. This issue, prescription drugs, is why we are here—one of the main reasons we are here, I should say. This will give everyone a chance to listen to what others have to say.

There will be some who do not want either one of these; they want something else. But they have a right to vote accordingly.

I think we have made great progress. If I can get Senator GREGG's attention, Senator STABENOW asked if there would be a problem with her having 5 minutes, and the Senator from New Hampshire having 5 minutes immediately prior to the vote.

Mr. GREGG. That is no problem at all.

Mr. REID. I say to the Senators who are watching, this vote will probably occur around 5:30, give or take a few minutes.

The PRESIDING OFFICER. Under the previous order, the Senator from Massachusetts is recognized for 20 minutes.

Mr. KENNEDY. Mr. President, I yield myself 15 minutes.

I thank our leaders, Senator REID, Senator DASCHLE, and our Republican leaders, for this agreement we have entered into. This is a historic time. It will be the first time in over 5 years since there have been prescription drug amendments before the Senate.

I am a cosponsor of the Graham-Miller bill and later in this debate, either tomorrow, Monday or Tuesday, I will have an opportunity to go over why I think that measure is so compelling and deserves strong support.

We were reminded, once again, earlier in the afternoon, of the publication of a study that reviewed the different options that are before the Congress most actively; that is, the Republican proposal that passed the House of Representatives, the tripartite, and the Graham-Miller proposal. The study examined the impact of each of these proposals on individual States and what impact each would have on seniors and others that would benefit from the program. In every single instance, every single State, without a single exception, the one that was embraced by the seniors, the one that provided the greatest coverage for the seniors, was the Graham-Miller proposal.

We will have more of a chance to debate that over the next couple of days.

It is very important as we come to vote on the amendment of Senator STABENOW to realize what has happened in the last couple of days.

The focus of the underlying legislation—which was originally introduced by Senator SCHUMER, Senator MCCAIN, and then altered or adjusted by Senator EDWARDS and Senator COLLINS—basically addresses the egregious situation taking place today all over our country by unscrupulous brand name drug companies gimmicking the patent laws in order to take unfair advantage of consumers in this country and maintaining higher costs. They are doing it by extending the patent process with a phony regime called ''evergreening'' and also through collusion with certain generic drug companies. This practice is resulting in costs of billions of dollars to our seniors.

If there are people who are watching this Senate proceeding, if there are cancer patients and they have been paying higher prices for various prescription drugs dealing with breast cancer, the fact is the pharmaceutical companies delayed Taxol, the generic drug, for 19 months. That means consumers paid $1.2 billion more because of the delay of competition. If patients suffer from epilepsy, as a result of this system, those patients have paid $1.4 billion more than they otherwise would have paid. That has been true with various brand name drugs for depression, and it also includes blood pressure as well.

In all those areas, there has been a gimmicking of the system, which permitted those companies that had the patents for a period of time, and under the old Hatch-Waxman legislation were going to have their time expired and the generics would be on the market, to be able to compete, and would have saved the consumers billions of dollars. The actions of those brand name companies have been such as to result in higher prices.

That is the basic issue we have before the Senate, whether we will pass that legislation.

The Dorgan amendment was favorably considered in a vote yesterday. It will also have a dampening down in the increase of prices of prescription drugs. And American taxpayers are paying taxes, and those resources go to fund expanded NIH research, which I strongly support.

This is the time of the life sciences, and we will see unbelievable opportunities in the future in breakthroughs with prescriptions. It is an enormously important time. I believe we will see these breakthroughs in the life sciences, as in the physical sciences last century. We have seen what is happening with the analysis of DNA, and the sequencing of the human genome, and all the breakthroughs with unlimited possibilities, using the high technology available and the advancements in biology. The opportunities are virtually unlimited. It is an enormously exciting time.

That is why it is important to have a policy that will make available to all Americans these lifesaving prescription drugs reasonably.

We had the excellent presentation made by our friend and fellow colleague, Senator DORGAN. The vote was a clear indication that the Members of this body are prepared to see that prescription drugs that are FDA approved, produced in an FDA-approved laboratory, imported here with the safety provisions included in the Dorgan amendment, would be available to American citizens.

Today we have the Stabenow amendment. We have had limited debate on the merits of the amendment. I hoped we would have seen an acceptance of the Stabenow amendment. It makes eminently good sense. We have heard a great deal of debate and discussion about the free enterprise system. That is what the Stabenow amendment is all about.

It is the ability of the States to use their economic power in order to negotiate with the various drug companies to try to get the lowest possible price for the neediest individuals, the poorest people in the United States. And the drug companies say no. Yesterday they said: We want to play by the free market system; and now we have a free market system being utilized and they say: No, no, we want to play by our own rules. What does that mean? They have now taken the various States to task and said: We will not permit that because that is government interference in the free market system.

The fact is, what is being tried in the State of Maine and the other States is the same kind of market experience we have seen with an HMO when they negotiate with various brand name companies. It is the same kind of negotiations insurance companies have. It is routine, the same as major companies. General Motors does this when they buy prescription drugs. It is the same element, to use market forces to try to get the lowest possible prices. When they do not want to do that, and companies do want them to do it, there is no reason they have to sell. It is a free and open exchange.

That is not good enough. We have seen where the drug industry has sued the State of Maine, they have sued the State of Vermont, they have sued Michigan, they have sued Illinois, they have sued Florida. The drug industry is waging war against our Governors and our State legislatures to bring them into court.

From the NGA statement of July 15, I quote Michigan Republican Governor Engler:

> The nation's governors are extremely disappointed with the course of action chosen by PhRMA. It is unfortunate that their organization feels compelled to use the court system to manipulate public policy.

I will mention another feature of the attack by the industries on the States. This is what they are about. First of all, the industry sued the State. That probably is not any surprise, given their abuse of the Hatch-Waxman. The drug industry instructed its front group, the so-called Citizens for Better Medicare, to run television, radio, and prints ads in Maine and Vermont attacking the laws. That is what the drug industry does to keep the prices sky high. They sue our State governments, and waste taxpayers' dollars defending against frivolous suits, because the States have to defend themselves; they have to use tax dollars. And then they run attack ads.

Lest anyone question whether the so-called Citizens for Better Medicare is anything but a front group for the drug industry, let me quote the June 18 Wall Street Journal, Tim Ryan: PhRMA's past marketing director founded the grassroots sounding Systems for better Medicare at the expense of the major drug companies.

So it is a phony organization, but they use the phony organization to attack the public officials in those States for resisting their action.

Enough is enough. The American people are sick and tired of the drug industry's abuses.

I have an IG report from the HHS inspector general, who issued a report in August of last year which documents the fiscal crisis of sky-high drug prices. Here is the inspector general's conclusion about the current Medicaid discounts shared by the States and the Federal Government:

> We believe it is not a sufficient discount to ensure that a reasonable price is paid for drugs.

This is done under a Republican administration, a Republican IG, August of last year.

The Department of Health and Human Services, Office of IG, Medicaid pharmacy. This is what he says in paragraph 2:

> Although this discount averaged 10.31 percent nationally, we believe that it is not a sufficient discount to ensure that a reasonable price is paid for drugs.
>
> We believe that there is a critical need for States to better control the costs of their Medicaid drug program because expenditures are rising at a dramatic rate. Medicaid drug expenditures increased by slightly over 90 percent since our previous review in 1994.

I repeat, 90 percent. So says the IG report, a Republican HHS discussing what is happening in the States.

Then we have the Governors try to do something about it and PhRMA comes right in and says no.

Senator STABENOW's amendment will clarify that. It will support the Governors—support Republican Governors, support Democratic Governors—support the findings of a Republican IG to help deal with this issue.

Just in the last day we had a meeting of the Governors, actually, out in the State of Idaho. The Nation's Governors met out in Idaho and the Governors voiced their concern over the lawsuit that seeks to bar the States from dealing with the Medicaid cost-controlling measures.

This is the Governors saying just what Senator STABENOW has been saying, Republican and Democrat alike.

This is a serious amendment. Therefore, I am very hopeful it will be accepted.

Let me bring to the attention of the membership, something that has developed in my own State of Massachusetts, in the U.S. attorney's office. One of the developments in recent times is the development of a health fraud unit, which has been extremely active. I was talking to our U.S. attorney recently up there. We were discussing the situation about health care fraud. He mentioned to me this particular case.

Just last October, the Federal authorities secured the largest health care fraud settlement in history. Not surprisingly, it was against a drug company for overcharging taxpayers through Medicaid—just what we are trying to deal with here in the U.S.

Senate. The Top Pharmaceuticals paid $875 million in criminal and civil fines for overcharging the States and the Federal Government for the cancer drug, Lupron. It is a life-or-death cancer drug, and here you have Top Pharmaceuticals found guilty of overcharging consumers and now having to pay the criminal fines and civil fines of $875 million. There are now class action litigations brought by consumer advocates in Boston to further recover the overpayments to this drug company.

We need to close ranks with our States, Republican and Democratic Governors alike—consumers against high drug prices. The Stabenow amendment is the right tool in the hands of the States to lower drug prices for low-income people and the uninsured.

I want to reiterate two facts. Who are the States looking out for? Are they trying to use their bargaining power in terms of a massive purchase of drugs for all the people in their States? No. They are trying to use it for the most needy people in their States in most instances—and I think in the State of Maine, in every instance—those who are uninsured, the poorest of the poor who cannot get insurance for one reason or another, or are not eligible for Medicaid, in order to get them lower costs. It is the poorest of the poor trying to get life-sustaining drugs, and PhRMA, the industry, is going after that and saying they do not want that to take place. They think that is un-American. They think it is price fixing and so forth.

We have seen, and I have certainly seen it in our committee because it was not believed we would get this legislation out of the committee because we heard the drug industry is strongly opposed to it—and we have certainly heard that from our friends on this side of the aisle—we understand that—they are opposed to it. They are opposed to the Schumer proposal. We understand that. They are opposed to the Dorgan proposal. We heard that yesterday. And they are opposed to the Stabenow proposal.

What we have not heard is what they are for. What we have not heard is what they would do. What we have not heard is their sense of outrage about these abuses. We have not heard that.

We have been here the better part of the day today, yesterday, the day before, and we have not heard that. That is a matter of deep concern to everyone on this side of the aisle. It is the reason the majority leader has brought this up to the Senate, on the floor of the Senate.

I heard my good friend—and he is my friend—the Senator from Tennessee, talk about the process and procedure, about whether we are circumventing the procedure in order to consider the legislation. Of course it did not bother him very much in May of 2000 when they brought up the energy bill, sponsored by Senator LOTT, without committee approval; or brought up, on March 20, a bill to eliminate the earnings test for individuals attaining retirement age, without committee approval. The list goes on. In June 1999, the Republicans brought up Social Security lockbox without committee approval. It didn't bother them at that time.

But what you did not hear about is a prescription drug program for the needy in this country. They were never willing to circumvent the rules to try to protect the seniors or try to get lower prices. No, there is no example for that. We have had legislation in the committees for over 5 years. This is the first time—the first time—the only time that we have had the opportunity to debate.

Next Tuesday will be the first time we have had the opportunity to vote. And people are complaining about process and procedure.

We know what happens. Every Member in this body knows what happens when you get back in those committee rooms, you get out in the corridors—we know what happens. That is the end of the legislation. That is the end of it. We all know it. But we know next Tuesday we are going to have a chance to vote on this. It will be the first time, and we would not have that opportunity unless Senator DASCHLE said: This is a matter of national priority. This is a matter of central concern. This is an issue that ought to be debated and discussed on the floor of the Senate. This is a moral issue of central concern to every family, young and old—not only those who take the drugs but the families who look at their parents and are concerned about whether they have the resources to purchase those drugs.

The parents themselves do not want to burden their children about their own kinds of conditions. They are proud men and women who want to live in dignity and who have paid a price for this Nation—fought in the wars, lifted the country out of the Depression.

The PRESIDING OFFICER. The time allocated to the Senator has expired.

Mr. KENNEDY. The last 5 minutes has expired? I asked to be reminded when I used 15 minutes.

The PRESIDING OFFICER. The Senator can use that time now—5 minutes.

Mr. KENNEDY. The remaining time.

Mr. President, these are people who have built the country. Now we are asking whether they have paid into the system. I was here in 1965 when that commitment was made here on the floor of the Senate, Republicans and Democrats alike. The President who signed it—President Johnson as well—said:

Look, play by the rules, pay under the system, and when you turn 65 you will have health security.

Everyone in this room understands it. This Chamber understands that we failed the elderly people on that promise. We provided physician services and hospitalization but not prescription drugs. That is a three-legged stool. If you only have two and you do not have the third, you do not have health security. Every family understands that, everyone except the Senate.

We are prepared to do something about it. Can you imagine if we had not provided hospitalization or physician services? We would certainly understand it. Would we not be debating that today? Does anybody believe it to be so? Does anybody believe this is not important?

Finally, I remind everyone in this body as we are coming in, and as I intend to remind them next week, every Member of this body has a prescription drug program.

Every Member of this body has a prescription drug program that is paid for by taxpayers by 80 percent. We understand that. Any Member of this body who wanted to go down to the clerk's office could go in there and say: Take my name off that. I don't want it. I don't believe as a matter of principle that we ought to have the Federal Government dealing with this policy.

Anyone could do that. I have checked on it. There isn't a single Member in here who has done that.

All we are trying to do with this particular proposal is to treat the American people the same way Republicans and Democrats and this President are being treated. Is that asking too much for this body to do? I don't believe so.

I withhold the remainder of my time.

The PRESIDING OFFICER (Mrs. CARNAHAN). The Senator from Oklahoma is recognized.

Mr. NICKLES. Madam President, I rise in opposition to the Stabenow amendment. I will mention several reasons.

First and foremost, it is going to increase in the price of Medicaid. I want to make sure our colleagues know that. I am going to say it about 10 times in the course of this debate. If we pass the Stabenow amendment, the price of Medicaid is going up. The price of drugs going into the Medicaid system is going up. That is just a fact that everybody should know.

If we think that we are going to pass this amendment and that this is a great deal for the State—I disagree. The States have to share in the cost of Medicaid, and the cost of Medicaid is going up.

I heard my good friend—he is my good friend—the Senator from Massachusetts say the Governors have united; we need to get cost controls on Medicaid.

This will mean a monumental increase in the cost of Medicaid. I think I can say that very plainly and very easily. I want to make sure everybody is aware of that.

Let me mention a couple of other reasons we should be opposed to this amendment.

Some people say ''process.'' Did we have a hearing on this bill? No. Did we have a markup on this bill? No. Was one even requested? I don't think so. The Democrats are in control of the

Senate. Senator BAUCUS is chairman of the Finance Committee. If he wanted to have a markup on this bill, he could have done that.

I see the sponsor of the legislation. I will ask her. Have we had a hearing on this bill, and have we had a markup on this bill in the Finance Committee?

Ms. STABENOW. Madam President, I think my friend from Oklahoma knows that in fact that did not have a hearing. That is not unusual. That happens sometimes in the process. I have only been here 1½ years. But there are many times when that has occurred. The Senator is correct. That has not occurred on this bill.

Mr. NICKLES. Let me ask another question. Is it not correct that your bill will increase the cost of drugs going into the Medicaid system?

Ms. STABENOW. I would argue that that is not the case, absolutely not. Under the program right now, States operate with companies, and I don't have any indication whatsoever that it is going to increase the cost of Medicaid. I certainly would have to object to that.

Mr. NICKLES. I will make the case that it does. I believe I will show that GAO happens to agree with me. GAO has studied this issue. They basically said it boils down to the fact that if everybody gets a discount, nobody gets a discount. That is the economics of it.

Right now, you have a system where Medicaid gets the best price. Medicaid gets the best price—lowest price—in the country. But if everybody gets it, nobody gets it. If everybody gets a 15-percent discount, that is the price. This is not a discount. That is exactly what we are doing here. You are going to increase the cost of Medicaid by not giving a discount. Does that mean everybody's drug costs are going down? Actually, no. It means the discount or the best price is going up.

Ms. STABENOW. Will the Senator yield?

Mr. NICKLES. I will not yield. I want to make a lot of comments, and I will be happy to discuss it. But I only have limited time. I want to make sure I make all of these points.

No. 1, this is an important issue. It hasn't had a hearing.

This committee is now controlled by the Democrats. It has been for a year and we haven't had a hearing. I don't know that one has been requested. I am on the committee, and I am on the subcommittee.

Some people say that is not insignificant, that we do a lot of things.

When you are talking about major issues—and we are talking about prescription drugs for all of our seniors—we should have a hearing on this. We should have a markup.

There happens to be, collectively, on the Finance Committee hundreds of years of experience dealing with Medicare, Medicaid, and prescription drugs. A lot of us are willing to put some input into it. That is the reason we have the committee process.

I am ashamed of the way the Senate is operating today in this fashion. We are taking probably the most important and most expensive piece of legislation considered in decades and it hasn't had a hearing, it hasn't had a markup, and it hasn't had a scoring by the Congressional Budget Office—none of the above—and yet we are in the process of marking it up. We are going to have votes on Tuesday on a proposal that nobody has a clue about how much it costs.

On one of these proposals, some say it will cost $500 billion. Others say it is closer to $800 billion. Although, they forgot to tell that it only lasts a few years, and it is sunset. Then we will stop paying for prescription drugs. No entitlement sunsets after a few years. If somebody thinks we are going to start paying for prescription drugs and then we are going to stop, that is more than hypothetical. That is misleading.

If we are talking about trying to put corporate officers in jail for misleading financial statements, we ought it be ashamed of what we are doing in the Senate. We are taking up the biggest expansion of an entitlement program, and no one has a clue about how much it costs. And we are going to say we are fiscally responsible? Shame on us. We do it without a hearing, without a markup, and without scoring from the Congressional Budget Office. That is a really poor way to legislate. That is the way you get things started, and you later say: Wow, I had no idea it would cost this much.

Let me be a little more specific about the amendment of my colleague and friends from Michigan.

Very seldom do we legislate by intervening ourselves before a case goes before the Supreme Court and say this is the way we mean for it to be. We usually let the Supreme Court make the decision. This issue is before the Supreme Court. The position of the Senator from Michigan lost at the district court level. Then she won at the circuit court level, which has now brought the case before the Supreme Court. But we are going to intervene before the Court and say: Oh, here is what we mean. Rewrite the law.

Basically, we are going to say: All right, under the Medicaid system, which gives a discount—the best price for Medicaid beneficiaries, low-income beneficiaries—we are going to say that is applicable to anybody the State deems eligible.

Guess what. A lot of States have programs for drugs that have no limitation on income.

Senator KENNEDY mentioned three times that we need this program. He said the Senator from Michigan is trying to help the neediest and the poorest of the poor.

I looked up in the State of Massachusetts. This drug program has no income limitation. You could be a billionaire in Massachusetts and you would be benefitting from this program. This has is no direct relationship to income.

In the State of New York, it is 419 percent of the poverty level. That is about $50,000 for a couple.

So this idea of saying this just applies to the neediest—no, this is hijacking. That happens to be the word used at the district court level—a program that was targeted to benefit the low-income people and say, wait a minute, we want it to apply to a lot of other people who do not need the income eligibility of Medicaid.

We are going to take a discount program that was designed and targeted to help low-income people and say it applies to a lot of people, let's make it apply to everybody.

Really, what you are talking about are price controls. But what you are talking about is saying, we are going to take a discount right now that is targeted towards low-income people, and we are going to spread it around to a lot of other people who aren't low-income, and who in some cases have unlimited income. Does that really make sense?

Let me give you an analogy. Maybe sometimes economics arguments are hard to follow, and maybe with prescription drugs it is harder than others. Let us take an example.

I see my good friend and colleague from New Hampshire. He is the former Governor of New Hampshire. As Governor, he purchased automobiles for the highway patrol and for the State police. My guess is that, as Governors, they get a good deal for the automobiles that are sold to the highway patrol and to the State police. He probably buys hundreds of them. Certainly, in a large State such as New York, or Michigan, they buy hundreds, and maybe thousands. So they get a good discounts. They get a better deal than the average consumer.

But if you are going to say, wait a minute, let us not just give this to the police, and a volume discount to the State, let us just give this to basically anybody in the State. That sounds pretty good, doesn't it? We are all going to get a good deal.

Guess what happens now. The price at which they were selling to the State before has just gone up.

In other words, if everybody gets the discount, nobody gets a discount. You are going to find out that the savings that the highway patrol had by buying several hundred vehicles just disappeared because they are not going to get any better deal than anybody else on the street.

That, in effect, is what is going to happen if we adopt the Stabenow amendment. This is a costly amendment if we are going apply this discount that Medicaid now gives on best price for Medicaid to every State program—and some State programs are quite generous. I mentioned for the State of New York it applies to individuals up to 419 percent of poverty; for a couple, incomes up to $50,000. In Massachusetts, there is no income limit.

So if you make it apply—incidentally, under this amendment, a Governor could say: For any drug sold in my State, I am going to have it come under this agreement because I want to offer low-priced drugs to anybody who comes in the State of Oklahoma. So if that is the State program, then every drug would fall under this program. So the net result is, everybody gets a discount. Let's break out the champagne. This is a great deal.

What you have done is, you have taken away—if that is the case—the discount for the low-income people on Medicaid and just taken it and spread it out to everybody else. Is that really what we want to do?

If we adopt the Stabenow amendment, I am just telling you right now, you are eliminating the discount, you are eliminating the low-targeted subsidy that we are now giving low-income people. So if everybody gets the discount, nobody gets the discount. You have just targeted and, quite frankly, greatly increased the cost of the Medicaid Program. You have increased the cost of what is targeted towards low-income people, the people who really need the help.

Keep in mind, this is not targeted to seniors. I have read the Stabenow amendment very closely, and it does not say anything about income limits. As a matter of fact, it says: Hey, you don't have to meet income limits in Medicaid. You don't have to meet eligibility. You don't have to be unemployed. You don't have to be uninsured to benefit under this amendment. It applies to almost everybody.

If the Governor and the legislature write a program broad enough, anybody can apply. Anybody would. So everybody gets a discount. How great is that? It means that nobody gets a discount. This is the impact of this amendment.

It is going to increase costs, as well as costs to the Federal Government. Maybe this thing will become law. Mark my words, we will just write it down. Today is July 18. DON NICKLES says if this amendment passes, you are going to see Medicaid costs go up. We will find out. Some of us will be here for a while. Sometimes we do things that have results. This will result in Medicaid costs going up.

So the very people we think we are trying to help—whoa, wait a minute, we are not helping Medicaid people; we are hurting Medicaid people because they will have to pay more for their drugs. They will lose their discount. This discount will be spread out amongst a lot of other people.

Let me make a couple other comments.

It not just me saying it. This is not my hypothetical situation: Well, DON NICKLES says: Wait a minute, this may backfire.

The General Accounting Office did a report. I will read part of this and then include it in the RECORD:

In an August 2000 report, the GAO determined:

> The larger the group that would be newly entitled to receive a federal price, the greater the incentive for drug manufacturers to raise that price. The Medicaid rebate experience suggests how federal and nonfederal drug price discounts could change if Medicare beneficiaries had access to the same price discounts available to federal purchasers. Following the enactment of the rebate program, discounts for outpatient drugs decreased significantly because manufacturers raised the prices they charge large private purchasers.

That is from the General Accounting Office. That is looking at the facts after we enacted the discount program some time ago. They are saying, if you expand that base of people eligible for a discount, costs are going to go up. It is just a fact.

The other thing is, the Stabenow amendment harms Medicaid beneficiaries. It will raise drug prices in Medicaid and raise Medicaid Program costs at a time when States can least afford it.

I will mention something from the administration. I have a note from them:

> The administration opposes any change in the Medicaid law that would increase Medicaid drug prices and reduce Medicaid coverage. This is what the Stabenow amendment would do. Medicaid law has always focused on what is best for Medicaid beneficiaries. The administration opposes changes in the Medicaid law that would harm Medicaid beneficiaries. The administration said this is what the Stabenow amendment would do. That is exactly what this amendment would do—exactly.

I do not find this to be rocket science. You just tell everybody they are going to be able to get a discount, then nobody gets a discount. Medicaid? Sorry, you are going to have to pay more. They do get a discount now. They do get the best price. They do get the lowest price of anybody in the country. But if you make that applicable to everybody in the country, then nobody gets it. That is what is going to happen.

I am just kind of against that people think: Oh, yeah, we will just do this, and this will save money. It is going to cost money. It is going to cost money from people who can least afford it. And it is going to greatly exacerbate the problems that many of our States right now are struggling with, and struggling with greatly. So I just wanted to mention that. I think it is important.

I will mention two or three things. Let's not increase the cost of Medicaid. That is what this amendment would do.

No. 2, let's not intervene in a case before the Supreme Court. That is pretty foolish.

How many of us really studied this case? How many of us have studied the Maine law? How many of us have studied the idea that: Oh, yes, we are going to say that this program, that was designed for Medicaid, should really be applicable to all programs?

Is that really a smart thing to do? Does it have some delusion or some negative impact on one small group if you say it applies to everybody? I think it is very shortsighted.

So I urge my colleagues to vote no on this amendment. And if, for whatever reason, this amendment is adopted, I will tell my friend and colleague from Michigan, I am going to offer an amendment, and the amendment is going to have the effect to guarantee that the amendment would not have an adverse impact on Medicaid.

My colleague stated, with assurances: Oh, I am sure it will not increase Medicaid costs. The administration says it would. GAO says it would. I think anybody who looks at it says it would. But if she is that confident, then I hope she will accept my amendment that says the proposal will not be effective if it is proven to have an adverse or increased cost in Medicaid drug prices.

I will have that amendment later should her amendment prevail. I hope it does not prevail. I think it is a mistake.

There is a reason we have a committee process. The reason we have a committee process is we have two different ideas on this and two different opinions. We could have experts come in and testify, and they could say exactly what they think the results would be of the Stabenow amendment.

We have not had that opportunity. I would love to have that. I will be happy to participate in a hearing on it next week, next month, 2 months from now, and find out what the experts think, the people who are in charge of CMS, the old HCFA. Let's see what they have to say. Let's see what other experts say.

Let's hear from Governors who not only have Medicaid that they are wrestling with, but other programs. Hey, there are some pluses and minuses in it for them. After all, they have to pay part of it.

Ms. STABENOW. Will my friend from Oklahoma yield for a question?

Mr. NICKLES. I will be happy to yield.

Ms. STABENOW. I am wondering if you are saying for the future, then, any amendment that comes to the floor that has not gone through a committee or subcommittee, you intend to oppose from here on out? Is that correct, for as long as you and I are here in the Senate, you would, in fact, oppose any amendment that comes before us that way?

Mr. NICKLES. I tell my friend and colleague, I think the committee process is being totally ignored by the present leadership in the Senate.

Ms. STABENOW. But does that mean you will, in the future—as opposed to what has happened in the past—object to anything that comes to the floor, any amendment that comes to the floor that has not gone through the committee process? I would be interested in knowing if, in fact, that is your position.

Mr. NICKLES. I would not go that far. But I tell my colleague, I will be

happy to join her in requesting Senator BAUCUS to have a hearing on her proposal as soon as possible. Let's bring in the experts. Let's see what they have to say.

I am a little bit chapped at the fact that I had been in the Senate for about 16-some years before I even got on the Finance Committee, and now it is not working. It has the reputation of being one of the most powerful, great committees, and it does not meet.

The chairman of the committee does not call meetings on this. We have not had a markup on the prescription drug bill. I would liked to have input. I would like to be able to offer an amendment. And I would like to have testimony so we can find out what the substance of the proposal is, what the impact will be. How much will it cost States? How much will it increase Medicaid costs?

I heard somebody say: Well, we think it would increase Medicaid costs by $1 billion or a couple of billion dollars. I think it may be a lot more than that. But I would like to know. Well, we don't know. We have not had estimates. It would be nice to have CMS give us an estimate.

Have we had the chance to do that? No. Because we have not had a hearing. I don't believe a hearing was requested, but it should have been. And the chairman of the committee should have agreed.

I will just tell my colleague, I am happy to participate in a hearing so we can get the facts out. But to change a program totally, and say, OK, we are going to have price controls and discounts for one group, and now we are going to expand it for everybody, with these great savings, assuming that everybody is going to get the savings—the net result is, nobody is going to get the savings. Instead of everybody getting a discount, nobody is going to get a discount. And that is the unfortunate result.

Ms. STABENOW. Will the Senator yield?

Mr. NICKLES. No, I will not yield.

That is the unfortunate result of her amendment. It is just too bad that we bypassed the committee. I don't know why the chairman of the Finance Committee and the ranking member are not saying: Wait a minute, this might be a good proposal. Let's have a hearing on it. We will mark it up. We will consider it.

We haven't done that; again, for something that involves State after State, a Supreme Court decision that will be made in probably a few months. We are going to interject ourselves with a trivial amount of debate on the floor, and we will have Senators vote on it and probably not half a dozen Senators have looked at the amendment in any detail. That is not a good way to legislate.

I reserve the remainder of my time.

Mr. GRASSLEY. Mr. President, I do not support Senator STABENOW's amendment No. 4305 to S. 812 to amend section 1927 of the Social Security Act. As my colleague Senator NICKLES pointed out during debate, this amendment raises important policy and budgetary questions that have not yet been considered by the Senate during a hearing or a committee mark-up. The far-reaching nature of this amendment deserves serious consideration by Congress prior to a vote. Additionally, at present there are pending legal decisions related to matters addressed in this amendment, and I believe it is worthwhile to await the decision of the courts prior to enactment of this amendment. For these reasons, I do not support this amendment, but I reserve the right to re-evaluate the matter at a later date.

Mr. KENNEDY. Madam President, what is the order now? We were allocated time to different individuals, and then at the conclusion of that we were going to recognize the Senator from Michigan to make final comments. I think Senator GREGG is here.

The PRESIDING OFFICER. The Senator from New Hampshire has 5 minutes and the Senator from Michigan has 5 minutes.

The Senator from New Hampshire.

Mr. GREGG. Madam President, it was my understanding that I had 5 minutes plus 7 minutes which would have been 12 minutes.

Mr. KENNEDY. That was my understanding as well. I think the Senator was recognized for 5 minutes and then when they extended the time of the Senator from Michigan, I think they extended the time of the Senator from New Hampshire as well. I would ask that he be accorded the 12 minutes.

The PRESIDING OFFICER. The Senator is recognized for 12 minutes.

Mr. GREGG. I understand there is a desire not to have us go to a vote until 5:40 or so. So there is extra time here. I would suggest that I take 12 minutes and the Senator from Michigan take 12 minutes, that we equally divide the time between now and 5:40, and then, at 5:40, proceed to a vote.

Mr. KENNEDY. That is satisfactory to me. I generally try to check with our leadership.

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

Mr. KENNEDY. I think, for the benefit of the Members, the time for the vote will be at 5:40.

Mr. GREGG. Let me first associate myself with the excellent comments made by the Senator from Oklahoma who has made most of the points I would have made but made them with more energy and eloquence.

If you look at this proposal which has come forward, offered by the Senator from Michigan, essentially its outcome will be that the discounts allowed under Medicaid, which States get for their Medicaid recipients, which are significant discounts—nobody should underestimate, these are big discounts which drug companies that make your product are required to give to the States through the Medicaid process—those discounts under the proposal of the Senator from Michigan, those discounts will now be transferable to a whole new population of people, a very large, potentially very large population of people.

As the Senator from Oklahoma pointed out rather correctly, that population is not necessarily going to be means tested, not necessarily going to be of need. It could simply be a population which qualifies for this new discount under a State plan.

As a result, what you are going to do is end up for those drugs significantly reducing the revenues which flow to whoever produced that drug. What is the impact of that? Assuming that this is not a situation where the people who produced the drug are charitable organizations but are, rather, organizations which, in order to be able to produce that drug, had to go out and borrow money from somebody through the capital markets or through actual borrowing in order to be able to raise enough money to be able to bring that drug to market, remembering that the average cost to bring a drug to market in America today is somewhere between $500 million and $800 million and it takes somewhere between 10 and 12 years, assuming that this is not a charitable organization, then that company, in order to be successful, those people who invented that drug, who created that drug, who put their life into that drug for 12 years, managed to manufacture it after going through all the hurdles—and believe me, there are an unlimited number of hurdles, an incredible number of hurdles, at incredible expense, had to go out and line up their financing to do this—those people are going to have to raise the cost to somebody else. Because they still have to pay off the people who financed the drug. They have to give a reasonable return to the people who invested in that company or they are not going to be able to produce another drug. The drug that they produce may put them into bankruptcy for all intents and purposes, if they can't get a fair recovery on it.

What is the practical implication? Essentially what we are doing here is another example of saying: The big, bad, greedy drug companies, they can take the hit no matter what. They can take the hit. We have seen it happen out here on the floor. We have heard the argument from the other side. We can just do this because the big, bad drug companies are going to take the hit.

Let's remember what we are talking about. We are talking about one of the most important elements of our society, organizations which are producing products which are making American lives better, longer, and more healthy. Is it our goal to fundamentally undermine the capacity to do that? If we continue on this course—and this is obviously not the most extreme example of it, but this is a clear example of price controls and an attempt to drive

down the return on the ability of somebody to produce a product, which saves lives—if we continue on this process, we are essentially going to be plucking the feathers, rather aggressively, of the guys who are laying the lifesaving drug.

In the end we are not going to have a whole lot of gooses or they are going to be geese that don't have enough ability to produce those lifesaving drugs anymore because they don't have any feathers left on their bodies. This is really pretty obvious, if you think about it logically.

Capital in a marketplace system—I understand this is an elementary concept which has escaped some people in the Government—flows where it gets a return. That is just simple fundamentals. By capital I mean money which allows people to invest in products, which creates jobs, and create items that give us as a nation a better chance to compete internationally but, more importantly, gives our American people a better standard of life.

Capital flows where it gets the best return. If you reduce radically or even if you reduce incrementally but in a way that is basically pyramiding on top of itself like straw on a camel's back, if you continue to reduce the ability of the people who are creating the new drugs which are saving lives to have a viable market to go into and get capital; in other words, to be able to go to somebody who is willing to lend them money or willing to invest in their business and expects a reasonable return, if you reduce their ability to get a reasonable return or to pay that debt, you inevitably reduce the amount of drugs coming to the marketplace that will benefit citizens.

In the process, you cut our productivity, cut our national competitiveness, and take what is a very vibrant part of our economy and undermine it.

I realize it is great politics to come to the floor of the Senate and claim that if we do this we will be helping the poor. We will be helping the indigent, helping people who need help. That is great politics. But if you are not producing the drugs, you are not helping anybody. If that lifesaving drug, that drug that is going to give people a better way of life, isn't going to come to market because the people who produce it can't get the money to make it because they can't go in the capital markets and get a decent return, then you are not helping anybody. It is a fraud to come to the floor and claim you are helping all these people. There was a statistic, which I found most interesting, cited today by a colleague on the other side of the aisle. They said that in the biotech industry today there are a thousand firms, but only a hundred of them have products on the market, and we are really excited to think the next 900 are going to come to market with their products.

Well, if we continue to pluck this goose, those 900 firms are not going to come to market with their products because they are not going to have the financial strength to survive the 9, 10, 11, 12 years it takes to get to market with their product. It takes money, cash, capital flowing into those companies—and paying the employees, by the way. It doesn't happen to go to somebody making a gazillion dollars; it goes to the employee. It takes money, cash, and capital to fund that period from the time you think of the product, from the time you invent that concept, from the time it germinates as an idea in some wonderful scientist's mind, to get it to the market, and $500 million to $800 million. So those 900 companies that are out there that don't have a product on the market, but if those products come to the market—this was their point—those products will save hundreds of thousands of lives.

Those products are not going to be there if we continue on this path of, every time we turn around, taking another nick—a fairly significant nick—out of the ability of those companies to be viable.

Are those companies evil and greedy because they want to bring to the marketplace something that is going to improve the lives, or extend the lives, and improve the quality of life of Americans—and, well, yes, be sold in Canada for less because they take advantage of all our research, in a very mercenary way, as does the rest of the world? No. They want to produce a product that is going to improve the quality of life of Americans; and they are willing to do it, willing to put at risk their time, effort, brain power, and their resources, including cash and capital.

But the argument on this floor is they are greedy, so let's just shut down their capacity to do that. And then, at the same time, we are out here claiming: But we are going to have a wonderful, viable drug industry in this country, and we are going to continue to be on the cutting edge.

Well, we are not. We cannot continue to say to people who are producing products you can't get a fair return on your product and expect that they are going to continue to produce their products.

This amendment is not overwhelmingly egregious, but it is one more straw on the back of the ability of the marketplace to move their capital into the production of quality health care products versus moving it into who knows what—software for video games or movies that are violent or whatever else for which the capital gets a better return.

The basic element of this amendment is that we are going to take a very limited program, which demands that people sell a product at significantly less than what the market will bear, and should bear, in order to give a reasonable return and demand that it be spread across a whole new population. And as a result, that population will get a lower cost drug, no question about it. But somebody else is going to have to pay more for the ones that come to market and are put under that system. It is like a balloon, when you squeeze it in one place, it pops out in another place. Other people—probably those on an insurance program—will pay more. So their insurance will go up and maybe they will become uninsured. We can also talk about that. More importantly, fewer people are going to be willing to pursue the path of producing quality drugs because you are not going to be able to go into the marketplace and get the capital to do it. That is what this debate comes down to—whether this feel good, ''I care about everybody'' concept that says that the way you feel good and you care is you basically say the drug companies are greedy, the production is greedy, the biotechs are greedy, and you drive their price down so they can no longer compete, but for a while at least people get a lower cost drug.

I will admit there will be a window where you will be successful. But 4 or 5 years from now, or 8 years or 10 years from now when that drug that might have addressed the issue of Alzheimer's, or of arthritis or addressed the issue of arteriosclerosis, multiple sclerosis, or any number of diseases, that drug didn't come to the market because the person who had the idea could not get the money in the capital market to finance the 8 to 12 years and the $500 million to $800 million to bring it to market because there was not a market that generated that kind of return. Have we done a lot of good for the American people then? I don't think so.

So as we move down this road, we have to be balanced. Good ideas may flow, things that seem appropriate to the moment. We can throw them out, but let's evaluate them in the context of what their ultimate outcome will be.

How much time do I have remaining?

The PRESIDING OFFICER. The Senator has 10 seconds.

Mr. GREGG. Well, I may use all my 10 seconds. I will reserve that time.

The PRESIDING OFFICER. The Senator from Michigan is recognized.

Ms. STABENOW. It is difficult for me to know where to begin with all of this what I view as misinformation. I will at least clarify what I believe to be the facts regarding the situation in the bill and, beyond the bill, the general issue regarding the pharmaceutical industry.

I ask unanimous consent that Senators CLINTON and LEAHY be added as cosponsors of the amendment.

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

Ms. STABENOW. I find it interesting, there is great concern about expanding discounts to people who are not on Medicaid. Do you know what is unfair in this country right now? The only people who pay retail, the only people who pay the highest prices in the world are people who are uninsured. No insurance company pays retail. Every insurance company, including Blue Cross Blue Shield, or any company, gets a discount. The States as well—when we

buy for the VA hospital, the Federal Government—we negotiate a discount. Under Medicaid, we have given the States the ability to get what is, frankly, a modest discount—15 percent on brand name drugs, 11 percent on generics. So they don't pay retail. Nobody pays retail. Everybody gets a discount, except for one group—the uninsured in this country.

The majority of those using prescriptions who are uninsured are our senior citizens—the seniors and the disabled of this country. How unfair that we would think they, too, should get a discount. This amendment only affects those who are uninsured. Why? Because everybody else already gets a discount. So if you vote no on this, you are saying this system right now that allows States to get discounts under Medicaid, the Federal Government for the VA, Blue Cross Blue Shield, and every other system—our own insurance system as Federal employees, we don't pay retail—if you vote no, you are saying the only people who don't deserve a discount from retail are uninsured seniors and families. The folks who are not seniors—most of those who are uninsured work and they work for small businesses. Those small businesses are struggling every day to provide health care and they are seeing premiums go up 30 to 40 percent a year, and most of that is because of prescription drugs.

This is a modest amendment. This is an amendment that simply says our States that are struggling right now, both to pay for Medicaid and also to provide some kind of lower cost prescriptions for their citizens, mostly seniors who don't have insurance, ought to be able to use the creativity of a State, the great ''laboratories of democracy'' that I hear about all the time from my colleagues on the other side of the aisle—let them continue to do what they are doing, be creative to lower prices.

I might just quote something that was quoted earlier today by my colleague from Massachusetts, and that is my own Governor of the State of Michigan, who is leading the National Governors Association. We have meeting now Governors who are concerned about prescription drug costs and wanting to provide programs for their citizens, being sued, many of them, because they want to expand the discount for lower prices, to be creative like Maine and Vermont.

We had from Governor Engler:

> The Nation's Governors are extremely disappointed with the course of action chosen by PhRMA, said NGA chairman Michigan Governor John Engler. It is unfortunate that their organization feels compelled to use the court system to manipulate public policy. With pharmacy costs alone rising 15 to 20 percent each year, all purchasers, including the manufacturers themselves, are using tools that manage costs while maintaining quality and access to affordable pharmaceuticals.

That is about an optional program to say to the States: If you choose to be creative and use your leverage under Medicaid to expand a discount to people who do not get a discount, who are the only people who do not get a discount, who are the uninsured, mostly seniors, that you can do that.

I commend the administration because under this administration, the Bush administration, the Solicitor General, Theodore Olson, went to court in support of the Maine plan. He said in his brief:

> The initiative should be allowed to go forward without further intervention.

Olson argued:

> States enjoy a broad measure of flexibility in tailoring the scope and coverage of their Medicaid plans and that court review of Maine Rx was not warranted.

I commend him and the administration for stepping in on the side of States rights, which is what this is all about. This is about States rights. It is not about concerns about the pharmaceutical industry.

I understand they will fight everything, they have been fighting everything, they will continue to fight everything. There is no question about that. We fully expect their arguments to be put forward on this floor.

I wish to make two other points; that is, when we talk about the industry as a whole and the concern that maybe the uninsured would get the same discounts as people with insurance, and what that would do to the poor pharmaceutical companies, we need to look at what the real picture is today economically with this industry as we are concerned about making sure our seniors pay, when they walk into a local pharmacy, the highest prices in the world.

A study that was put out yesterday by Families USA shows some startling comparisons. We all want research. We want those new lifesaving drugs. Unfortunately, 80 percent of the new patents being approved by the FDA are ''me too'' drugs, not new lifesaving drugs, but we want those.

I am deeply concerned about the direction of the companies. The pharmaceutical company is more about being a sales machine, sales and marketing, quarterly reports and profits than about creating new lifesaving drugs, and that is of deep concern to me as to the future for all of us in health care.

A number of companies were outlined yesterday. As an example, Merck spends 5 percent on research and development; 15 percent profits last year, there were three times more profits than what was spent on R&D; and 13 percent was spent on advertising, marketing, and administration. It is almost three times as much on advertising and marketing and three times more in profits than they are spending on R&D.

Pfizer received 1½ times more in profits than they spent on research and development, more than two times more on advertising, marketing, and administration than on research and development. It is a pattern that continues. R&D is not the top expenditure of the companies today.

When we look at the individuals, it is difficult for me, representing the great State of Michigan where people work hard every day for a living, most people working hard for that paycheck, concerned about their kids, whether they are going to be able to send them to college, whether they can afford their health care, working hard every day, and then we hear we cannot possibly lower prescription drug prices, we cannot possibly even get them down to the rate of inflation—they are going up an average of three times the rate of inflation—we could not possibly give a 15-percent discount to uninsured seniors.

Then we look at the numbers, and we see astounding salaries in the drug companies. I mentioned this morning—not to be personal but this is public information—the comparisons are astounding. The former chairman and CEO of Bristol-Myers, $74.9 million last year in earnings and, in addition, $76.1 million in unexercised stock options.

We have been talking in this Chamber about corporate responsibility and integrity and, I would argue, morality. What is the morality of huge, tens of millions of dollars in salaries and huge amounts of profits, and when we say just get the prices in line so people can afford these new lifesaving drugs so they are not cutting the pills in half, taking them every other day—worst yet, not affording them at all—and we are told, no, nothing can be done, nothing can be done. They fight every single attempt to rein in prices or expand coverage.

This is a fundamental battle, I believe. I think we are needing to help an industry save itself and get back to its soul, which is research and development in new drugs, and to get back in touch with the American people.

I commend the States that are involved right now. They are close to the people. They are close to the people in their States and they know, they hear the stories every day, and they are trying to do something. They want us to act. I do not know if we are going to be able to get this all the way through. I certainly hope so, and I will do everything I can humanly do to work with my colleagues to make it happen.

In the meantime, the States are trying to help. We have 30 States that are doing something in the area of prescription drugs trying to help, and we have States being sued by the drug lobby because they are trying to help.

I will simply say, as we bring this debate to a close, that this is an amendment that does not force a State to do anything. It only affects the States that want to expand their drug discounts to those without coverage. It is an issue of flexibility.

The administration has gone on record in support of the Maine project which we use as an example of what can be done, and we appreciate that. It will stop unnecessary litigation. I know there is a great deal of concern by my colleagues about unnecessary

litigation. It will allow States to stop spending money on litigation and put money in essential services, such as being able to make available prescription drugs to their citizens.

I hope my colleagues will join in support of this bipartisan—tripartisan—amendment this evening and send a message that we support our States and we support their right to be involved in putting together efforts to lower prices and make lifesaving medicine available to their citizens.

I ask for the yeas and nays on my amendment.

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The yeas and nays were ordered.

Ms. STABENOW. I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

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

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

## UNANIMOUS-CONSENT AGREEMENT—EXECUTIVE CALENDAR

Mr. REID. Madam President, I ask unanimous consent that the cloture vote on Executive Calendar No. 825, Richard Clifton to be United States Circuit Court Judge, occur immediately following the disposition of Senator STABENOW's amendment. I further ask unanimous consent that following the confirmation of Judge Clifton, the Senate move to proceed to the nomination of Richard Carmona to be United States Surgeon General; that following the filing of cloture on the nomination, the Senate resume legislative session; that the live quorum for that cloture vote be waived, and that the cloture vote on the Carmona nomination occur on Tuesday, July 23, at 10:30 a.m.; and that the preceding all occur without any intervening action or debate.

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

Mr. REID. Madam President, there is also the possibility of a third vote this evening on confirmation following the two votes previously announced in this unanimous consent agreement.

### VOTE ON AMENDMENT NO. 4305, AS MODIFIED

Mr. REID. We are now ready to proceed to the Stabenow amendment. Have the yeas and nays been ordered on Stabenow?

Mr. GREGG. Yes.

The PRESIDING OFFICER. The yeas and nays have been ordered.

The question is on agreeing to amendment No. 4305, as modified. The clerk will call the roll.

The legislative clerk called the roll.

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

The PRESIDING OFFICER (Ms. CANTWELL). Are there any other Senators in the chamber desiring to vote?

The result was announced—yeas 56, nays 43, as follows:

[Rollcall Vote No. 182 Leg.]

YEAS—56

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

NAYS—43

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

NOT VOTING—1

Helms

The amendment (No. 4305), as modified, was agreed to.

Mr. DASCHLE. Madam President, I move to reconsider the vote.

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

The motion to lay on the table was agreed to.

Mr. DASCHLE. Madam President, there are two additional votes. I ask unanimous consent that they be 10 minutes each.

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

Mr. DASCHLE. Madam President, I would like everybody to stay right here. At the end of 10 minutes, we will go to a third vote. That will be the last vote for the week. I appreciate everybody's cooperation in staying here and voting, and staying here for the second of the two votes. Then we will be finished for the evening.

## EXECUTIVE SESSION

## NOMINATION OF RICHARD R. CLIFTON, OF HAWAII, TO BE UNITED STATES CIRCUIT JUDGE FOR THE NINTH CIRCUIT

### CLOTURE MOTION

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

The legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, do hereby move to bring to a close debate on Executive Calendar No. 825, the nomination of Richard R. Clifton, to be United States Circuit Judge for the Ninth Circuit.

Jeff Bingaman, Patrick Leahy, Daniel Inouye, Harry Reid, Tom Daschle, Dianne Feinstein, Orrin Hatch, Chuck Grassley, Michael B. Enzi, Craig Thomas, Christopher Bond, Jeff Sessions, Jon Kyl, Rick Santorum, Pat Roberts, Trent Lott.

The PRESIDING OFFICER. Under the previous order, the quorum call is waived.

The question is, Is it the sense of the Senate that debate on Executive Calendar No. 825, the nomination of Richard R. Clifton of Hawaii, to be United States Circuit Judge for the Ninth Circuit, shall be brought to a close?

The yeas and nays are required under the rule.

The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. REID. I announce that the Senator from Iowa (Mr. HARKIN) is necessarily absent.

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

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

The yeas and nays resulted—yeas 97, nays 1, as follows:

[Rollcall Vote No. 183 Ex.]

YEAS—97

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

NAYS—1

McCain

NOT VOTING—2

Harkin Helms

The PRESIDING OFFICER. On this vote, the yeas are 97, the nays are 1. Three-fifths of the Senators duly chosen and sworn having voted in the affirmative, the motion is agreed to.

Mr. LEAHY. With today's vote, the Senate will confirm its 11th judge to our Federal Courts of Appeals and our 59th judicial nominee since the change in Senate majority little more than