

1 BUSINESS MEETING - MEDICARE PRICE NEGOTIATION

2 THURSDAY, APRIL 12, 2007

3 U.S. Senate,

4 Committee on Finance,

5 Washington, DC.

6 The hearing was convened, pursuant to notice, at 6:43  
7 p.m., in room 219, Dirksen Senate Office Building, Hon.  
8 Max Baucus (chairman of the committee) presiding.

9 Present: Senators Rockefeller, Conrad, Bingaman,  
10 Kerry, Lincoln, Wyden, Schumer, Stabenow, Cantwell,  
11 Salazar, Grassley, Hatch, Snowe, Kyl, Thomas, Smith,  
12 Crapo, and Roberts.

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1 OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM  
2 MONTANA, CHAIRMAN, COMMITTEE ON FINANCE

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4 The Chairman. The committee will come to order.  
5 The committee meets today to consider a substitute to S.  
6 3, the Medicare Prescription Drug Price Negotiation Act  
7 of 2007.

8 Forty-five years ago, not far from this site,  
9 President John F. Kennedy said, "Let us never fear to  
10 negotiate." Today we meet to consider whether we can  
11 allow the Government to negotiate over drug prices. Some  
12 find that prospect simply too frightening. Some would  
13 argue that the only thing that we have to fear is  
14 negotiation itself. But, my colleagues, I believe that  
15 we are made of sterner stuff.

16 Today we consider legislation that has considered a  
17 great deal of controversy. Proponents and detractors of  
18 negotiation have voiced strong opinions. But, my  
19 colleagues, the legislation before us today is nothing to  
20 fear. Let me start from the beginning.

21 First, what is the non-interference clause? The  
22 clause prohibits the Secretary of Health and Human  
23 Services from interfering with the negotiations between  
24 drug manufacturers and pharmacies and drug plan sponsors.  
25 Essentially, the clause bans the Secretary from affecting

1 the prices that Medicare pays for drugs.

2 What was the purpose of the non-interference clause?  
3 When we created the Medicare drug benefit, we could only  
4 imagine how it might work. We really did not know. In  
5 some respects, our work was theoretical. First, we  
6 established a private sector delivery approach, and that  
7 is the foundation. Next, in an abundance of caution, we  
8 went a step further. We took what I am now convinced was  
9 a step too far--that is, we tied the hands of the  
10 Secretary with the non-interference clause. We  
11 eliminated the Government's role in getting fair drug  
12 prices for seniors.

13 Now, the drug benefits exists. It is in the law. It  
14 is in its second year. And while it is not perfect, it  
15 is working for millions of Americans. We need to do all  
16 we can to make sure that it works well for everyone.

17 Now that the program is established, it is time for  
18 us to look at it from a longer-term perspective. Our  
19 initial concerns about whether there would be enough  
20 interest from beneficiaries and from plans are behind us.  
21 There certainly has been. From here on out, our  
22 responsibility is to monitor and to guide the program as  
23 it matures.

24 Looking at the program today, the non-interference  
25 clause, I believe, is an unnecessary hindrance. We want

1 the Secretary to use the tools in the toolbox so that he  
2 can shape the drug benefit into a strong and thriving  
3 program. It is time to untie the Secretary's hands.

4 I cannot recall when so few words caused as much of a  
5 stir as the non-interference clause. I counted 14 words.  
6 Whether seniors in Medicare are getting the best prices  
7 evokes passionate debate, as does the appropriate role of  
8 Government in health care. The philosophical divides in  
9 this debate are ones that we have struggled over before.  
10 It is no wonder this issue is so hot politically.

11 But we here today, as is certainly the tradition of  
12 this committee, must put politics aside. We must tackle  
13 this issue once and for all.

14 I am anxious to have the Finance Committee consider  
15 this legislation because I believe it is the right thing  
16 to do. We need to take the steps so that we can move on  
17 to other aspects of the program.

18 Just to name a few, we need to look at CMS oversight  
19 of private plans. We need to address pharmacy access.  
20 We need to revisit the low-income subsidy asset test.  
21 Again, just to name a few.

22 I hope and expect future improvements to the drug  
23 benefit will be bipartisan. So why strike the non-  
24 interference clause? We should strike it because we know  
25 the drug benefit is not perfect. We should strike it

1 because we cannot envision every scenario or situation in  
2 the future of this program. And we should strike it  
3 because we must untie the Secretary's hands and make sure  
4 that the toolbox is available for him.

5 It is important to note what striking the clause does  
6 not mean. It does not mean the Secretary can impose  
7 price controls or set drug prices. It does not mean the  
8 Secretary can create a national formulary. It does not  
9 mean the Secretary can administer pricing, nor does it  
10 mean the Secretary can intervene in the market in a  
11 heavy-handed way. Rather, we want the Secretary to be  
12 able to check under the hood and see if there is there is  
13 a problem. And if there is one, we want the Secretary  
14 not to be barred from doing something about it.

15 I believe that the Secretary has a role and  
16 responsibility here short of creating a national  
17 formulary. The non-interference clause prohibits us from  
18 pursuing constructive efforts to make the drug benefit  
19 work better for seniors, and I think that, therefore, it  
20 should be eliminated. I have included policies regarding  
21 transparency and also regarding comparative effectiveness  
22 in the mark. They are key to the issue of drug pricing  
23 and represent steps the Secretary should take as a good  
24 steward of the Medicare program. There are also areas of  
25 bipartisan interest when it comes to drug pricing. I

1 think these two provisions are very, very important.  
2 They are going to turn out to be more important as we  
3 proceed in the upcoming months and years.

4 It is clear that we need a better understanding of  
5 prescription drug pricing in the Medicare market. We  
6 also need to know more about the effectiveness of the  
7 drugs Medicare pays for, and I believe increased  
8 transparency and the use of comparative effectiveness  
9 will make Medicare a smarter shopper and help us evaluate  
10 the success of the program.

11 I am not trying to write the book on these issues  
12 with this mark, but I do believe we should move forward.  
13 I anticipate many more policy discussions this year, and  
14 more progress, and I hope today's mark will initiate that  
15 dialogue and start us down a path toward improving and  
16 strengthening the Medicare drug benefit.

17 This has been a long road to get to this markup. I  
18 want to thank my colleagues who paved the way. Many are  
19 here at this moment. Senator Wyden and Senator Snowe  
20 have led us through the many policy considerations that  
21 put forth this thoughtful legislation, and I thank both  
22 of you very much. Senator Stabenow and Senator Smith  
23 have also devoted a great deal of time effort to this  
24 issue, and I appreciate both of you--and others who have  
25 worked so hard--for your commitment to making the



1 Medicare drug benefit better.

2 I also want to thank all the members who gave me  
3 thoughtful input as we put this mark together. The mark  
4 represents a common desire to make sure seniors have  
5 access to affordable medicines. It symbolizes our shared  
6 concern about how Medicare dollars are spent and, most  
7 importantly, it shows our continued willingness to move  
8 forward and make improvements.

9 So let us not fear to negotiate. Let us not fear to  
10 improve the Medicare drug bill. And let us continue in  
11 our effort to bring the best to America's seniors.

12 Senator Grassley?

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1 OPENING STATEMENT OF HON. CHARLES E. Grassley, A U.S.

2 SENATOR FROM IOWA

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4 Senator Grassley. Thank you very much, Mr.  
5 Chairman. I would rather not be here, not because it is  
6 Thursday night and I could be on my way to Iowa, but  
7 because you and I have had such a close relationship on  
8 building up the legislation that is before us in the  
9 first place. And for the audience and everybody else who  
10 might observe this committee but not to my committee  
11 members, there might be some feeling that since Senator  
12 Grassley and Senator Baucus are not together on this  
13 issue, that this might be a breakdown of bipartisanship  
14 in this committee. Let me assure you that it will not  
15 be, because I think as time goes on you will see that we  
16 are working together on SCHIP reauthorization, physician  
17 payment reform, some issues dealing on trade, the issues  
18 of the uninsured, and even some improvements that  
19 hopefully this committee will be able to do that are more  
20 important than this issue, making some improvements to  
21 Part D that I think Senator Baucus and I will be able to  
22 work out. So anybody that thinks that this is a change  
23 of direction, get that out of your head.

24 Now, if I could say a couple things--

25 The Chairman. Senator, I appreciate that very much.

1 Thank you.

2 Senator Grassley. Thank you. And if I could tell  
3 you something to, I think, everybody on this side of the  
4 aisle, and probably Senator Snowe and Senator Smith on  
5 this side of the aisle, I have some remarks that will  
6 probably be considered very sharp, but I would like to  
7 give you four sentences to think about as background to  
8 why I am making the statements that I am making. And  
9 these are all things you have heard me say before, and  
10 unless you are like I am, you do not pay any attention to  
11 what other people say on the Senate floor. But if you  
12 have, then you have heard them say it.

13 First of all, remember that this language that is in  
14 here was in a bill presented by President Clinton before  
15 he left office. It was in several bills that Democrats  
16 introduced and even bipartisan bills that were introduced  
17 before we ever put it in here. And one of my motivations  
18 for putting it in here was if I could take something that  
19 the Democrats like and put it in, it would make it an  
20 even more bipartisan bill than maybe otherwise.

21 Now, we ended up passing a bipartisan bill, so we are  
22 changing--I suppose you are changing in a bipartisan way  
23 something that was in a bipartisan bill because you will  
24 have some Republican support. So that is the first one--  
25 Democrat language.

1           The second point I think you ought to consider is  
2 whether or not negotiations are working out. I think  
3 that these plans that we have out there--and some people  
4 take the position we have too many plans, but whether we  
5 have got too many or not, there are ample plans out there  
6 where there is enough competition for membership that  
7 they got big enough membership that they are negotiating  
8 down prices. So this is a point I want you to remember.  
9 The 25 most used drugs are 35 percent below what we  
10 thought we would be paying for these drugs in the first  
11 place.

12           The second thing is, if any of you make the  
13 statement--and maybe you will not make the statement.  
14 But if somebody says, "Well, we want to do it like the VA  
15 does it," just remember that the people that are on VA  
16 have 23 percent of the drugs that are available for  
17 Medicare people. And, remember, you have people leaving  
18 the veterans program to go into Part D because there is  
19 something about the veterans program that does not fit  
20 the need of that veteran. And also remember that 83  
21 percent of the drugs that go to veterans are mailed out.

22           Now, remember that when Senator Baucus and I put this  
23 bill together, we had a requirement that every plan had  
24 to have brick-and-mortar type--well, local pharmacies, in  
25 other words. And what is going to happen, if you start

1 doing it in Medicare like you do it with the VA, mail out  
2 83 percent of the drugs, explain that to everyone of your  
3 local pharmacists.

4 And the fourth point is, as I am going to be speaking  
5 to in just a minute, we had just less than 6 weeks ago a  
6 panel of people here, and a couple of them said that when  
7 you do this for 43 million people, prices are going to go  
8 up for everybody else. When you have got half of the  
9 people that you are going to be negotiating for, it  
10 cannot help but make prices go up for everybody else.  
11 Now, that is a Princeton professor, that is not a Chuck  
12 Grassley, Iowa farmer, saying that.

13 Now, will you keep those things in mind as I make my  
14 comments?

15 A lot of political hay has been made about the so-  
16 called prohibition on Medicare negotiation with drug  
17 makers for lower prices under Medicare drug benefits.  
18 First, everyone should recognize that opponents of the  
19 drug benefit have tried to tear this benefit apart since  
20 Day One. The naysayers want a Government-run benefit  
21 with the Federal Government dictating drug prices. The  
22 naysayers said that there would be no prescription drug  
23 plans. Then when that did not happen, they said that  
24 there would be too many plans. The naysayers said that  
25 it was too confusing, the seniors would not be able to

1 choose a plan. But seniors have enrolled, and the  
2 surveys show that they are satisfied with their plans.

3 The naysayers' biggest criticism of the drug benefit  
4 is that, according to them, the Government does not  
5 negotiate with drug makers for lower prices. I say  
6 "according to them" because they have gone to great  
7 lengths to make it sound like nobody is negotiating with  
8 the drug companies. If you believe the naysayers, you  
9 would think drug companies name their price and Medicare  
10 beneficiaries are forced to pay for it. That is so wrong  
11 that it boggles the mind.

12 Opponents of the Medicare drug benefits have gone to  
13 great lengths to make sure that it sounds like no one is  
14 negotiating. To say there is no negotiation is just  
15 plain nonsense.

16 Now, it is correct, of course, to say that the  
17 Secretary himself does not negotiate with drug companies.  
18 It is absolutely not correct to say that there is no  
19 negotiations. That is complete and utter nonsense, and  
20 it ought to be embarrassingly wrong. I have said it  
21 before and I will say it again: Having the Government  
22 negotiate drug prices for Medicare might be a good sound  
23 bite, but it is not sound policy.

24 H.R. 4, the bill that passed the House, falls into  
25 that category. S. 3, the bill before us, is no

1 different, although it is worded differently.

2 At the beginning of the year, I expressed my  
3 disappointment that we were going to have to spend a lot  
4 of time on this issue when there were a number of other  
5 pressing issues for this most important committee, the  
6 most important committee in the Congress to work on. We  
7 have reauthorization of SCHIP. We have physician payment  
8 issues. There are areas of prescription drug benefits  
9 that I think that we should devote some time to.

10 So I filed a series of amendments: coverage of  
11 benzodi--whatever you call it. [Laughter.]

12 More funding for outreach and education, the asset  
13 test, the pharmacy issues--that is what we should be  
14 working on. That is where we can make a difference. It  
15 is something that needs to be done to improve a bill that  
16 I think when Senator Baucus and I wrote it thought it was  
17 perfect. But we need to make some changes. The only  
18 thing wrong is Senator Baucus has figured out the first  
19 issue is the one that is working and so why change it.  
20 "If it ain't broke, don't fix it," see? But there are a  
21 lot of things we can work together on Part D to make it  
22 even better.

23 Nevertheless, here we are considering this bill that,  
24 like the House bill, keeps the current law prohibition on  
25 instituting a particular formulary. Expert after expert,

1 whether they are from the Congressional Budget Office,  
2 the Government Accountability Office, academia, agree.  
3 No formulary means no leverage. No leverage means no way  
4 to get lower prices. No lower prices then means no  
5 savings.

6 At a January Senate Finance Committee hearing,  
7 Professor Scott Morton said that, without a formulary,  
8 the Secretary would have about as much negotiating power  
9 that you would get by calling a drug maker and saying, "I  
10 would like you to offer a lower price." Their answer  
11 would be, "Why should I? You have to buy my drug, so why  
12 would I offer you a lower price?"

13 About all you have got left after that is just to  
14 say, "Please, Mr. Pharmaceutical Company, will you not  
15 help us out." And, of course, everybody knows with that  
16 strong segment of our economy, it is not going to get you  
17 very far. But it has gotten the seniors of this country,  
18 by negotiation, the 25 most used drugs 35 percent  
19 cheaper.

20 Professor Scott Morton also pointed out the obvious:  
21 that we all want to obtain discounts on drugs for  
22 seniors. But she said, and I quote, "With close to half  
23 of all spending being generated by those seniors"--  
24 remember, I asked you to consider this. "With close to  
25 half of all spending being generated by those seniors,



1 whatever price they pay will tend to be the average price  
2 in the market."

3 Her point was that if you are half the market, the  
4 math--the math--makes it virtually impossible for your  
5 prices to be below average. Professor Scott Morton said  
6 that because Medicare is so large, if drug makers had to  
7 give it the lowest price they give any customer, they  
8 would have a strong incentive--to do what? To increase  
9 their prices for everybody else. Professor Scott Morton  
10 also state, and I quote, "This approach to controlling  
11 prices harms all the other consumers of pharmaceuticals  
12 in the United States and is a bad policy."

13 So it is great. It is great out there to help  
14 seniors. But there is no free lunch. Everybody,  
15 regardless of age, will pay more for prescription drugs.

16 A representative of the nonpartisan Government  
17 Accountability Office, who also testified at the same  
18 hearing, talked about its--meaning the GAO--2000 year  
19 report on this issue and echoed Dr. Scott Morton's view.  
20 In 2000, the GAO said this: "Mandating that Federal  
21 prices for outpatient prescription drugs will be extended  
22 to a large group of purchasers, such as Medicare  
23 beneficiaries, could lower the price they pay, but raise  
24 prices for others."

25 Now, one thing we keep hearing is that Medicare

1 should not pay more than VA pays. When asked what would  
2 happen if Medicare got the same prices that the VA gets,  
3 drug maker witnesses agreed that it would likely raise VA  
4 prices for all drugs. The VA itself expressed the same  
5 concern in a 2001 hearing before the Senate Committee on  
6 Veterans' Affairs. Higher prices for veterans. Yes, the  
7 path of this legislation charts a course for higher  
8 prices for veterans. I cannot imagine who would want to  
9 do that.

10 Another key point made at the Finance Committee  
11 hearings was that it is not simply about the number of  
12 people you are buying prescription drugs for. In  
13 response to a question I asked, Professor Scott Morton  
14 said it does not matter whether you negotiate on behalf  
15 of a million people or 43 million people. What matters  
16 is what leverage you have and how you use that leverage.  
17 And that goes back to the point that I made earlier about  
18 this bill. The Secretary has no leverage under the House  
19 bill or under this bill.

20 I am not for a national formulary. A single national  
21 formulary would limit access to drugs. Today  
22 beneficiaries have choices of formularies. They can pick  
23 a plan that covers their drug. But let me repeat: No  
24 formulary means no leverage. No leverage means that you  
25 have no way of getting lower prices. No lower prices

1 means no savings. And so for all the talk about getting  
2 savings from Government negotiation, this bill takes away  
3 a key tool to get lower prices. That was the key lesson  
4 from the January Finance Committee hearing.

5 And here is what the Congressional Budget Office said  
6 about the chairman's mark, S. 3. The chairman's mark  
7 would have "a negligible effect on Federal spending."  
8 So, to repeat, a negligible effect on Federal spending.  
9 The CBO said again, and I am quoting, "Without the  
10 authority to establish a formulary or other tools to  
11 reduce drug prices, we believe that the Secretary would  
12 not obtain significant discounts from drug manufacturers  
13 across a broad range of drugs." That statement is pretty  
14 clear. What we are being told will happen as a result of  
15 this bill--and that would be lower prices--just "ain't"  
16 going to happen.

17 Now, I want to go back and remind everyone where the  
18 prohibition on negotiations comes from. This is a point  
19 I made that I asked you to pay attention to. That is the  
20 non-interference clause. The opponents of the drug  
21 benefits seem to conveniently forget that their own bills  
22 had the same language and that they supported a benefit  
23 run by private plans. In fact, the prohibition of  
24 Government negotiation, the non-interference language,  
25 first appeared in Democratic bills. In total, seven

1 bills introduced and supported by 34 Senate Democrats and  
2 more than 100 House Democrats had the prohibition in  
3 them. Seven different bills. On top of that, many of  
4 the people who are now twisting that language around  
5 cosponsored those bills.

6 I also want to point out that even President  
7 Clinton's proposal created a Medicare prescription drug  
8 benefit taking the same approach. President Clinton said  
9 so many good things about having private plans to  
10 negotiate lower drug prices for Medicare beneficiaries  
11 that I did not have to think up new things to say. And  
12 it seems to me like many people on this committee or in  
13 this Congress have forgot that there was a President  
14 Clinton. His plan was introduced by the late Senator  
15 Moynihan, S. 2342.

16 Mr. Chairman, the Secretary does not need authority  
17 to negotiate, and a national formulary is a bad idea.  
18 Under the drug benefits today, with the plans negotiating  
19 with drug makers and competing with each other, we now  
20 have--we have already got it--lower drug prices for  
21 beneficiaries, lower program costs for the Government.  
22 How many Government programs have we ever made that have  
23 come in under cost? I think the number is \$260 billion  
24 than what was projected here 3 years ago. Competition is  
25 working.

1           So, Mr. Chairman, with all due respect to my friend  
2           from Montana, I know you want to do the right thing, but  
3           this bill does nothing more than keep alive a political  
4           pandering approach that Democrats have committed against  
5           Medicare beneficiaries and the public on this issue. So,  
6           obviously, I do not support what you are doing, but it is  
7           not going to keep us from working together on all these  
8           other things that we ought to be working on right now  
9           instead of doing what we are doing today.

10          Thank you.

11          The Chairman. Thank you very much, Senator. I  
12          appreciate those remarks.

13          I would now like to turn to the stage where Senators  
14          can and should make remarks, but I would remind us all  
15          that there are a lot of us here, and we have a lot of  
16          work ahead of us and if Senators could confine their  
17          remarks, say, to 4 minutes. We do have an early-bird  
18          rule here, and I am going to go down the list: Senator  
19          Conrad, Senator Smith, Senator Wyden, Senator Stabenow,  
20          Cantwell, Bingaman, Salazar, Snowe, Kerry, Rockefeller,  
21          Lincoln, Kyl, Schumer.

22          Senator Conrad, Senator Smith, Senator Wyden.

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1 OPENING STATEMENT OF HON. KENT CONRAD, A U.S. SENATOR  
2 FROM NORTH DAKOTA

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4 Senator Conrad. Can I just observe, Mr. Chairman--I  
5 am going to be very brief--that Senator Grassley  
6 yesterday had a beautiful tie on, and he was in such a  
7 very positive mood. And we had such a pleasant  
8 conversation that I really hesitate to engage him in  
9 debate at this hour. But just on the question of  
10 leverage, when you are negotiating on behalf of 43  
11 million people, that is leverage--and even without a  
12 formulary. I think one has to believe that if the  
13 Secretary were given this authority, he would have  
14 enormous leverage because he is negotiating on behalf of  
15 43 million people. So this notion that he would have no  
16 leverage I do not think stands up to much scrutiny.

17 With that, I want to thank the chairman for really  
18 constructive work to bring us here. We need something  
19 that can pass, something that can move the process  
20 forward, and I think the chairman has done a very good  
21 job of bringing us to that point.

22 The Chairman. Thank you, Senator.

23 Senator Smith?

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1 OPENING STATEMENT OF HON. GORDON H. SMITH, A U.S. SENATOR  
2 FROM OREGON

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4 Senator Smith. Thank you, Mr. Chairman.

5 I support your bill. It is not without some  
6 misgivings. For the reasons that Senator Grassley has  
7 stated, my desire is that we do no harm, and I guess only  
8 time will tell. But I have voted for this in the past  
9 and will do so again, but I would like to put my  
10 statement in the record, and later I do have an amendment  
11 that I intend to offer and then withdraw and work with  
12 you, Mr. Chairman, to find a more appropriate vehicle for  
13 it to be attached to. But I do want to say something  
14 about it at the appropriate time so that I can have it on  
15 the record.

16 The Chairman. You bet. You are setting a good  
17 precedent. Thank you, Senator, very much. [Laughter.]

18 [The prepared statement of Senator Smith appears in  
19 the appendix.]

20 The Chairman. Senator Wyden?

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1 OPENING STATEMENT OF HON. RON WYDEN, A U.S. SENATOR FROM  
2 OREGON

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4 Senator Wyden. Mr. Chairman, thank you. I will be  
5 in the under-4-minute precedent.

6 I want to thank you for your kind words, Mr.  
7 Chairman. I especially appreciate the fact that the  
8 Baucus-Grassley partnership is going to remain alive  
9 after this markup.

10 Mr. Chairman and colleagues, for more than 3 years,  
11 Senator Snowe and I have worked to maximize the  
12 bargaining power of seniors and taxpayers to hold down  
13 the cost of medicine. We both voted for the original  
14 law, and we have wanted to make it work better.

15 Our legislation goes further than the committee  
16 measure before us now. We would, for example, require  
17 the Secretary of Health to negotiate on critical  
18 instances, such as where there are sole-source drugs or  
19 drugs developed with significant amounts of taxpayer  
20 money. We explicitly rejected price controls or  
21 restrictive formularies, but we stood up for the  
22 consumer.

23 The Senate has voted three times on our legislation.  
24 The first time we got 49 votes; then we got 51 votes;  
25 last spring we got 54 votes. And everybody knows around



1 here, hope springs eternal and you look for that magical  
2 60.

3 Here is why we have had the support. Almost every  
4 senior knows that it does not pass the smell test for  
5 Congress to have outlawed negotiating lower prices for  
6 them. Almost every taxpayer knows that it does not pass  
7 the smell test for Congress to have outlawed negotiating  
8 tax savings for them.

9 I am going to do everything I can to build support on  
10 a bipartisan basis for going further than the Committee  
11 is going today, and I am going to look at trying to do  
12 that at every step in the legislative process. But in my  
13 view, it is critically important for this Committee to  
14 act tonight. Removing the provision that outlaws  
15 Medicare from bargaining is a fundamental first step.  
16 Let us build on it and go from there in the days ahead.  
17 Everybody in America negotiates for the best possible  
18 deal. Employers negotiate. Unions negotiate. People  
19 going into stores from coast to coast maximize their  
20 bargaining power by being savvy shoppers.

21 Certainly more needs to be done to improve Part D,  
22 and I appreciated your comments, Mr. Chairman, and  
23 Senator Grassley's comments. We all know that this  
24 program is still far, far too complicated. You almost  
25 have to have an advanced degree in some instances to

1 maximize your value, and that is something we can work on  
2 in a bipartisan way. But let us vote tonight to remove  
3 this provision so that Medicare can negotiate in the key  
4 instances. Send it to the floor, and I hope colleagues  
5 will keep working with Senator Snowe and me and, in fact,  
6 all of the members of this committee, all of the members  
7 of the committee, to improve this program and make  
8 Medicare Part D work better in the days ahead.

9 Thank you, Mr. Chairman.

10 The Chairman. Thank you, Senator, very much.

11 Senator Stabenow?

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1 OPENING STATEMENT OF HON. DEBBIE STABENOW, A U.S. SENATOR  
2 FROM MICHIGAN

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4 Senator Stabenow. Thank you, Mr. Chairman. I  
5 appreciate the kind words as well as your hard work. And  
6 to my office neighbor and friend, Senator Grassley and I  
7 find ourselves on opposite sides, passionately on  
8 opposite sides of this issue. But I am very pleased that  
9 this committee has such a wonderful tradition of working  
10 together.

11 I do feel compelled to say that I find it interesting  
12 in looking at the arguments. On the one hand, we hear  
13 over and over again that this bill will do nothing and  
14 yet this bill will do great harm. I find it difficult to  
15 reconcile it doing both. We have seen pharma, frankly,  
16 do millions, I would assume tens of millions of dollars,  
17 in ads on television and newspaper ads and ads that we  
18 see every day to tell us that this bill will do nothing.  
19 That does not make sense. If that is, in fact, true,  
20 that is not very wise use of their dollars. We also have  
21 heard that it will have an impact of raising costs for  
22 citizens or the VA, or it will take away R&D dollars, and  
23 yet it will do nothing.

24 I think common sense tells us it will do something,  
25 Mr. Chairman, and what it will do is give the ability to

1 negotiate for our seniors to get them the best price.

2 A couple of points I would like, Mr. Chairman, just  
3 to clarify on the record, just to give an alternative set  
4 of numbers. It has been talked about that the VA covers  
5 only a fraction of the drugs covered by Medicare. In  
6 fact, according to the VA, the VA actually covers 4,778  
7 separate drugs, about 478 more than the average 4,300  
8 drugs covered by Part D plans.

9 I also for the record just want to indicate that it  
10 is true that President Clinton and ultimately Senator  
11 Moynihan--there was a Moynihan bill that had what was  
12 called non-interference language in them. The reason was  
13 simple. It was a very different model. It had one  
14 negotiator, one prescription drug benefit manager. In  
15 that case, where you have one negotiator, it was  
16 appropriate to say the Secretary would not interfere.

17 But since that time, every bill--Senator Bob Graham  
18 introduced a bill with multiple different negotiators;  
19 Senator Daschle introduced one for our Democratic Caucus  
20 that had multiple PBMs in it. And in neither of those  
21 did the non-interference language occur because there was  
22 competition from the multiple benefit managers.

23 So I would just argue that the delivery model  
24 determines the language, and now that we have thousands  
25 of different approaches, it certainly is not necessary to

1 have that non-interference language. It is a very  
2 different model from what was cited in terms of the  
3 legislation that was introduced in the past.

4 Mr. Chairman, I thank you again. This is a very  
5 important first step. I support going farther, but I  
6 also support this bill because I think it is a very  
7 important first step to helping our seniors get the very  
8 best price for their medicine.

9 Thank you.

10 The Chairman. Thank you, Senator, very much.

11 Senator Cantwell?

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1 OPENING STATEMENT OF HON. MARIA CANTWELL, A U.S. SENATOR  
2 FROM WASHINGTON

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4 Senator Cantwell. Thank you, Mr. Chairman, and  
5 thank you for your work to include transparency  
6 provisions in this mark. I believe this has been an  
7 important step in the right direction, and as you know,  
8 and as Senator Grassley knows, I have been working to  
9 improve transparency in the Part D program since before  
10 it was enacted, and I am pleased that we are advancing  
11 that agenda tonight.

12 I believe the Government needs to be smart in its  
13 health care purchases, and smart purchasers are demanding  
14 accountability for the dollars that they put on the  
15 table.

16 Consider what is happening at Caterpillar, a \$40  
17 billion company and one of the biggest manufacturers of  
18 construction equipment in the country. The Wall Street  
19 Journal recently interviewed Caterpillar's head of human  
20 resources. He shared his frustrations with the way  
21 prescription drug benefits are managed and paid for,  
22 particularly his inability to tell how much Caterpillar  
23 actually pays for drugs versus how much of their money is  
24 going to their pharmacy benefit manager.

25 Well, Caterpillar did something about their

1 frustration. They changed how they buy drugs. Today  
2 they are demanding transportation from PBMs, insisting  
3 that Caterpillar, not PBM middlemen, get the benefit of  
4 drug company rebates. These changes have saved  
5 Caterpillar \$9 million in one year. Today Caterpillar  
6 leads a coalition of 56 business companies demanding  
7 accountability and transparency from PBMs. Ten PBMs have  
8 agreed to comply with the coalition's transparency  
9 standards. The Wall Street Journal reports that the  
10 employer coalition is now saving 3 to 6 percent a year on  
11 their drugs at a time when other employers are seeing a  
12 rise in costs. We should be demanding no less from the  
13 Federal Government's drug purchasing through Medicare  
14 Part D.

15 This mark takes us an important step in this  
16 direction by increasing the availability of information  
17 about the discounts and price concessions drug plans are  
18 getting, but the discounts happening behind the scenes  
19 between drug plan contractors, the PBMs, and the drug  
20 manufacturers remain opaque.

21 We need to do more on transparency, so I am delighted  
22 that my colleagues on the other side of the aisle know  
23 that transparency is important in Part D. We need to be  
24 thinking and acting smart about our health care  
25 purchases, just as they are in the private market. I

1 look forward to working with my colleagues in a  
2 bipartisan fashion to improve transparency as this bill  
3 moves through the Senate.

4 Thank you.

5 The Chairman. Thank you, Senator.

6 Senator Bingaman, you are next.

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1 OPENING STATEMENT OF HON. JEFF BINGAMAN, A U.S. SENATOR  
2 FROM NEW MEXICO

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4 Senator Bingaman. Thank you very much, Mr.  
5 Chairman. I congratulate you on getting this chairman's  
6 mark before us, and I do think it will move us in the  
7 right direction. I particularly also appreciate what you  
8 are doing in trying to give people better information  
9 with regard to these prescription drugs which people are  
10 buying under Part D. And your willingness to include the  
11 suggested amendment that I have developed on ensuring  
12 that I very much appreciate.

13 Thank you.

14 The Chairman. You bet. Thank you very much,  
15 Senator.

16 Senator Salazar?

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1 OPENING STATEMENT OF HON. KEN SALAZAR, A U.S. SENATOR  
2 FROM COLORADO

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4 Senator Salazar. Mr. Chairman, I just associate  
5 myself with your comments and congratulate you for  
6 getting us to this mark. And to Senator Grassley, I  
7 appreciate your statement of camaraderie in terms of  
8 wanting to move forward on all the rest of the issues  
9 that this committee will continue to work on in the  
10 bipartisan tradition of the Finance Committee.

11 Thank you very much.

12 The Chairman. Thank you, Senator.

13 Senator Snowe?

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1 OPENING STATEMENT OF HON. OLYMPIA SNOWE, A U.S. SENATOR  
2 FROM MAINE

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4 Senator Snowe. Thank you, Mr. Chairman. I want to  
5 thank you as well for your commitment to bringing this  
6 issue forward.

7 I cannot help but think about how far we have come in  
8 the sense that we have already enacted a prescription  
9 drug benefit as part of the Medicare program. Obviously,  
10 we would not be having this debate this evening if we did  
11 not have that as part of the overall Medicare program.  
12 But I cannot help but think, although we have come far in  
13 this debate, that I wish that we could go much further  
14 tonight in the mark that appears before this committee in  
15 strengthening and preserving this benefit.

16 I am somewhat dismayed that we are just permitting  
17 negotiations without establishing certain requirements  
18 for when that negotiating authority should be utilized,  
19 particularly in obvious and reasonable instances where it  
20 has been demonstrated that we can actually achieve  
21 savings. And as Senator Wyden indicated, for the last 3  
22 years we have introduced legislation to specify certain  
23 instances where it has been documented we can achieve  
24 actual savings. And, in fact, that has been the track  
25 record in the Senate. Last year, as an amendment to the

1 budget resolution, we got the support of 54 Senators--  
2 including 12 Republicans, I might add--in supporting our  
3 amendment with specific mandates.

4 I would think that we would want to do everything we  
5 can as the committee of jurisdiction to achieve the  
6 savings now--something that this legislation does not  
7 accomplish. And as the committee of jurisdiction, we  
8 have the obligation to establish the best possible  
9 benchmark, both in terms of the issue and also in  
10 applying sound principles of fiscal management, in the  
11 instances that Senator Wyden and I had identified as  
12 being important.

13 One, of course, is on sole-source drugs, and that was  
14 certified by the CBO in a letter to both Senator Wyden  
15 and me that indicated that we could achieve actual  
16 savings. And it makes sense. If a sole-source drug has  
17 no competitive alternative drug, then obviously they can  
18 command the highest prices. The fact is we could achieve  
19 savings in that particular instance because there is no  
20 competing alternative. And so why are we not including  
21 that specific mandate and requirement for the Secretary  
22 to exercise that authority within this legislation?

23 Secondly, when there are no fallback plans, when the  
24 Government has to create a fallback plan for a particular  
25 region of the country, that area does not have the

1 leverage, you know, for competing plans and for  
2 competition. Therefore, we could face the adverse  
3 consequence of the highest prices possible. Why, again,  
4 would we not want to require the Secretary to enter into  
5 negotiations to ensure that that area of the country is  
6 going to achieve the maximum and the best price possible  
7 for that particular fallback plan.

8 In a third instance, when the taxpayers are  
9 supporting the development of a medication through  
10 research and development dollars, why on the one hand are  
11 the taxpayer financing the research and development and  
12 then on the other hand we are subsidizing the prices of  
13 these medications, the very same drugs in which the  
14 taxpayers are underwriting the research and development?  
15 Again, should not the Secretary be involved in  
16 negotiating the maximum and the best price possible?  
17 Because what is at stake here is the American taxpayer.  
18 It is the seniors in this country. This is a national  
19 interest. So why are we not identifying and carving out  
20 those areas where we recognize that it would be  
21 reasonable for the Secretary to assert his authority in  
22 those particular instances? After all, what we are  
23 facing in the Medicare Part D program is a \$700-billion-  
24 plus program, not to mention I would believe we would be  
25 having a very different conversation here tonight if at

1 the time in which many seniors will be falling into the  
2 doughnut hole and where they will not have access to any  
3 comprehensive coverage, because there are more than 11  
4 States currently that will have no comprehensive coverage  
5 available for these seniors to purchase in order to fill  
6 that gap. And they are going to be paying the highest  
7 price possible.

8 Again, when you talk about price escalation, all the  
9 documentation indicates is a 10-percent increase in the  
10 premiums under the Part D, increases in total expense  
11 costs, increases in deductible, and also the rising cost  
12 of medications themselves, which is now 2 and 3 times the  
13 rate of inflation and recently affirmed by AARP in its  
14 study of last month that indicated brand names were now  
15 rising at 6.2 percent in the year 2006 alone.

16 So when you consider the collective weight of what we  
17 can expect in the future with the cost of this program,  
18 it seems that we should not lower the threshold and lower  
19 the bar but, rather, raise it in terms of exercising this  
20 authority. And I think that is our responsibility as a  
21 committee of jurisdiction, to set that bar higher than  
22 what we are doing here this evening.

23 I recognize it is a step in the right direction, but  
24 I think that we certainly could do more.

25 The Chairman. Thank you, Senator, and again, thank

1 you for your efforts in this area. You have done a lot,  
2 and you have plowed a lot of ground. People are very  
3 appreciative of what you have done.

4 Senator Kerry.

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1 OPENING STATEMENT OF HON. JOHN F. KERRY, A U.S. SENATOR  
2 FROM MASSACHUSETTS

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4 Senator Kerry. Mr. Chairman, thank you for your  
5 efforts to bring this bill to where it is tonight. A lot  
6 of us, as Senator Snowe said and Senator Wyden and  
7 Senator Conrad and others, we would certainly like to go  
8 further even than we are able to go here at this point in  
9 time, but I think you have done extraordinarily to be  
10 able to get this to the point where it is common sense  
11 and makes sense to proceed forward.

12 I think it is important to have the real debate here.  
13 I heard the ranking member a number of times refer to  
14 President Clinton and to the Democrats' earlier efforts,  
15 you know, in a search for consistency. But the fact is  
16 that the Republican claim that Clinton and Democrats took  
17 the same approach in the prescription drug benefit  
18 previously is just not true. It is not the same. And we  
19 ought to not spend a lot of time tonight having  
20 amendments that sort of try to hoist people on a petard  
21 that does not fit. I mean, that is just not real.

22 The fact is that that effort by President Clinton  
23 maximized the purchasing power of Medicare by leveraging  
24 the program's purchasing power for prescription drugs by  
25 creating a drug manager in large regions under contract



1 with Medicare. And there was one manager. And so they  
2 were, in fact, leveraging their purchasing power. They  
3 did not need to do it otherwise. That was the way in  
4 which they took the purchasing power and put it to effect  
5 for low drug prices. And then pharma opposed it, and  
6 many Republicans opposed it and called it "price  
7 controls."

8 Now, tonight there is notion that we are going to  
9 sort of propose this and say that is really a better  
10 proposal. I mean, the fact is that you specifically  
11 chose otherwise, which was to create multiple  
12 opportunities, multiple plans, multiple providers, and so  
13 forth, which is exactly why the consumer and seniors are  
14 not getting the best deal that they could get today and  
15 why there is a problem.

16 So the notion that in the VA you can go out and  
17 negotiate, I mean, it is not apples and oranges. It is  
18 the same thing. It is taxpayer money. It is a  
19 Government benefit. It is purchasing power. It is the  
20 marketplace at its best in the sense that you have this  
21 large entity which we have decided to create a benefit  
22 for that is buying. And you ought to use the marketplace  
23 effectively to get a better price and save the taxpayer  
24 dollars and make this more available to people.

25 So, you know, I hope when push comes to shove, in the

1 end this is going to pass, and we are going to go do what  
2 makes sense for the consumer, and for seniors  
3 particularly and a lot of folks on fixed income and use  
4 the market to its best ability.

5 For the rest of the folks out there, the market will  
6 establish what those prices are going to be based on what  
7 appropriate profit levels ought to be and what the market  
8 will bear. But we should not pass up the opportunity to  
9 be able to negotiate like any entity does. Blue Cross  
10 Blue Shield does it. Different companies do it. If you  
11 have additional purchasing power, you negotiate, and that  
12 is all we are looking for here.

13 In fact, we are not even mandating it. As the  
14 Senator from Maine has said, we are simply removing the  
15 prohibition. So obviously it is not going to happen for  
16 at least 2 years, but we could lay the groundwork.

17 Thank you, Mr. Chairman.

18 The Chairman. Thank you, Senator, very much.

19 Senator Rockefeller?  
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1 OPENING STATEMENT OF HON. JOHN D. ROCKEFELLER, IV, A U.S.  
2 SENATOR FROM WEST VIRGINIA

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4 Senator Rockefeller. Thank you, Mr. Chairman, and  
5 thank you, Senator Grassley, very much. Everything  
6 people say about the two of you is true, and--

7 Senator Kerry. Everything?

8 Senator Grassley. Everything good they say about  
9 us. [Laughter.]

10 Senator Rockefeller. I was just keeping my options  
11 open. [Laughter.]

12 All I want to say is two things: number one, that I  
13 had the good fortune to, in conference, negotiate the  
14 veterans prescription drug benefit cut with John Chafee,  
15 and that was quite a long time ago. The price went down  
16 50 percent. Maybe the price will go up; maybe the price  
17 will go down. The price of everything tends to go up.  
18 But there is no way that you can look at 43 million  
19 people and say, well, if he wants to, he can go ahead and  
20 ask for there to be Medicare volume buying.

21 I remember when I was Governor, all the universities  
22 and the colleges in our small State were buying all by  
23 themselves, and, yes, we could order, you know, an order,  
24 a Governor's order that they all had to go ahead and buy  
25 together. But that is not the way to do it. You do it

1 through legislation. Then there is just no question  
2 about it, and it is over. And the savings on Medicare at  
3 43 million people would be absolutely enormous. So I  
4 just want to say that.

5 I also want to say that I really appreciate Chairman  
6 Baucus has agreed to work with me on getting a CBO report  
7 on the cost of including mental health drugs in the  
8 Medicare prescription drug program. That is amendment  
9 number 3. And I am getting more detailed data from CMS  
10 on the enrollment of veterans in Medicare Part D. That  
11 is amendment number 4. And, therefore, we have agreed to  
12 withdraw amendments 3 and 4, and we have also agreed to  
13 withdraw number 2 amendment on the PACE frailty adjuster  
14 pending for the discussion with the West Virginia Rural  
15 PACE Program.

16 So I am a very happy camper. I agree with Olympia  
17 Snowe that we have not done as much as we could, but if  
18 we do this first amendment on the Medicare prescription  
19 drugs, we will have done a great service for our country.

20 The Chairman. Thank you, Senator, very much.

21 Senator Lincoln?

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1 OPENING STATEMENT OF HON. BLANCHE L. LINCOLN, A U.S.  
2 SENATOR FROM ARKANSAS

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4 Senator Lincoln. Thank you, Mr. Chairman, and I too  
5 appreciate your leadership on the Medicare prescription  
6 drug benefit. We worked on this together when it came  
7 through. I voted for it. I appreciate Senator  
8 Grassley's work as well there. And I know that we share  
9 in the goal of making it the best possible program that  
10 it can be for our seniors, and I appreciate the fact that  
11 we are here tonight moving forward, recognizing that we  
12 are not here to create a work of art but a work in  
13 progress and to continue to look for the ways that we can  
14 improve on things that we have done not only in years  
15 past, but as we move forward in this.

16 One of the particulars that I have brought before us  
17 tonight was a bill that you and I cosponsored last year,  
18 which was the Pharmacy Access Improvement Act, which I  
19 felt like was very appropriate to bring before us today  
20 and offering it as an amendment. The provisions would  
21 make great strides towards improving the Medicare  
22 prescription drug benefit for pharmacists and for our  
23 Medicare beneficiaries.

24 I know many of us represent rural States, and like my  
25 rural State of Arkansas, seniors depend on their local

1 pharmacists as a primary source of health care.  
2 Oftentimes in some of our small communities where we have  
3 lost other health care providers, the pharmacists are the  
4 only one there they have on a regular basis. And the  
5 bill that we introduced last year ensures that  
6 pharmacists will be able to continue providing the  
7 quality of care as the implementation of the drug program  
8 continues. And that is all we simply wanted to do last  
9 year and I would hope to do here. With the chairman's  
10 reassurances that that will be something we can bring up  
11 really in the near future, I am certainly, as others,  
12 willing to withdraw the amendment. But I just hope that  
13 we will recognize that there are differences, just as we  
14 have seen in our hearings, whether it is with Medicare  
15 Advantage or other, that the implementation of the  
16 Medicare Part D is very different in rural areas in terms  
17 of making sure that the access for seniors there exists  
18 and that it is fair and balanced for them as well as for  
19 seniors in other parts of the country is critically  
20 important for me, I know, and I think for many other  
21 members of the committee.

22 So I certainly appreciate all your hard work in  
23 bringing together what we have got here tonight as a step  
24 forward in improving on what we had already done before.  
25 As I said, the bill that we had worked on really did work

1 towards giving the pharmacists, particularly in the rural  
2 areas, the capabilities to truly serve our seniors, and I  
3 hope that we will continue to work on that, and I hope  
4 that as we move forward you will certainly commit the  
5 time to bringing that up.

6 The Chairman. Thank you, Senator. You are actually  
7 right about pharmacies. So often major legislation,  
8 health care legislation we pass here, the pharmacies,  
9 particular the independent pharmacies, are in a very  
10 difficult spot. That has to be addressed and corrected,  
11 and that is particularly true in rural areas, and I thank  
12 you very much. I do pledge my support to help address  
13 that. Thank you very much.

14 Senator Lincoln. Great. Thank you, Mr. Chairman.

15 The Chairman. Thank you very much, Senator.

16 Senator Kyl?

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1 OPENING STATEMENT OF HON. JON KYL, A U.S. SENATOR FROM  
2 ARIZONA

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4 Senator Kyl. Thank you, Mr. Chairman.

5 First of all, it is not true, as asserted, that  
6 Congress has outlawed negotiating drug prices. I think  
7 we all know that the bill that was passed a couple years  
8 ago specifically provides for negotiation of drug prices.  
9 It is by the pharmacy benefit managers who do that in the  
10 marketplace, which is why they have been able to reduce  
11 drug costs so much and why the specific statistics that  
12 Senator Grassley cited demonstrate that this is a  
13 solution in search of a problem. And I associate myself  
14 with Senator Grassley's remarks.

15 It is not that the bill will do nothing. It is that  
16 it will do nothing good. It could limit seniors' choice  
17 and access to drugs. It could interfere with local  
18 access to pharmacies. It could result in cost-shifting  
19 to other players, including VA, Medicaid, Medicare. So I  
20 will have amendments to prevent these bad results and  
21 would suggest that we follow the doctor's advise, to  
22 first do no harm.

23 The Chairman. Thank you, Senator. We will get to  
24 those in due time.

25 Senator Schumer?



1 OPENING STATEMENT OF HON. CHARLES E. SCHUMER, A U.S.  
2 SENATOR FROM NEW YORK

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4 Senator Schumer. Thank you, Mr. Chairman, and let  
5 me also add my plaudits to you for the work you have done  
6 here, to Senator Grassley as well for the passion with  
7 which he has approached this issue, as much as we might  
8 disagree.

9 I would like to make three points. The first is that  
10 what we believe is when the President proposed adding  
11 prescription drugs to Medicare, it was a good thing, long  
12 overdue. Our problem is in the execution. When it came  
13 to a conflict between the recipient and the  
14 pharmaceutical industry. In the bill, the pharmaceutical  
15 industry prevailed far too often. That is our problem  
16 with the bill.

17 I do not quite get it. We applaud the fact that HMOs  
18 can use their bargaining power to lower prices, and we  
19 prohibit Medicare from using its bargaining power to  
20 lower prices. There is no logic there. It is good for  
21 one if it is good for the other. You do not have to be  
22 somebody who believes the Government should do everything  
23 or somebody who believes the private sector should do  
24 everything. You do not have to be doctrinaire to  
25 understand if it is good for one, it is good for the

1 other. The act of using size to bring the price down for  
2 the people you represent is a good thing, and if it  
3 applies to HMOs and to public benefit companies, it also  
4 ought to apply to Medicare.

5 The second thing I would say here is there are a lot  
6 of amendments that are wolf-in-sheep's-clothing  
7 amendments. They are amendments that sound very, very  
8 good from the other side. I am not referring to my  
9 colleague from Maine, but some of the others are quite  
10 good from people who do not believe them, and they are  
11 trying to kill the bill. And we are not going to fall  
12 for that, plain and simple, because we have a mission  
13 here, and the mission is to make it better for the  
14 recipient, not for the pharmaceutical industry, not for  
15 any political side, but simply for the recipient.

16 My colleague from Maine does ask a question: Why  
17 cannot we go further? We would love to go further. But  
18 there is a five-letter word that stands in the way--  
19 votes. If we had 60 votes on the floor for some of her  
20 proposals and some of the other proposals, we would vote  
21 for it in a minute. But we are not going to let the  
22 perfect be the enemy of the good. That has brought down  
23 too many good enterprises.

24 And so under the chairman's leadership, I think we  
25 are going to make a careful, smart step in the right

1 direction in hopes that we can make further steps as the  
2 process unfolds. And that is why I am proud to be part  
3 of what we are doing here tonight, as much as one might  
4 chafe that we would like to go further.

5 I yield back the balance of my time.

6 The Chairman. Thank you, Senator.

7 Senator Thomas?

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1 OPENING STATEMENT OF HON. CRAIG THOMAS, A U.S. SENATOR  
2 FROM WYOMING

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4 Senator Thomas. Thank you very much, Mr. Chairman.

5 I want to--

6 The Chairman. We are making progress here. I have  
7 only three more listed here. Excuse me.

8 Senator Thomas. Well, I had sort of gotten out of  
9 it. I want to associate myself with the comments of the  
10 gentleman from Iowa. Senators in my State have been  
11 calling to tell me they like their Medicare benefits and  
12 they do not want Congress to change it. Why would we  
13 want to revert back to a one-size-fits-all approach?  
14 Clearly, Government price fixing is not the answer. The  
15 Medicare law has proven to give Senators the best deal  
16 through market competition. The Washington Post, which  
17 is not exactly the right-wing newspaper, said it best in  
18 a November 2nd article, "Election on drugs: A switch to  
19 Government purchasing of Medicare drugs will choke off  
20 this experiment before it has had a chance to play out  
21 and would usher in its own problems. For the moment, of  
22 course, the Democrats would do better to invest their  
23 health care energy somewhere else," according to the  
24 paper. I could not agree more.

25 Thank you, sir.

1           The Chairman.    Thank you, Senator.

2           Senator Hatch?

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1 OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR  
2 FROM UTAH

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4 Senator Hatch. Well, as somebody who sat right with  
5 you, Mr. Chairman, Senator Grassley, and others when we  
6 developed Part D, sat through all of the many, many days,  
7 weeks, and months, and hours and hours every day to come  
8 up with what is now 80 percent approved by the public, I  
9 just do not think we should be tinkering with this, and  
10 let me tell you why. I have a number of reasons.

11 Number one, if we do what you are saying here, there  
12 are 4,400 drugs from which under Part D seniors and  
13 others can choose. Now, can you imagine having HHS start  
14 to set prices for 4,400 drugs and how much that is going  
15 to cost and how little good it is going to do?

16 I think we ought to give Part D some more time to  
17 work because it is working well; 80 percent of the people  
18 out there who are really familiar with it love. And,  
19 frankly, why would we be tinkering around with it when  
20 you have had--let me put into the record the letter to  
21 Congressman Dingell over in the House. It says, "H.R.  
22 4"--this is their bill--"would require the Secretary to  
23 negotiate with drug manufacturers the prices that could  
24 be charged to PDPs"--prescription drug plans--"for  
25 covered drugs. However, the bill would prohibit the

1 Secretary from requiring a particular formulary."

2 The only way you are going to bring prices down is to  
3 require a formulary. If you require a formulary, that  
4 means you are not going to have access to the full wide  
5 panoply of drugs. To me, this does not make sense. I  
6 would like to put that in the record. I will save time  
7 and put the letter to my dear friend and colleague, Ron  
8 Wyden, who takes such a great interest in this, and, of  
9 course, the letter--these are all dated April--one is  
10 January 10th, Congressman Dingell to Senator Wyden, it is  
11 April 10th, and, of course, to you, Mr. Chairman, April  
12 10th.

13 The Chairman. Without objection, they will be  
14 included.

15 Senator Hatch. Thank you, Mr. Chairman.

16 [The letters appear in the appendix.]

17 Senator Hatch. Now, while I understand this mark  
18 does not require the HHS Secretary to negotiate drug  
19 prices--and I commend the chairman for trying to find a  
20 middle ground here--it does open up the door. First, CBO  
21 told us on January 10th that H.R. 4, the House-passed  
22 bill that does require the Secretary to negotiate the  
23 price of Part D drugs, that the bill would have a  
24 "negligible effect" on Federal spending.

25 Now, the GAO has warned us that veterans' drug prices

1 will go up if we mandate that Federal prices for drugs be  
2 extended to a large group of purchasers such as Medicare  
3 beneficiaries. In other words, this could lower prices  
4 perhaps for some and raise prices for others who can ill  
5 afford to pay them.

6 The Veterans Administration expressed the same  
7 concern at a 2001 hearing before the Senate Committee on  
8 Veterans' Affairs. Now, I do not believe that there can  
9 be an effective negotiation unless a buyer, any buyer, is  
10 willing to walk away. If the Secretary negotiates and  
11 when the results are negligible savings, a national  
12 formulary that restricts availability of drugs to  
13 Medicare patients, that is going to surely follow. Only  
14 then can the Secretary walk away from the negotiation.

15 Now, that is the only way he is going to be able to  
16 do it and bring drug prices down, but by then he narrows  
17 the scope of the number of drugs that can be called upon.  
18 How on Earth would HHS begin to decide how to price  
19 individual drugs? How long would that take? Months?  
20 Years? The tripartisan bill that was supported by  
21 Senator Grassley, Senator Jeffords, Senator Snowe,  
22 Senator Breaux, all members of this committee, including  
23 non-interference language. In fact, the Democrat  
24 alternative to the tripartisan bill that we thought we  
25 might be able to put through included the same language.



1 Why was it okay then? Now suddenly we are going to  
2 experiment with a bill that is 80 percent approved and  
3 working very, very well as these prescription drug plans  
4 brought down drug prices.

5 Well, all I can do is raise this as a caveat, because  
6 I have dealt with these matters now for 31 years, and I  
7 have got to tell you, I think we are playing with an  
8 awful lot of fire here in a way that really is not going  
9 to do an awful lot of good for a lot of seniors out  
10 there, and above all, for veterans who now are going to  
11 Part D because they can get their drugs cheaper. And the  
12 Veterans Administration confirms that.

13 Thank you, Mr. Chairman.

14 The Chairman. Thank you, Senator, very much.

15 Senator Crapo.

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1 OPENING STATEMENT OF HON. MIKE CRAPO, A U.S. SENATOR FROM  
2 IDAHO

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4 Senator Crapo. Thank you very much, Mr. Chairman. I  
5 will be brief. I know we want to get into the meat of  
6 the markup tonight.

7 I would associate in terms of my own approach and  
8 philosophy on this matter with the comments of our  
9 ranking member, Senator Grassley, and Senator Kyl and  
10 others who have spoken here. But I just wanted to make  
11 one point. I am going to be proposing a couple of  
12 amendments.

13 As you listen to the debate, as anyone listens to the  
14 debate tonight, it is going to become evident that there  
15 is a deep, philosophical disagreement about how we should  
16 approach Medicare drug pricing. There are those who  
17 believe and are asking tonight that we authorize the  
18 Government to negotiate. And there are those who believe  
19 that that will result in price fixing and that ultimately  
20 it will result in higher prices.

21 Those on the one side will say we should use the  
22 bargaining power of the Government in this large group of  
23 buyers, to use that power to drive prices down in the  
24 negotiations. There are others who will say that that  
25 will result, since it is the Government negotiating, in a

1 price-fixing circumstance and in a deviation in the  
2 market that will ultimately drive prices up.

3 The amendments I am proposing say let us study it.  
4 That is not to change anything else in the bill. I would  
5 like to change other things in the bill, but my  
6 amendments, two amendments, one says let us authorize--  
7 let us have the Secretary identify what the negotiation  
8 process would be so that we know what it is that we are  
9 authorizing here, and then let us have GAO study--two  
10 things, two amendments: first let us have the GAO study  
11 what the impact is going to be on the price for those who  
12 are private drug purchasers; and, number two, what will  
13 the impact of these negotiations, if they occur, be on  
14 the Veterans Administration system.

15 We could study a lot of different pieces of all this,  
16 but I picked these two. And I would hope that those  
17 amendments would be agreeable. I do not know what the  
18 outcome will be. I personally think I know how it all  
19 works, because I take one side in this debate. But my  
20 amendment does not change the bill other than to say let  
21 us study a couple of pieces of this and get some answers.  
22 Because if this bill is not simply mandating but is  
23 simply authorizing the negotiations to take place, it  
24 would be appropriate and, I think, prudent for us to have  
25 the Government Accounting Office to study it so that we

1 can determine whether that authority should be utilized  
2 and, if it is utilized, how it will be utilized.

3 So that is just kind of a headline as to what I will  
4 be proposing when my turn comes, and I appreciate your  
5 allowing me to bring those amendments, Mr. Chairman.

6 The Chairman. You bet, Senator Crapo. Absolutely.  
7 Mr. Roberts, you are our last speaker.

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1 OPENING STATEMENT OF HON. PAT ROBERTS, A U.S. SENATOR  
2 FROM KANSAS

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4 Senator Roberts. Well, that is good. [Laughter.]

5 I have some more good news. I have six amendments.  
6 I am going to withdraw five. I see Senator Rockefeller  
7 had seven. I do not know if he is going to withdraw six  
8 or not, but that certainly is headed in the right  
9 direction. And let me ask a parliamentary inquiry, being  
10 new on the block. What is the time requirement, if any,  
11 or the limitation in regards to when a Senator introduces  
12 an amendment? Because I can skip all that right now in  
13 my opening statement, and we can get down to business.  
14 In other words, will I have enough time to shine the  
15 light of truth into darkness at that point, or what?

16 The Chairman. You will always have time, Senator.  
17 We will make that available.

18 Senator Roberts. Thank you, Mr. Chairman. The only  
19 thing that I would say is that this reminds me a lot of a  
20 very often used tactic around here, and it is called  
21 "Rock the baby." And I know in regards to the  
22 Agriculture Committee, of which I am fully aware and  
23 experienced in terms of those matters along with Senator  
24 Conrad and all of that--and I am trying to think if we  
25 did this when I was chairman of Intelligence, along with

1 Jay, with Senator Rockefeller. I do not think we did.  
2 It did not work very well with things that are  
3 classified.

4 What you have got here is a mix with a very strong  
5 promise by one side, my friends across the aisle, to  
6 address a perceived and in some cases very real political  
7 problem that everybody would like to see lower  
8 prescription drug prices for seniors. It is obvious.  
9 And then the other side of it, the law of unintended  
10 effects, which Senator Hatch has brought out, Senator  
11 Grassley has brought out, I think everybody on our side,  
12 Senator Kyl has adequately spoken to this; Senator Crapo  
13 says we ought to study it first so we do not get  
14 ourselves wrapped around an axle and, you know, cause  
15 something that is even worse than the current plans. And  
16 by "worse," I do not know how you could say that that  
17 would be the definition because the current plans are  
18 working and working very well.

19 And so what we do is we pass something and we say to  
20 the Secretary, well, you can do it. It is not a mandate.  
21 It is not a "shall." It is a "may." And then we say we  
22 have given the Secretary authority, and we say, "Rock the  
23 baby." And then the Secretary rocks the baby, and it is  
24 about a three-press-release deal. The first press  
25 release says, well, here is the problem and, by golly, we

1 are going to solve it. We are going to give the  
2 Secretary authority to solve it. How are you going to do  
3 that? Well, he just got the authority, and, by golly, he  
4 ought to do something about it.

5 I note there is a report that he has to make, so that  
6 would be the third press release. And so you would say  
7 we have given the Secretary the authority. Now, of  
8 course, he is not going to do it, and so then you--that  
9 is the second release. He is not going to do it. We  
10 gave him authority, and now he did not do it, so, by  
11 golly, you know, that is really bad. I can see that, you  
12 know, Senator Schumer would have a release yesterday.

13 And so then, finally, you have this report that says,  
14 see, you did not really bring the prices down. We have  
15 got to do something different. So we are rocking the  
16 baby here.

17 Senator Conrad. Could we get that order again?

18 [Laughter.]

19 Senator Roberts. I had a chart, but I do not--

20 [Laughter.]

21 The Chairman. Sometimes you get what you ask for.

22 Senator Roberts. I yield back my time.

23 The Chairman. Thank you, Senator, and thank you for  
24 not producing the chart.

25 We certainly have a quorum here, enough Senators for

1 conducting business. Accordingly, I might ask that the  
2 modification before the committee be a modification  
3 before the committee and the mark be modified in  
4 accordance with the changes we have made in this bill.

5 I would now like to ask Ms. Bishop to very briefly  
6 walk through the bill. The next stage will be the  
7 opportunity for Senators to ask questions they may want  
8 to ask. After that, then I will open it up for  
9 amendments.

10 So, Ms. Bishop, if you could very briefly walk  
11 through the bill.

12 Ms. Bishop. Thank you, Mr. Chairman.

13 The chairman's mark would repeal section 1860D-  
14 11(i)(1) of the Social Security Act. Thus, the Secretary  
15 would no longer be prohibited from interfering with the  
16 negotiations between drug manufacturers and pharmacies  
17 and prescription drug plan sponsors.

18 The chairman's mark would retain Section 1860D-  
19 11(i)(2), the prohibition on a national formulary, or  
20 price controls. Those provisions would remain intact.

21 The chairman's mark would require the Secretary to  
22 submit an annual report on activities conducted to ensure  
23 access to fair prices under Part D, and that report would  
24 be submitted to the Congress.

25 In addition, the mark provides for greater



1 transparency of Part D prices and information. The data  
2 identified in the bill would be provided to congressional  
3 support agencies only. Certain data would be provided  
4 only to the Congressional Budget Office. They would have  
5 the ability to produce reports for the Congress. And the  
6 mark also requires the Congressional Budget Office to  
7 produce certain reports for the Congress, and they would  
8 have to do with the effect of competition on prices under  
9 the Medicare Part D program.

10 CBO would also be requested, required to study the  
11 effect of any action that the Secretary takes to promote,  
12 ensure prices under the Part D program, to study the  
13 effects that those actions would have on prices in non-  
14 Medicare markets.

15 In addition, the mark requires the Secretary to  
16 develop a prioritized list of comparative effectiveness  
17 studies that need to be done to improve medical  
18 decisionmaking and value-based purchasing in the Medicare  
19 Part D program.

20 The Chairman. Thank you.

21 Any questions?

22 Senator Grassley. I have quite a few questions, and  
23 I hope you can give short answers because it is not my  
24 intention to ask these questions to prolong the night  
25 because we know where we are going to end up tonight. We

1 are going to end up with this bill being voted out of  
2 this committee.

3 But I think we need to understand what the bill does,  
4 so I start with the first question. What exactly does  
5 the chairman's mark contemplate in Section 2?

6 Ms. Bishop. This is the repeal of the non-  
7 interference clause.

8 Senator Grassley. All right. Go ahead.

9 Ms. Bishop. Briefly, the intent--I am sorry. Did  
10 you--

11 Senator Grassley. No, no. You should go ahead.

12 Ms. Bishop. I think just briefly the intent of the  
13 repeal is to provide the space, the opportunity for the  
14 Secretary to take actions that are afforded the Secretary  
15 under the Social Security Act. It is really removing a  
16 bar.

17 Senator Grassley. What is the purpose of this  
18 change in the Medicare drug benefit?

19 Ms. Bishop. The purpose of the change would be to  
20 remove a bar on the Secretary's ability to take action in  
21 circumstances where the Secretary feels it is necessary.

22 Senator Grassley. That is a fair answer.

23 There is very little detail about how the secretarial  
24 negotiation is intended to work. The Medicare drug  
25 benefit law has 114 pages describing how the drug benefit

1 works. The chairman's mark does not seem to provide any  
2 details about how the negotiation would work. Are there  
3 any details? How is the secretarial negotiation intended  
4 to work?

5 Ms. Bishop. The secretarial negotiation really could  
6 take a number of forms, and the forms that the  
7 negotiation would reflect would have to do with the  
8 authorities inherent in the Office of the Secretary. And  
9 I think that the mark did not want to tie the Secretary's  
10 hands in other ways by specifying types of activities or  
11 requiring certain circumstances, because the thought is  
12 that the Secretary, in his inherent authority and with  
13 the resources available to him or her, would be able to  
14 identify situations and use the power of its agencies to  
15 move ahead, and we did not want to circumscribe what  
16 those activities would be.

17 So they could take a number of forms, and I guess it  
18 would take an interest and an imagination to use the  
19 power of the Secretary's inherent authority in this area.

20 Senator Grassley. All right. Now, the  
21 Congressional Budget Office, Medicare actuaries, and a  
22 lot of experts in this area have been clear that if the  
23 Secretary has no leverage to negotiate, Government  
24 negotiation will not result in lower prices.

25 Now, with that in mind, what leverage would you

1 foresee the using then to obtain lower prices?

2 Ms. Bishop. Well, Senator, the Congressional Budget  
3 Office does say that removing the clause would not  
4 provide leverage because the prohibition on the formulary  
5 is retained.

6 Senator Grassley. Sure.

7 Ms. Bishop. But they say that the Secretary would  
8 not have leverage over a broad range of drugs--over a  
9 broad range--because that is how the formulary tool  
10 works. But the Secretary would have the authority and  
11 could potentially achieve savings if he negotiated in  
12 select circumstances, and that is reflected in the letter  
13 sent to Senator Wyden on April 10th. In that letter--

14 Senator Grassley. But I thought in that letter it  
15 said that there would not be savings.

16 Ms. Bishop. Can I just--

17 Senator Grassley. Go ahead. Please do, yes.

18 Ms. Bishop. "Negotiations limited to a few selected  
19 drugs or types of drugs could potentially generate cost  
20 savings. For example, negotiations could be focused on  
21 drugs with no close substitutes or those with relatively  
22 high prices under Medicare."

23 And so being able to negotiate over a broad range of  
24 drugs is one type of negotiation, and that is what  
25 happened to the formulary. Being able to negotiate in

1 specific circumstances is what is being referred to here.

2 The Chairman. I think the whole point here is the  
3 two letters from CBO. One is it is CBO's conclusion  
4 that, as Ms. Bishop said, of a broad range, to see that  
5 conclusion there would not be a significant effect on the  
6 budget. But with respect to specific drugs, there may  
7 also not be a huge change in the budget, but that those--  
8 the result could make a budget difference to that certain  
9 group, say it is Alzheimer's or whatever it might.

10 So the whole point of this less is there is a  
11 difference between broad range where there would not be  
12 an effect and a few specific instances where there would  
13 also from a budget perspective not have huge savings but  
14 would make a big difference to those beneficiaries who  
15 would otherwise be paying high prices.

16 Senator Wyden. If the chairman would just yield  
17 very briefly, that goes to the important point made by  
18 the Senator from Utah. It has never been the intent of  
19 Senator Snowe and me to have the Government negotiating  
20 in 4,400 cases. That would be absolutely absurd, and we  
21 share the view of the Senator from Utah. What we sought  
22 to do is what the CBO letter addresses, which is a  
23 selected number of cases.

24 Senator Hatch. But how do you avoid it? That is the  
25 mandate of this.

1           Senator Wyden.    No, there is no mandate, of course,  
2   because if you simply lift the restriction, you are not  
3   mandating anything.  You are simply saying that the  
4   Secretary would have the discretion to proceed.  And as  
5   we have tried to indicate for 3 years now, Senator Snowe  
6   and I never, ever wanted to see something like mandatory  
7   negotiations on 4,400--

8           Senator Hatch.  If the Senator would yield--

9           The Chairman.  Senator Grassley has the floor, so if  
10   he wants to yield--

11          Senator Hatch.  Would the Senator yield to me?

12          Senator Grassley.  Yes, I would yield, as long as I  
13   do not get accused of holding up the--

14          Senator Hatch.  It is nice to say that they can limit  
15   themselves, but how could any Secretary limit themselves  
16   under this bill?  They are not going to be able to limit  
17   themselves.  They have got 4,400 drugs out there.  They  
18   have got to look at all of them.  They cannot just pick  
19   and choose.

20          Senator Wyden.  If the Senator would just yield for  
21   a response.

22          Senator Hatch.  Sure.

23          Senator Wyden.  The text of the legislation has no  
24   mandate in it, none whatsoever.  There is no mandate in  
25   the text of this legislation.  The Secretary has total

1 discretion. That is why we think if the Secretary does  
2 use it, they are going to use it, as the CBO indicated,  
3 in these selected cases.

4 Senator Grassley. May I go on then--no, please. Go  
5 ahead.

6 Senator Snowe. Thank you, Senator Grassley. I just  
7 want to follow up on that point. In fact, the Medicare  
8 actuary and CBO indicated it is not a question of giving  
9 that authority to the Secretary in realizing savings. It  
10 is a question of how that authority is used. And that is  
11 why crafting specific circumstances under which it would  
12 be utilized would be most effective in accomplishing the  
13 savings, not just giving broad discretion or mandate but,  
14 rather, you know, in carefully crafted circumstances  
15 similar to what Senator Wyden and I had introduced in our  
16 legislation that would document the savings.

17 Senator Hatch. Yes, but on that point, the Secretary  
18 cannot ignore the other 4,399 drugs. They just cannot do  
19 it, under the way you have got this written. And I have  
20 got a question here that I think is a pertinent question  
21 in that area.

22 I am sorry to interrupt, Mr. Chairman, but this is an  
23 important issue here. Sorry.

24 Senator Grassley. On this point, then, I will get  
25 back to my line of questioning. But on the letter that

1. Senator Wyden got, April the 10th, in the middle of the  
2 fourth paragraph, maybe fifth paragraph, "Furthermore,  
3 even if the Secretary focused on a select number of  
4 drugs, the effect might be limited because pressure from  
5 PDPs and public relations concerns already affecting  
6 pricing. So the incremental effect of giving HHS  
7 additional options for exerting pressure would generally  
8 be small."

9 Now, so we do not have a national formulary, Ms.  
10 Bishop. Could the Secretary us a preferred drug list,  
11 like Medicaid uses?

12 Ms. Bishop. Under the chairman's mark, formularies  
13 are prohibited. And to the extent that a PDL would  
14 operate like a formulary, no, it would not be allowed.  
15 To the extent that a formulary is instituted that looks  
16 like price structure, no, that is not allowed under the  
17 mark.

18 The statute, the underlying statute, the MMA, made  
19 clear that formularies are the purview--excuse me, drug  
20 plans have jurisdiction over formularies. They are the  
21 ones who utilize formularies, not the Secretary. So it  
22 is pretty clear that they would not be allowed to do  
23 that.

24 Senator Grassley. But then the courts have said  
25 that PDLs are not formularies.



1 Ms. Bishop. That is in the Medicaid context.

2 Senator Grassley. All right. Could the Secretary  
3 issue a national coverage decision to disallow coverage  
4 for a drug if the drug company did not lower the price so  
5 no beneficiary would get that drug?

6 Ms. Bishop. No.

7 Senator Grassley. Could he threaten to not allow  
8 the new drug to get approved by the FDA if they did not  
9 lower the price?

10 Ms. Bishop. I do not see how the chairman's mark  
11 would change the underlying prohibition to do that.

12 Senator Grassley. That is good enough.

13 Ms. Bishop. And my colleague was saying the FDA  
14 needs to approve that drug before Medicare would cover,  
15 so we would say no.

16 Senator Grassley. All right. Could the Secretary  
17 exercise compulsory licensing, that is, could he threaten  
18 to take away the company's patent rights and give them to  
19 a generic company to make the drug?

20 Ms. Bishop. The chairman's mark would not change any  
21 authority that the Secretary would have to do that now.  
22 So to the extent that the Secretary could do that now, he  
23 could do that under the chairman's mark.

24 Senator Grassley. All right. Could the Secretary  
25 use his contracting authority with the prescription drug

1 plans to get lower prices? Let me explain. Here is how  
2 that could work. The Secretary decides that a particular  
3 drug costs too much, so he tells the drug company that if  
4 they do not lower their prices, Medicare will not  
5 contract with plans that cover that drug.

6 In other words, the Secretary would say to a  
7 prescription drug plan, "I am not signing a contract with  
8 you to be a Medicare drug plan if you offer that drug  
9 because the price is too high." Could he do that?

10 [Pause.]

11 Ms. Bishop. I wanted to confer with the legal--  
12 Senator Grassley. That is perfectly all right.

13 Ms. Bishop. Senator, we do not see how the  
14 chairman's mark repealing this prohibition would give the  
15 Secretary authority to disapprove a drug plan because  
16 their prices are set at a certain level. The Secretary  
17 regulates the drug plans, but would not be allowed to bar  
18 them from the program.

19 Senator Grassley. All right. Well, it happens to  
20 be my belief that without the non-interference clause,  
21 the Secretary could do that, and I see that as a real  
22 problem.

23 Let me go on. Since the chairman's mark does not  
24 make it explicit that the Secretary cannot do these  
25 things I have just mentioned, we need to make it crystal

1 clear, and we need to do that to protect beneficiaries'  
2 access to their prescription drugs, and those would be  
3 some amendments I am offering. Since we know it is not  
4 your intention that the Secretary have these negotiation  
5 tools, it is not clear what negotiating power the  
6 Secretary will have to use.

7 Is it negotiating authority in name only and no tools  
8 to negotiate?

9 Ms. Bishop. I do not believe so, Senator. The  
10 chairman's mark really allows the Secretary to utilize  
11 the resources at its disposal and the statutory authority  
12 at its disposal in this circumstance because the  
13 prohibition had really set a gate between the Secretary  
14 and this program in using its authorities in any way. So  
15 the Secretary could do different types of activities  
16 besides negotiation. And so we see that there is  
17 probably a wide range of activities that he could engage  
18 in besides, you know, just direct negotiation.

19 Senator Grassley. All right. The chairman's mark  
20 may be modified to accept the Hatch amendment, which  
21 prohibits CMS from contracting out negotiating authority  
22 to the private sector. Would it work like Medicaid or  
23 DOD or VA?

24 Ms. Bishop. By accepting the amendment? Is that  
25 what you mean, Senator?

1 Senator Grassley. Yes.

2 Ms. Bishop. I think the intent of accepting the  
3 amendment was to really strengthen the Secretary's role  
4 to say that it shall be the Secretary and the Secretary's  
5 resources--the Secretary and his resources--who would be  
6 doing the negotiating. You could not contract that out  
7 or you could not ask the Secretary of VA to do that. It  
8 was really be the Secretary of HHS who would conduct the  
9 activity.

10 Senator Grassley. Well, in the end, I am trying to  
11 find out whether it is going to be patterned like  
12 Medicaid or Department of Defense or the VA.

13 Ms. Bishop. Senator, I guess I have--is your  
14 concern--I guess I do not understand the nature of your  
15 question, your concern.

16 The Chairman. I think the answer is that is up to  
17 the Secretary. There is no requirement that he pattern  
18 his decisions after VA, no requirement that he pattern  
19 decisions after DOD or whatnot. That is his decision.

20 Senator Grassley. All right.

21 The Chairman. Well, in the right direction.

22 [Laughter.]

23 Senator Grassley. Well, I might have some other  
24 questions, but let me just say that, in summation, I  
25 think it is clear that the mark before us is not clear on

1 some important details. Without any details on how the  
2 Secretary would negotiate, how do you know how it would  
3 work? How do we know it will not undermine the current  
4 negotiations that prescription drug plans are already  
5 doing? Those negotiations are working so that we do not  
6 want to reduce their bargaining power. Without any  
7 details on how the Secretary would negotiate, how do we  
8 know that the mark does not affect the Secretary's  
9 authority to ensure appropriate and adequate access to  
10 drugs? And without any details on how the Secretary  
11 would negotiate, how do we know that the mark does not  
12 affect the Secretary's authority to ensure appropriate  
13 and adequate access to drugs?

14 I think that is where I come out. There are a lot of  
15 unanswered questions, and if you want to comment you can  
16 comment, but I think that I am done, unless you want to  
17 say something.

18 The Chairman. Are there any more questions?  
19 Senator Hatch.

20 Senator Hatch. When I look at this Section 4 of the  
21 explanation of the mark, it basically is entitled  
22 "Prioritizing Studies of Comparative Clinical  
23 Effectiveness of Covered Part D Drugs." And it goes  
24 further and says, "This mark would instruct the Secretary  
25 of HHS to develop a new prioritized list of comparative

1 clinical effectiveness studies, which would include the  
2 comparison of one Part D drug to any drug, biological  
3 product, item, or service covered under the Medicare  
4 program. The prioritized list would specify the items  
5 and services to be evaluated and the general methodology  
6 to be used to conduct each study."

7 Then this line: "The Secretary would be required to  
8 consider all methodologies available, from systematic  
9 reviews to clinical trials"--which sounds to me like a  
10 mandate. But what exactly is meant by "comparative  
11 effectiveness"? How does it work?

12 I just want to make sure that I understand why that  
13 concept is included in the chairman's mark. Does not  
14 comparative effectiveness go beyond prescription drugs?  
15 I am asking you this. It could extend to other health  
16 care services? Is that correct?

17 Ms. Bishop. Yes. Not under this mark, but the  
18 concept and in practice it does, but not under this mark.

19 Senator Hatch. Well, how do you interpret, "The  
20 Secretary would be required to consider all  
21 methodologies"--would be required to consider all  
22 methodologies--"available, from systematic reviews to  
23 clinical trials"?

24 The Chairman. Well, I think, again, the point here  
25 is this matter is covered by Part D. It is not intended

1 to cover comparative effectiveness and areas outside of  
2 Part D.

3 Senator Hatch. That is pretty loose language, is  
4 what I am saying.

5 The Chairman. We could tighten that up. We will  
6 find a way.

7 Senator Hatch. All right. If the Secretary does end  
8 up negotiating Medicare Part D drug prices, how would the  
9 Secretary be able to accurately determine the price of  
10 prescription drugs? Let me just go through this.

11 The Secretary could just match U.S. prices to foreign  
12 prices, but in the absence of markets in other countries,  
13 are they underpaying or is the U.S. overpaying at  
14 present? If they are underpaying and we would follow  
15 their lead, then drug innovation will be out the window,  
16 and we will lose our premier advantage throughout the  
17 world in the innovation of new drugs.

18 How would the Secretary determine a price that  
19 provides adequate incentives for innovation and yet is  
20 not too high?

21 Ms. Bishop. That would be up to the Secretary, that  
22 there is really no restrictions on the Secretary's  
23 ability to take a look at the prices in this program and  
24 compare them to other programs. That would be at his  
25 discretion.

1 Senator Hatch. All right.

2 Ms. Bishop. Or other countries, for that matter.

3 Senator Hatch. Well, just one last little comment.

4 In the letter from the Congressional Budget Office to my  
5 friend, Senator Wyden, it does say this. It says, "Under  
6 the title, could negotiating by the Secretary over drug  
7 prices obtain savings for the Medicare program if those  
8 negotiations were limited to selective instances?"

9 And then this paragraph, I find it extremely  
10 interesting. It says, "Although cost savings might be  
11 possible in selective instances, the impact on Medicare's  
12 overall drug spending would likely be limited. Bully  
13 pulpit strategies would probably be effective only if  
14 they were constrained to a small number of drugs"--which  
15 this bill does not do, by the way. "Otherwise," it says,  
16 it continues, "the pressure of the spotlight would be  
17 dissipated. Consequently, spending on the small number  
18 of affected drugs would like account for only a small  
19 fraction of expenditures under the Medicare drug benefit.  
20 Furthermore, even if the Secretary focused on a select  
21 number of drugs, the effect might be limited because  
22 pressure from PDPs"--prescription drug plans, in other  
23 words--"and public relations concerns already affect  
24 pricing. So the incremental effect of giving HHS  
25 additional options for exerting pressure would generally



1 be small. Finally, drug manufacturers could seek to  
2 limit the impact of the Secretary's actions by setting  
3 higher initial prices for their drugs to offset any  
4 potential price concessions from negotiations with the  
5 Secretary. As a result, CBO expects that the overall  
6 impact on Federal spending from negotiations targeted at  
7 selected drugs would be modest. Beyond that general  
8 conclusion, the precise effect of any specific proposal  
9 would depend importantly on its details."

10 My worry about this--and I know that there is  
11 sincerity on the part of those who are pushing this,  
12 especially the chairman, and he is trying to find some  
13 way of resolving this problem. But my concern is that we  
14 are tinkering with a bill that is doing a terrific job,  
15 and we are going to bring the almighty power of the  
16 Federal Government and all the bureaucracy into it, and  
17 they cannot ignore all 4,400 drugs that are available  
18 without getting into real difficult problems and  
19 criticisms, so they will not ignore that. And you are  
20 talking about an increase in bureaucracy, an increase in  
21 Federal Government controls, an increase in what some  
22 think is price controls. And in the end, you are going  
23 to mess up a program that is doing very, very well. I am  
24 not saying you personally, but we. We will mess up a  
25 program that is doing perfectly fine.

1           Enough said.

2           The Chairman.   We are trying to find a solution  
3 here, and I might say just looking at a fair reading of  
4 both those CBO letters is they cannot do both. That is,  
5 on the one hand, one CBO letter says you cannot do all  
6 4,400 drugs. They are talking about broad brush. On the  
7 other hand, it does say only "modest fiscal savings on a  
8 few drugs." But--

9           Senator Hatch.   Just 15 seconds.

10          The Chairman.   When I finish my 15 seconds.

11          Senator Hatch.   Oh, I am sorry.

12          The Chairman.   Which is, but it still could have a  
13 great beneficial effect for a class of seniors, again,  
14 whether it is a cancer drug, for Alzheimer's, or  
15 something. You know, some of these sole-source areas--

16          Senator Hatch.   Sure.

17          The Chairman.   Although there is not great overall  
18 fiscal Medicare budget savings in the whole scheme of  
19 things because the Medicare budget is so large, it could  
20 have a real great beneficial effect for a certain group  
21 of people who use these drugs.

22          Senator Hatch.   Mr. Chairman, I respect my chairman,  
23 and I know you are trying to do what is right here. But  
24 this bill, as far as I am concerned, is a Trojan horse  
25 leading to a national formulary. I think that is a fair

1 way of describing it.

2 The Chairman. Even though this bill prohibits  
3 formularies?

4 Senator Hatch. It says it does, but that is what is  
5 going to happen. If you are going to save any money at  
6 all, it is going to be a limited national formulary that  
7 really screws up the whole process--to use Utah terms.

8 [Laughter.]

9 Senator Kyl. Between the Utah terms and "Rock the  
10 baby"--

11 Senator Hatch. I think Arizona probably would agree  
12 with me.

13 Senator Kyl. I have heard the term before.

14 Mr. Chairman, first of all, Ms. Bishop has done a  
15 very good job, I think, of providing literal  
16 interpretations of the proposal here to try to answer our  
17 questions, and I very much appreciate your inability to  
18 precisely describe, for example, the answer to Senator  
19 Grassley's question, which is the one that interests me  
20 the most. And I just wonder if it would be appropriate  
21 maybe to--and I do not look at anybody in particular, but  
22 Senator Stabenow has been so active in this and has  
23 gotten into it so much. To any of the sponsors, and  
24 particularly Senator Stabenow, do you have something in  
25 mind that obviously cannot be provided by staff in terms

1 of the literal answer to the question about how you think  
2 the Secretary would actually, as a practical matter, go  
3 about doing the negotiating? Even though it is not in  
4 the language of the proposal itself, you must have some  
5 concept of how as a practical matter he would go about  
6 doing it, if it is not inappropriate to ask a colleague a  
7 question.

8 Senator Stabenow. Thank you, Mr. Chairman.  
9 Actually, I do not have specifics. First of all, my  
10 preference would be to go farther and require, and then I  
11 could tell you what I would like to see them do. This  
12 language does not do that. It leaves it to a judgment of  
13 the Secretary. As all other parts of their jobs are, I  
14 am assuming they might look as the Secretary did with  
15 Cipro when it was an unusual circumstance and stepped in  
16 and negotiated after anthrax occurred here. There are a  
17 number of ways in which the Secretary could make a  
18 judgment, but I really do not have, truthfully, an  
19 approach that I would assume.

20 Senator Kyl. Thank you.

21 Senator Stabenow. Thank you.

22 The Chairman. All right. Let us go to the  
23 amendment stage, unless there are further questions.

24 Senator Grassley. Could I say one thing? And it is  
25 only because of the exchange that just took place, but it

1 is also because Senator Wyden has brought up Cipro as an  
2 example. So I would like to just take a minute, I think,  
3 to set the record straight. I am sure that a couple of  
4 my colleagues here will disagree with me. But I think we  
5 ought to put an end to this use of Cipro.

6 In fact, just the other day, the Congressional Budget  
7 Office, in response to a letter to Senator Wyden,  
8 addressed this point. They said, "Recent negotiations  
9 over Cipro showed significant savings relative to  
10 prevailing commercial prices, but several factors  
11 substantially limited its relevance to Medicare  
12 negotiations."

13 Continuing, "The relative negotiations were conducted  
14 in a climate of a national emergency immediately  
15 following the attacks of September the 11th and the  
16 deaths from anthrax-laced letters."

17 Continuing the quote, "The threat issued by Secretary  
18 Thompson to seek authority for generic production of  
19 Cipro was apparently instrumental in bringing the  
20 negotiations to a close."

21 This is not at all the same as the situation with the  
22 Medicare drug benefit. The case with Cipro was not for  
23 the day-to-day delivery of prescription drugs to Medicare  
24 beneficiaries. If there is another public health crisis  
25 like we had with Cipro, then I agree that the Government

1 should step in. In an emergency, that is what is called  
2 for. And nothing in current law prevents the Secretary  
3 from acting in a similar manner should the health of the  
4 public again be at risk. In fact, I offered an amendment  
5 that explicitly protects the ability of the Secretary to  
6 negotiate in times of public emergency. And, second,  
7 while publicly singling out a company for charging high  
8 prices or using the bully pulpit make work in the short  
9 run, CBO explicitly states these strategies will have  
10 little or no effect in the long run. The idea that the  
11 Secretary should seize intellectual property to get lower  
12 prices for Medicare is simply not supportable, and those  
13 who choose to continue to use Cipro as an example of  
14 Government negotiations I think are misleading.

15 The Chairman. All right. Amendments. Let us not  
16 debate this too much here. Let us move on. Amendments.  
17 The mark is now open to amendments. Senator Hatch?

18 Senator Grassley. Go ahead, Senator Hatch. Please  
19 go ahead.

20 Senator Hatch. Mr. Chairman, while I appreciate your  
21 accepting my amendment number 2, I must say that I am  
22 deeply disappointed that you have found my amendment  
23 number 3 non-germane, and to me that is very unfortunate  
24 because that amendment states that if Congress implements  
25 improvements to Medicare, Medicaid, or CHIP, it may not

1 do so in a way that leads to fewer coverage choices for  
2 Medicare beneficiaries. It also may not reduce the  
3 benefits of those beneficiaries who are enrolled in  
4 Medicare Advantage plans. That is all there is to it.

5 Mr. Chairman, while I respect your decision, I want  
6 to continue to work with you on this issue because I  
7 truly believe that Medicare Advantage plans have made a  
8 tremendous difference in the lives of many Medicare  
9 beneficiaries, so I look forward to continuing our  
10 discussions on this important issue.

11 But now I would call up my Hatch amendment number 1,  
12 and this amendment is simple. It really does not need a  
13 great deal of discussion among the committee members. It  
14 simply says that in order for the Medicare Fair  
15 Prescription Drug Price Act to be implemented, CBO must  
16 determine that there would be significant savings for  
17 both Medicare beneficiaries and the Medicare program. It  
18 is that simple. I do not know how anyone could vote  
19 against this amendment, especially since time and time  
20 again, the biggest argument that I have heard in favor of  
21 both H.R. 4 and this bill is that we in Congress need to  
22 help lower prescription drug costs for both beneficiaries  
23 and taxpayers.

24 In fact, let me just read a couple of sentences from  
25 a letter that the AARP sent to Chairman Baucus yesterday.

1 "AARP continues to believe that we must use all available  
2 tools to help lower prescription drug costs for both  
3 beneficiaries and taxpayers. We applaud your leadership  
4 on this issue and look forward to working with you to  
5 enacting legislation that takes additional steps to  
6 ensure the affordability of prescription drugs for all  
7 older Americans."

8 Mr. Chairman, my amendment ensures that this goal  
9 will be reached, and I urge my colleagues to support the  
10 amendment, and I would ask that the letter from the AARP  
11 to you, Chairman Baucus, be placed in the record at this  
12 point.

13 [The letter appears in the appendix.]

14 Senator Grassley. Could I have 30 seconds?

15 The Chairman. Sure.

16 Senator Grassley. Your side, Mr. Chairman, contents  
17 that the Government negotiation will save Medicare money.  
18 I have said so many times about the Congressional Budget  
19 Office disagreeing on that point. If people are so  
20 convinced that Government negotiations will save so much,  
21 if that is their true purpose in pursuing the whole  
22 issue, then I cannot see why they would oppose this  
23 amendment, so I urge the committee to support Senator  
24 Hatch.

25 The Chairman. Just one point here. We all have



1 very high regard for the competence of the CBO Budget  
2 Director and CBO, but I do not think we want CBO to  
3 determine what efforts or acts the Secretary takes or  
4 does not take. That just is tying our hands in a way  
5 that I think is not appropriate or in the interest of  
6 beneficiaries, the program, and I think that is, frankly,  
7 an inappropriate role for the CBO. I do not think they  
8 should be saddled with that responsibility. So I would  
9 urge that this amendment not be adopted.

10 All those in favor of the amendment, say aye?

11 [A chorus of ayes.]

12 The Chairman. Those opposed, no?

13 [A chorus of noes.]

14 The Chairman. The amendment is not agreed to.

15 Other amendments?

16 Senator Grassley. I would call up my amendment  
17 number 6. Under current law, the Secretary is not  
18 allowed to interfere in the negotiations that occur in  
19 Part D. The bill before us would strike that  
20 prohibition. Current law prohibits the Secretary from  
21 establishing a formulary. We are told the bill that we  
22 are marking up today does nothing to change that, but  
23 that is not the end of the story. it is not so simple.

24 We can learn a lot by watching how Medicaid works.  
25 Under current law, States cannot establish a formulary.

1     However, we know that States do use something called a  
2     "preferred drug list," or PDL. Through PDLs, a State can  
3     give a drug manufacturer preferred status in a State  
4     Medicaid program. PDLs are functionally similar to  
5     formularies. We also know that the courts have ruled  
6     that PDLs are not a violation of the Medicaid ban on  
7     formularies.

8             So that brings me to my amendment. The Medicare  
9     statute does not allow the Secretary to require any  
10    particular formulary or institute a price structure. The  
11    statute, however, does not prevent the Secretary from  
12    setting up a preferred drug list. We need to change  
13    that; hence, my amendment.

14            As I read the mark, it is not your intent to give the  
15    Secretary authority to set up a formulary. If that is  
16    your intent, then we should make clear that the Secretary  
17    does not have the authority to set up a PDL either.

18            The Chairman. With all due respect, I would say to  
19    my good colleagues, this is an example of a solution in  
20    search of a problem. The preferred drug list today is a  
21    Medicaid issue. It is not a Medicare issue. And States  
22    do set up preferred drug lists in Medicaid because there  
23    is no formulary involved under the Medicaid program; that  
24    is, the States set these preferred drug lists.

25            This bill does not deal with that. That is a whole

1 separate issue. This bill deals with Medicare, and as we  
2 all know, the plans do have formularies. And the bill  
3 before us, the mark before us prohibited the Secretary  
4 from establishing formularies. And since formularies are  
5 already prohibited under the mark and because preferred  
6 drug lists are not an issue here, this amendment really  
7 is not necessary, and I urge it not be adopted.

8 Senator Grassley. My rebuttal would be very short,  
9 and that is--and you stated it--what the courts say for  
10 Medicaid, the courts are going to say the same thing for  
11 Medicare.

12 The Chairman. No, because the States system under  
13 Medicaid is totally different from what HHS does and the  
14 PDPs do, the plans do, under Medicare. That was a  
15 Medicaid issue. This is a Medicare bill. Besides, the  
16 bill itself prohibits formularies.

17 Senator Grassley. It is the same Social Security  
18 law. That is all I can say in response to you.

19 The Chairman. Ms. Bishop, is that--I see you shaking  
20 your head. Is that the same Social Security law?

21 Ms. Bishop. The statute for Medicaid is different  
22 than the statute for Medicare. The statute for Medicaid,  
23 actually Congress had banned formularies under Medicaid  
24 in 1990 and then permitted them again in 1993. So that  
25 is what has allowed States to implement preferred drug

1 lists, was the statute that came back in 1993. So that  
2 prohibition does not exist--excuse me. The prohibition  
3 in Medicare is not parallel to the statute that is in  
4 Medicaid. That is what we are trying to--the underlying  
5 statute is different.

6 The Chairman. I do not want to prolong this. If  
7 you want to, that is fine, but--

8 Senator Kyl. Mr. Chairman?

9 The Chairman. Senator Kyl.

10 Senator Kyl. I do not mean to prolong it, just--

11 The Chairman. I think we know the issue.

12 Senator Kyl. Yes, and it seems to me that,  
13 therefore, there should be no harm in adopting the  
14 language that Senator Grassley has offered. If that is  
15 what everybody intends to be the result, let us just make  
16 sure. And I would like to see a roll call vote on  
17 Senator Grassley's amendment.

18 The Chairman. Fine, but I just do not think we want  
19 to ratify red herrings, and this amendment essentially is  
20 a red herring.

21 The clerk will call the roll.

22 The Clerk. Mr. Rockefeller?

23 Senator Rockefeller. No.

24 The Clerk. Mr. Rockefeller, no. Mr. Conrad?

25 Senator Conrad. No.

1 The Clerk. Mr. Conrad, no. Mr. Bingaman?  
2 The Chairman. No, by proxy.  
3 The Clerk. Mr. Bingaman, no, by proxy. Mr. Kerry?  
4 The Chairman. No, by proxy.  
5 The Clerk. Mr. Kerry, no, by proxy. Mrs. Lincoln?  
6 Senator Lincoln. No.  
7 The Clerk. Mrs. Lincoln, no. Mr. Wyden?  
8 Senator Wyden. No.  
9 The Clerk. Mr. Wyden, no. Mr. Schumer?  
10 The Chairman. No, by proxy.  
11 The Clerk. Mr. Schumer, no, by proxy. Ms. Stabenow?  
12 Senator Stabenow. No.  
13 The Clerk. Ms. Stabenow, no. Ms. Cantwell?  
14 Senator Cantwell. No.  
15 The Clerk. Ms. Cantwell, no. Mr. Salazar?  
16 Senator Salazar. No.  
17 The Clerk. Mr. Salazar, no. Mr. Grassley?  
18 Senator Grassley. Aye.  
19 The Clerk. Mr. Grassley, aye. Mr. Hatch?  
20 Senator Hatch. Aye.  
21 The Clerk. Mr. Hatch, aye. Mr. Lott?  
22 Senator Grassley. Aye.  
23 The Clerk. Mr. Lott, aye, by proxy. Ms. Snowe?  
24 Senator Snowe. No.  
25 The Clerk. Ms. Snowe, no. Mr. Kyl?

1 Senator Kyl. Aye.

2 The Clerk. Mr. Kyl, aye. Mr. Thomas?

3 Senator Grassley. Aye.

4 The Clerk. Mr. Thomas, aye, by proxy. Mr. Smith?

5 Senator Smith. Aye.

6 The Clerk. Mr. Smith, aye. Mr. Bunning?

7 Senator Grassley. Mr. Bunning is no, by proxy.

8 The Clerk. Mr. Bunning, no, by proxy. Mr. Crapo?

9 Senator Crapo. Aye.

10 The Clerk. Mr. Crapo, aye. Mr. Roberts?

11 Senator Roberts. Aye.

12 The Clerk. Mr. Roberts, aye. Mr. Chairman?

13 The Chairman. No.

14 The Clerk. The chairman votes no.

15 The Chairman. Senator Kerry is present.

16 Senator Kerry. Could I be recorded no, in person?

17 The Clerk. Mr. Kerry votes no.

18 Mr. Chairman, the total is 8 ayes, 13 nays.

19 The Chairman. The amendment is not agreed to.

20 Are there further amendments? Yes, Senator Kyl.

21 Senator Kyl. Thank you very much.

22 Mr. Chairman, earlier this year our committee held a

23 hearing on prescription drug pricing and negotiation, and

24 we heard testimony from Dr. Fiona Scott Morton, who is a

25 professor of economics at the Yale School of Management.

1 I was very impressed with her testimony.

2 Among the points she made were these two, and I am  
3 quoting from her testimony--

4 The Chairman. Do you have one amendment, Senator?

5 Senator Kyl. I only intend to offer three. This is  
6 my amendment number 2. I am sorry.

7 The Chairman. Thank you.

8 Senator Kyl. She said, and I quote, "The  
9 individuals eligible to participate in Medicare Part D  
10 generate approximately 40 percent of prescription drug  
11 spending in the United States....with close to half of  
12 all spending being generated by seniors, whatever price  
13 they pay will tend to be the average price in the market.  
14 It is arithmetically very difficult for such a large  
15 group to receive below-average prices."

16 Now, Mr. Chairman, the Secretary cannot negotiate a  
17 lower price than average price for such a large  
18 population by arithmetic, as she said. Medicare is  
19 simply too large. It is the average.

20 The second point she made, and I am quoting from her  
21 testimony again: "Because Medicare is so large, it would  
22 be in the interest of pharmaceutical companies to raise  
23 almost any reference price rather than accept a low price  
24 for Medicare....This approach to controlling prices harms  
25 all other consumers of pharmaceuticals in the U.S. and is

1 bad policy."

2 So, Mr. Chairman, the private market will respond,  
3 but it will not be the desired response. Costs will  
4 increase. And this explains why I received a letter from  
5 the American Legion asking me to consider, and their  
6 words were, "serious collateral damage" that would result  
7 from lifting the MMA's non-interference provision."

8 Let me read just three lines from this letter. "The  
9 VA is a health care provider, whereas Medicare is a  
10 health insurer. Any possible Medicare savings would  
11 likely result in a reciprocal cost to the VA.  
12 Compromising the non-interference provision by striking  
13 Section 1860D-11(i) is not in the best interest of  
14 America's veterans and their families."

15 I would also note Senator Stabenow cited some  
16 testimony from VA relating to the number of drugs  
17 covered, but the Lewin Group looked at this exact  
18 statistics and said that it was misleading. The 4,778  
19 figure that was cited includes over-the-counter products  
20 like aspirin, cosmetic drugs, devices and drugs that are  
21 used in inpatient or ambulatory settings and the like.

22 We know that there are significantly fewer drugs  
23 covered by the formulary in VA. We also know from this  
24 testimony that VA is one of the entities that would  
25 likely see costs increased as a result of negotiation



1 that would have any impact on Medicare.

2 So I oppose this mark. It is not only the wrong  
3 thing for seniors, but it is also the wrong thing for  
4 veterans. The same thing would occur for Medicaid  
5 beneficiaries, and even uninsured, at least those who pay  
6 out-of-pocket for their prescription drugs. These are  
7 the groups that, if this is successful by reducing prices  
8 for Medicare, will see their costs go up, again, because  
9 of the reasons from the expert witness at our committee.

10 So this committee should focus on health care reform,  
11 real ways to address the challenge of health care costs  
12 and coverage, rather than acting in what I would say is a  
13 haphazard way that could end up raising health care costs  
14 for all consumers. There must be safeguards.

15 So my amendment is very simple. It would simply  
16 prohibit the Secretary from interfering in drug price  
17 negotiations if such interference may result in cost  
18 shifting to private or public entities, such as Medicare,  
19 Medicaid, veterans, or the uninsured. We owe these folks  
20 no less.

21 The Chairman. Is there any discussion?

22 Senator Grassley. Yes, I would like to say that  
23 obviously the proponents of this bill either would deny  
24 that there is cost shifting or would want to ignore this  
25 point. I think when you have the panel that we had back

1 in January, when you have not only the American Legion  
2 but other veterans organizations have said the same  
3 thing, that it is just silly to think that it will not  
4 happen. It will happen, and that is why we should  
5 support this amendment.

6 The Chairman. Any further discussion before we  
7 vote?

8 Senator Stabenow. Mr. Chairman, if I might just,  
9 again, for the record--and we may need to go further in  
10 terms of clarifying what the VA says. But I would just  
11 say again, in looking at the numbers that we have  
12 received, the VA formulary, actually prescription drugs,  
13 the formulary actually covers 4,778 separate drugs,  
14 according to the VA. So we may want to find out more  
15 about that.

16 But I also would just say, Mr. Chairman, just that  
17 there are huge differences in pricing between the VA and  
18 the lowest Medicare Part D price on a number of different  
19 drugs, you know, in one case, over a 1,000-percent  
20 difference in price.

21 So, again, we have hard time arguing on the one hand  
22 it will not do anything, but yet it will do damage. But  
23 the reality is that there are huge price differences. I  
24 cannot believe that they cannot negotiate in a way that  
25 brings those high prices down.

1           The Chairman. All right. Let us move on here. I  
2 do not think it makes sense, this amendment, for a lot of  
3 reasons, many of which have already been expressed.  
4 There is a study in this bill, too, to look at potential  
5 cost effects on this; that is, CBO is required to under  
6 this bill to look at potential cost effects. I think  
7 that is sufficient.

8           All in favor--

9           Senator Kyl. Mr. Chairman, I really believe we need  
10 to think very carefully about the potential effect on  
11 other of our constituents here. I would like a roll call  
12 vote.

13          The Chairman. The clerk will call the roll. All  
14 those in favor, vote aye.

15          The Clerk. Mr. Rockefeller?

16          Senator Rockefeller. No.

17          The Clerk. Mr. Rockefeller, no. Mr. Conrad?

18          Senator Conrad. No.

19          The Clerk. Mr. Conrad, no. Mr. Bingaman?

20          The Chairman. No, by proxy.

21          The Clerk. Mr. Bingaman, no, by proxy. Mr. Kerry?

22          Senator Kerry. No.

23          The Clerk. Mr. Kerry, no. Mrs. Lincoln?

24          Senator Lincoln. No.

25          The Clerk. Mrs. Lincoln, no. Mr. Wyden?

1 Senator Wyden. No.

2 The Clerk. Mr. Wyden, no. Mr. Schumer?

3 The Chairman. No, by proxy.

4 The Clerk. Mr. Schumer, no, by proxy. Ms. Stabenow?

5 Senator Stabenow. No.

6 The Clerk. Ms. Stabenow, no. Ms. Cantwell?

7 Senator Cantwell. No.

8 The Clerk. Ms. Cantwell, no. Mr. Salazar?

9 Senator Salazar. No.

10 The Clerk. Mr. Salazar, no. Mr. Grassley?

11 Senator Grassley. Aye.

12 The Clerk. Mr. Grassley, aye. Mr. Hatch?

13 Senator Hatch. Aye.

14 The Clerk. Mr. Hatch, aye. Mr. Lott?

15 Senator Grassley. Aye, by proxy.

16 The Clerk. Mr. Lott, aye, by proxy. Ms. Snowe?

17 Senator Snowe. No.

18 The Clerk. Ms. Snowe, no. Mr. Kyl?

19 Senator Kyl. Aye.

20 The Clerk. Mr. Kyl, aye. Mr. Thomas?

21 Senator Grassley. Aye, by proxy.

22 The Clerk. Mr. Thomas, aye, by proxy. Mr. Smith?

23 Senator Smith. No.

24 The Clerk. Mr. Smith, no. Mr. Bunning?

25 Senator Grassley. Aye, by proxy.

1 The Clerk. Mr. Bunning, aye, by proxy. Mr. Crapo?

2 Senator Grassley. Aye, by proxy.

3 The Clerk. Mr. Crapo, aye, by proxy. Mr. Roberts?

4 Senator Roberts. Aye.

5 The Clerk. Mr. Roberts, aye. Mr. Chairman?

6 The Chairman. No.

7 The Clerk. The chairman votes no.

8 Mr. Chairman, the tally is 8 ayes, 13 nays.

9 The Chairman. The amendment is not agreed to.

10 Any further amendments? Go ahead.

11 Senator Kyl. Thank you. This is my amendment  
12 number 3, and, Mr. Chairman, there is a modification of  
13 amendment 3, which I know you have or your staff has. I  
14 have extra copies here. It just changes a couple of  
15 words. And I might explain this while that is being  
16 handed out.

17 The Chairman. I do not know if have the latest or  
18 not. What words are changed in the latest?

19 Senator Kyl. I will have the staff pass it to you.  
20 It is simply the difference between a certification and--  
21 I forget what the other word was.

22 The Chairman. Do you want to explain your  
23 amendment?

24 Senator Kyl. Yes, I do. Mr. Chairman, obviously,  
25 all of us have worked hard to ensure that seniors

1 received access to comprehensive prescription drug  
2 coverage and private health plan options similar to those  
3 that Members of Congress receive. Our constituents have  
4 told us loud and clear they want access, they want  
5 choice, and affordability from a drug benefit.

6 I do not think they asked us for a one-size-fits-all,  
7 Government-run prescription drug plan, nor did they ask  
8 for the Government to interfere between a physician and a  
9 patient by putting any restrictions on their drug  
10 choices.

11 We delivered on that promise, and as Senator Grassley  
12 said earlier, Medicare Part D is working better than  
13 anyone anticipated. Seniors are saving on their  
14 prescription drug costs approximately \$1,200, on average,  
15 in the year 2006. And, Mr. Chairman, you said it best  
16 earlier this year when you stated, "Let us not kill the  
17 goose that lays the golden eggs." So I am asking why we  
18 would be potentially taking a giant step backward here,  
19 repealing the first half of the MMA's non-interference  
20 provision.

21 While the mark retains the second half of the  
22 provision, which prohibits the Secretary from  
23 establishing a formulary, as was noted by Senator  
24 Grassley's questions, the formulary is only one tool that  
25 the Secretary may use to restrict access to prescription

1 drugs. I am not as confident that a preferred drug list  
2 could not be used, for example, prior authorization  
3 procedures, possibly a national coverage determination,  
4 and it has been very clear from the lack of specificity  
5 here this evening that no one knows for sure how the  
6 Secretary would do this and how he would exercise his  
7 leverage. I do not even know all the tools that are at  
8 his disposal, but it would have been nice, Mr. Chairman,  
9 if we had actually been able to bring Secretary Leavitt  
10 up here in testimony and asked him these questions, and I  
11 think he would have happy to provide his testimony.

12 But what I do know is that this mark provides, in  
13 effect, total discretionary with regard to what his tools  
14 are. And based on what I said before, it could be at the  
15 expense not only of seniors, but also of others. They  
16 could also differ from administration to administration.

17 So this amendment is quite simple. It is an  
18 insurance plan, in effect. It is a belt-and-suspenders.  
19 It prohibits the Secretary from interfering in drug price  
20 negotiations unless he certifies the satisfaction of four  
21 beneficiary protections:

22 Number one, no interference with an individual's  
23 choice of a prescription drug plan that best suits his or  
24 her health care needs;

25 Number two, no interference with an individual's

1 access to prescription drugs, including single source  
2 drugs and biologics, by prohibiting the establishment of  
3 a Government formulary or any other mechanism to restrict  
4 drug access;

5 Three, no interference with an individual's access to  
6 local pharmacies, particularly in rural communities;

7 And, four, no actions that result in cost shifting to  
8 other payers such as Medicare, Medicaid, the VA, or  
9 uninsured.

10 If you support secretarial dictates and restrictions,  
11 and you want to give the Secretary the tools to negotiate  
12 lower prices, then vote against my amendment. But if you  
13 support--and I would say also if you support a  
14 Government-run health care plan, obviously vote against  
15 it. But if you support ensuring beneficiary access to  
16 needed prescription drugs and finding ways to make the  
17 private market work, then I hope you will join me in  
18 supporting this amendment.

19 Senator Wyden. Mr. Chairman?

20 The Chairman. The Senator from Oregon.

21 Senator Wyden. I am not for a Government-run health  
22 plan, A. I voted for the prescription drug plan, B. C,  
23 I am against this particular amendment because, once  
24 again, it includes this cost-shifting language. Cost  
25 shifting is arguably the most elusive thing in American



1 health care today. There is cost shifting morning, noon,  
2 and night, constantly. Senator Baucus had handled the  
3 cost-shifting issue.

4 Absolutely right, we are going to have a study of it  
5 under this particular mark. I urge the rejection of the  
6 amendment.

7 Senator Conrad. Mr. Chairman?

8 The Chairman. Senator Conrad.

9 Senator Conrad. Mr. Chairman, I was not going to  
10 respond. I did not on the previous amendment, but I feel  
11 constrained to respond on this one. The Senator is  
12 advancing what I think is a concept of a zero-sum game of  
13 prescription drug pricing. I just do not think it is  
14 true. He has this notion that if you lower prices for  
15 somebody, you have got to raise them for somebody else.  
16 I do not believe that.

17 So I reject both his previous amendment and this one  
18 on the same grounds. I just think this notion of a zero-  
19 sum game of drug pricing is not the real-world  
20 application of drug pricing.

21 The Chairman. Ms. Bishop, could you just outline  
22 the provisions in this bill which address those concerns?  
23 The bill already addresses them, and I would just like  
24 you to explain in more detail how it does so.

25 Ms. Bishop. Right. Well, in terms of the first

1 point and in terms of interfering with the individual's  
2 choice, the mark does nothing to replace, affect, modify  
3 the underlying structure of the benefit, which is private  
4 plans delivering options to beneficiaries. That remains  
5 intact.

6 In terms of point number two, interfering with an  
7 individual's access to needed drugs, the mark does  
8 nothing, again, to change the underlying structure of the  
9 benefit, which allows private drug plans to offer drugs  
10 with formularies in place.

11 The mark also has a rule of construction that says  
12 nothing in this mark shall allow the Secretary to affect  
13 access to drugs. We would include a rule of construction  
14 just to make sure that we mean that there is no  
15 additional authorities given to the Secretary to impede  
16 access.

17 Then, number three, we also have a rule of  
18 construction that would basically say that there is  
19 nothing in this mark that would allow the Secretary to  
20 prohibit access to local pharmacies. So, again, we are  
21 preserving the underlying structure of the benefit, the  
22 underlying such of the program.

23 And for number four, as Chairman Baucus said, we have  
24 the Congressional Budget Office conducting a study that  
25 would look at the effects of any actions the Secretary

1 takes, any actions the Secretary reports to Congress that  
2 he took on how those actions would affect any prices in  
3 non-Medicare markets, including VA and commercial.

4 The Chairman. Thank you. I am ready for the vote.  
5 All those--

6 Senator Kyl. No, Mr. Chairman. Hold on just a  
7 second. That answer is, in effect, stating a tautology.  
8 Red is red because it is red.

9 Of course, the mark does not do any of these things.  
10 As Ms. Bishop pointed out originally, the mark simply  
11 removes a provision of law. As she pointed out and as  
12 everybody here recognizes, the Secretary will have to  
13 utilize whatever authorities he has, whatever leverage he  
14 has. They are not stated in the mark. So, of course,  
15 the mark does not change anything in terms of underlying.  
16 That is the whole point. It does not change his power  
17 either. And if he is to achieve any results at all, he  
18 has to exercise his power. That is what we want to try  
19 to prevent bad results flowing from, is the exercise of  
20 his underlying power. And there has been no specificity  
21 about how he would do that. In fact, it is not even real  
22 clear tonight what the Secretary's powers are.

23 Remember the testimony of Dr. Scott Morton. She made  
24 the point very clearly. It is a zero-sum game precisely  
25 because Medicare is just about half of the population.

1 It does represent the average. You cannot push the  
2 pillow in here without having it pop out over there.  
3 That is precisely her testimony. She has got a degree  
4 from the Yale School of Management. She is a lot smarter  
5 than I suspect most of us are on this. But what she says  
6 makes sense to me. If you have got half of the market  
7 and you are going to reduce the cost for that market, the  
8 average has got to be affected by the decision that the  
9 Secretary makes. And, again, it is not the mark that  
10 changes it. It is the Secretary's inherent authority.

11 So what my amendment would do is to prevent the use  
12 of that inherent power in the negotiation that he would  
13 intend to engage in, in resulting in any of these  
14 negative consequences.

15 Senator Conrad. Mr. Chairman, might I just observe,  
16 as a Stanford graduate, we have great respect for Yale.  
17 But we just do not accept anything that some graduate  
18 from Yale says. [Laughter.]

19 The Chairman. All those in favor of the amendment--

20 Senator Kyl. Mr. Chairman, could we have a roll  
21 call vote on that, too, please?

22 The Chairman. All right. A roll call vote. Those  
23 in favor will vote aye.

24 The Clerk. Mr. Rockefeller?

25 Senator Rockefeller. No.

1 The Clerk. Mr. Rockefeller, no. Mr. Conrad?  
2 Senator Conrad. No.  
3 The Clerk. Mr. Conrad, no. Mr. Bingaman?  
4 The Chairman. No, by proxy.  
5 The Clerk. Mr. Bingaman, no, by proxy. Mr. Kerry?  
6 The Chairman. No, by proxy.  
7 The Clerk. Mr. Kerry, no, by proxy. Mrs. Lincoln?  
8 Senator Lincoln. No.  
9 The Clerk. Mrs. Lincoln, no. Mr. Wyden?  
10 Senator Wyden. No.  
11 The Clerk. Mr. Wyden, no. Mr. Schumer?  
12 The Chairman. No, by proxy.  
13 The Clerk. Mr. Schumer, no, by proxy. Ms. Stabenow?  
14 Senator Stabenow. No.  
15 The Clerk. Ms. Stabenow, no. Ms. Cantwell?  
16 Senator Cantwell. No.  
17 The Clerk. Ms. Cantwell, no. Mr. Salazar?  
18 Senator Salazar. No.  
19 The Clerk. Mr. Salazar, no. Mr. Grassley?  
20 Senator Grassley. Aye.  
21 The Clerk. Mr. Grassley, aye. Mr. Hatch?  
22 Senator Hatch. Aye.  
23 The Clerk. Mr. Hatch, aye. Mr. Lott?  
24 Senator Grassley. Aye, by proxy.  
25 The Clerk. Mr. Lott, aye, by proxy. Ms. Snowe?

- 1 Senator Snowe. No.
- 2 The Clerk. Ms. Snowe, no. Mr. Kyl?
- 3 Senator Kyl. Aye.
- 4 The Clerk. Mr. Kyl, aye. Mr. Thomas?
- 5 Senator Grassley. Aye, by proxy.
- 6 The Clerk. Mr. Thomas, aye, by proxy. Mr. Smith?
- 7 Senator Smith. No.
- 8 The Clerk. Mr. Smith, no. Mr. Bunning?
- 9 Senator Grassley. Aye, by proxy.
- 10 The Clerk. Mr. Bunning, aye, by proxy. Mr. Crapo?
- 11 Senator Grassley. Aye, by proxy.
- 12 The Clerk. Mr. Crapo, aye, by proxy. Mr. Roberts?
- 13 Senator Grassley. Aye, by proxy.
- 14 The Clerk. Mr. Roberts, aye, by proxy. Mr.
- 15 Chairman?
- 16 The Chairman. No.
- 17 The Clerk. The chairman votes no.
- 18 The Chairman. The mark is open to any further
- 19 amendments.
- 20 Senator Grassley. Mr. Chairman, I would--
- 21 Senator Smith. Mr. Chairman?
- 22 Senator Grassley. Please go ahead.
- 23 Senator Smith. Mr. Chairman, my amendment would
- 24 codify the guidance--
- 25 Senator Grassley. Would you let him vote in person?

1           Senator Roberts.    Would you count me being here  
2 instead of by proxy?

3           The Chairman.    Absolutely.

4           Senator Roberts.    Thank you.

5           The Clerk.    Mr. Roberts, aye.

6           The Chairman.    Yes, I am sorry.    Ms. Martin, could  
7 you announce the vote?

8           The Clerk.    Mr. Chairman, the total is 8 ayes, 13  
9 nays.

10          The Chairman.    The amendment fails.    Thank you.

11          Senator Smith.    Mr. Chairman, my amendment would  
12 codify the guidance the CMS has given prescription drug  
13 plans to cover "all or substantially all drug therapies  
14 in six protected classes."    These vital medications treat  
15 a number of critical health conditions, including mental  
16 illness, HIV/AIDS, and cancer.

17          While achieving value for drug purchases is certainly  
18 very important, I also believe that seniors should have  
19 access to a wide range of drug options, including the  
20 most innovative treatments on the market.    The current  
21 "all or substantially all" policy helps to ensure that  
22 that happens in Medicare, but there is a chance that it  
23 could be weakened over time because it is now just merely  
24 guidance.    I believe Congress should make the policy  
25 permanent so that beneficiaries can be assured that they

1 have access to the vital drugs they need, regardless of  
2 any changes that might occur to the drug benefit.

3 For the sake of moving this process forward, though,  
4 Mr. Chairman, I withdraw my amendment at this time, and I  
5 would ask Chairman Baucus and my colleagues to work with  
6 me in the months ahead to make this policy law, not just  
7 guidance, so that beneficiaries have guaranteed access to  
8 critical drug therapies for mental illness, HIV/AIDS, and  
9 cancer.

10 The Chairman. Thank you, Senator. You make a good  
11 point. It is very needed, and we will very much work  
12 with you as we try to find a solution. Thank you very  
13 much. Appreciate it.

14 Senator Salazar. Mr. Chairman?

15 The Chairman. Senator Salazar.

16 Senator Salazar. I would like to offer my amendment  
17 number 1, but let me make just a couple of quick  
18 observations at the beginning.

19 First, it baffles me that our efforts here to put  
20 another toolbox into the Secretary of HHS to deal with  
21 the price of prescription drug coverages is ending up  
22 with this kind of opposition. When I look at someone  
23 like Secretary Leavitt, whom Senator Hatch praised  
24 yesterday, I would think that a Secretary of HHS would  
25 welcome this additional tool in his toolbox, and so I am



1 supportive of the chairman's mark.

2 Second of all, I think there are some great ideas  
3 that are being proposed here tonight, some of which are  
4 not being considered because amendments are being  
5 withdrawn. For example, the proposed amendment by  
6 Senator Smith is an amendment which I would fully  
7 support, but I recognize that the process here is trying  
8 to move forward with this legislation so that we can get  
9 it on the floor.

10 But I think that the point that I want to make is  
11 that when you have a program like Medicare Part D that  
12 has now been operational for several years, it is timely  
13 for us to take a look at how we might be able to improve  
14 the program. And I think many of the ideas that are  
15 being discussed here in terms of amendments will be  
16 important ideas that you and the rest of this committee  
17 should consider as we move forward.

18 I want to, thirdly, just talk a bit about my  
19 amendment. It is an amendment that would make three  
20 simple changes to the Medicare law. It is essentially  
21 part of legislation that was supported last year and led  
22 by both you, Chairman Baucus, and Senator Lincoln,  
23 Senator Schumer, and Senator Conrad. The legislation  
24 would do three simple things:

25 It would require prescription drug plans to pay

1 pharmacies within 14 days of the submission of a claim.  
2 As I travel around Colorado and as I am sure most of us  
3 around this committee travel around our States, we hear  
4 many complaints from pharmacies that they are not being  
5 reimbursed in a timely basis. This would do it on a 14-  
6 day basis, and it would, therefore, help pharmacies,  
7 especially those in rural communities. Some of them are  
8 hanging on by a shoestring.

9 Secondly, my amendment would require the Department  
10 of Health and Human Services to conduct a study on the  
11 appropriate dispensing fees that pharmacies should  
12 receive.

13 And, thirdly, the amendment would allow the nursing  
14 home administrators to assist seniors who have no one  
15 else to help them in selecting a prescription drug plan.  
16 I think one of the realities that we have seen as  
17 Medicare Part D has been implemented is that there is a  
18 tremendous amount of confusion, and I think that in many  
19 States, like my State, where there are 47 different  
20 plans, it would be important to authorize these nursing  
21 home administrators to provide that kind of assistance.

22 I think it is a good amendment, Chairman Baucus. For  
23 purposes of moving our work forward this evening, I  
24 propose the amendment and withdraw the amendment as well.

25 The Chairman. It is a very good amendment, as the

1 Senator well knows. He and I have been working on this  
2 very issue, and it is similar to the bill last year. You  
3 cite the needs that we often hear repeatedly, and it is  
4 kind of distressing, frankly, that is, the plight of  
5 pharmacies and not getting paid on a timely basis. I  
6 hear that very often. But we certainly will find a way  
7 to deal with that, and thank you for--

8 Senator Stabenow. Mr. Chairman, can I just again  
9 support my colleague, Senator Salazar? Because it is a  
10 much needed efforts, and we worked hard on that last  
11 year, and we appreciate the chairman being willing to  
12 work to make it really a reality this year. So I thank  
13 Senator Salazar and the chairman for his leadership on  
14 that.

15 The Chairman. I see no more amendments, so if we  
16 are ready to--

17 Senator Grassley. Amendment number 7.

18 The Chairman. Oh, amendment number 7, all right.

19 Senator Grassley. If I could comment, though, just  
20 before, so that Senator Salazar knows that I am concerned  
21 about local pharmacists not only being paid on time, but  
22 even existing, and that is, do not forget, the way the VA  
23 does it, they mail them out; 83 percent of their drugs  
24 are received in the mail. You are not going to have any  
25 pharmacists to worry about paying on time if we are going

1 to start doing it the way VA does it.

2 Now, this amendment number 7, referring again to this  
3 hearing that we thought was pretty good that we had back  
4 in January, at that hearing we heard testimony from these  
5 expert witnesses. They testified that the Government  
6 negotiation in Medicare produced real savings will lead  
7 to cost shifting. This means that it would make drug  
8 prices go up for everyone else. We should all worry  
9 about the impact that this would have on VA and private  
10 payers. We should also worry about the impact it will  
11 have on Medicaid, and I have some questions that I want  
12 to ask people from CBO if they would come to the table.

13 The Chairman. Would you do that, please? Whoever  
14 is most appropriate. What is the subject, so they know?

15 Senator Grassley. It would be either Phil Ellis or  
16 Peter Orszag.

17 The Chairman. Peter Orszag is not here at the  
18 moment, so whoever will want to replace Peter.

19 Senator Grassley. Well, then, if they are not here,  
20 then I will withhold this.

21 The Chairman. Could somebody speak for CBO?

22 Senator Grassley. I thought you said no one was  
23 here from CBO.

24 The Chairman. They are, but I do not--maybe you can  
25 delay.

1           Senator Grassley. I will withhold and offer another  
2 amendment until he gets back.

3           The Chairman. He will be back in 5 minutes.

4           Senator Grassley. All right. Then let us go to  
5 amendment number 19. This amendment gets at a point  
6 often mentioned by Democrats and people that support this  
7 amendment. The point is that the Secretary negotiated  
8 prices for Cipro during the anthrax scare, so they say  
9 let us just have the Secretary negotiate for Part D the  
10 same way as Cipro.

11           I have stated in that letter that I read that the  
12 Secretary did not negotiate Cipro. The Secretary  
13 threatened to allow a generic version, and that is what  
14 brought down the price. Even the Congressional Budget  
15 Office made that point, and that is what I read from.

16           We had that letter to Senator Wyden. CBO said, to  
17 remind everybody, "The relative negotiations were  
18 conducted in a climate of a national emergency  
19 immediately following the attacks of September the 11th  
20 and the deaths from anthrax-laced letters."

21           It went on to say, "The threat issued by Secretary  
22 Thompson to seek authority for generic production of  
23 Cipro was apparently instrumental in bringing the  
24 negotiations to a close."

25           This is not at all the same as the situation with

1 Medicare drug benefits. The case with Cipro was not for  
2 day-to-day delivery of prescription drugs to Medicare  
3 beneficiaries. If there is another public health crisis  
4 like we had with Cipro, then we all would agree--at least  
5 I am going to agree, that the Government should step in.  
6 Emergencies call for that.

7 Nothing in current law prevents the Secretary from  
8 acting in a similar manner should public health again be  
9 at risk, but, nevertheless, I am offering this amendment  
10 to make that crystal clear. Under my amendment, the  
11 Secretary could negotiate for prices on drugs necessary  
12 for the treatment of conditions related to public health  
13 emergencies. It is that simple.

14 The Chairman. Thank you, Senator, and I appreciate  
15 the Senator's interest in negotiated prices. Frankly, my  
16 view is if we are going to negotiate in an emergency, we  
17 ought to negotiate for folks that are not in an  
18 emergency. And besides that, I just think that it would  
19 make a lot more sense to give the power--repeal this  
20 provision, let the Secretary negotiate if he wishes to,  
21 but I do not think it makes sense to restrict it only to  
22 a national emergency.

23 Senator Wyden. Mr. Chairman, just very briefly,  
24 because we have pummeled the same point again and again.  
25 Essentially, all of these letters have said the same

1 thing: that there may be savings in a selected class of  
2 instances. And I would just add that you cannot  
3 anticipate every situation, and there may be different  
4 situations in the future where a different Secretary  
5 might use negotiating authority to get savings that  
6 nobody ever anticipated. And I think that is why we have  
7 not been citing specific examples. CBO has said the same  
8 thing in all of these letters--selected instances, some  
9 savings.

10 Thank you, Mr. Chairman.

11 The Chairman. All those in favor of the amendment,  
12 say aye?

13 [A chorus of ayes.]

14 The Chairman. Those opposed, no?

15 [A chorus of noes.]

16 The Chairman. The amendment is not agreed to.

17 Further amendments?

18 Senator Kyl. Mr. Chairman, just one final  
19 amendment. Even though I am from Arizona, Mr. Chairman,  
20 I have to commend you for forcing us to conclude this by  
21 cranking the temperature up to about 120 degrees here.

22 [Laughter.]

23 It is just about the same temperature in Yuma,  
24 Arizona, where I was on Monday. But I have to say I give  
25 up. I have only one amendment more, and I will be very

1 brief.

2 Obviously, the whole point of this exercise--and it  
3 kind of goes to what Senator Wyden just said a moment  
4 ago--is to try to provide seniors with lower costs for  
5 their prescription drugs. One of the things quoted was  
6 the reference to--

7 The Chairman. Senator, could you tell us which  
8 amendment?

9 Senator Kyl. Yes, this is my amendment number 4. I  
10 am sorry, Mr. Chairman.

11 The Chairman. Thank you.

12 Senator Kyl. This letter of CBO dated April 10th  
13 makes part of the point that Senator Wyden just did, and  
14 I am just going to quote a couple lines.

15 "CBO estimates that modifying the non-interference  
16 provision would have a negligible effect on Federal  
17 spending because we anticipate that under the bill the  
18 Secretary would lack the leverage to negotiate the price  
19 across the broad range of covered Part D drug that are  
20 more favorable than those obtained by PDPs under current  
21 law. Without the authority to establish a formulary or  
22 other tools to reduce drug prices, we believe the  
23 Secretary would not obtain significant discounts from  
24 drug manufacturers across a broad range of drugs."

25 Now, what is the point of this exercise, especially



1 since there have been a lot of promises made to seniors--  
2 and I know a lot of us have heard from seniors' groups  
3 about what their expectations are. According to CBO,  
4 those expectations are not going to be satisfied by this  
5 legislation.

6 So my amendment is quite simple. It would require  
7 the Office of Management and Budget to certify that  
8 secretarial interference in drug price negotiations would  
9 result in significant discounts from drug manufacturers  
10 across a broad range of drugs. If my colleagues really  
11 believe that repealing the non-interference provision  
12 will result in the savings despite these economic expert  
13 opinions to the contrary, then I hope they would join me  
14 in supporting the amendment, and I will leave it at that,  
15 Mr. Chairman.

16 The Chairman. Thank you. Again, the provisions in  
17 this mark to deal with potential cost problems, that is  
18 up to the Secretary.

19 Second, I do not know if we would want to put this in  
20 the hands of the OMB Director. My thinking about it is  
21 that the Secretary is much more qualified to make those  
22 decisions.

23 All those in--

24 Senator Kyl. Mr. Chairman, I just wanted to quickly  
25 respond to that last point. As you know, originally my

1 amendment did relate to the CBO Director, but we  
2 eventually concluded that it would probably be  
3 inappropriate to limit the executive branch's authority  
4 to a certification by a congressional support agency, and  
5 that is why OMB was the selected agency for the  
6 certification. I would ask for a roll call vote, please.

7 The Chairman. A recorded vote has been requested.  
8 All those in favor vote aye.

9 The Clerk. Mr. Rockefeller?

10 Senator Rockefeller. No.

11 The Clerk. Mr. Rockefeller, no. Mr. Conrad?

12 Senator Conrad. No.

13 The Clerk. Mr. Conrad, no. Mr. Bingaman?

14 The Chairman. No, by proxy.

15 The Clerk. Mr. Bingaman, no, by proxy. Mr. Kerry?

16 The Chairman. No, by proxy.

17 The Clerk. Mr. Kerry, no, by proxy. Mrs. Lincoln?

18 Senator Lincoln. No.

19 The Clerk. Mrs. Lincoln, no. Mr. Wyden?

20 Senator Wyden. No.

21 The Clerk. Mr. Wyden, no. Mr. Schumer?

22 Senator Schumer. No.

23 The Clerk. Mr. Schumer, no. Ms. Stabenow?

24 Senator Stabenow. No.

25 The Clerk. Ms. Stabenow, no. Ms. Cantwell?

1 Senator Cantwell. No.

2 The Clerk. Ms. Cantwell, no. Mr. Salazar?

3 Senator Salazar. No.

4 The Clerk. Mr. Salazar, no. Mr. Grassley?

5 Senator Grassley. Aye.

6 The Clerk. Mr. Grassley, aye. Mr. Hatch?

7 Senator Hatch. Aye.

8 The Clerk. Mr. Hatch, aye. Mr. Lott?

9 Senator Grassley. Aye, by proxy.

10 The Clerk. Mr. Lott, aye, by proxy. Ms. Snowe?

11 Senator Snowe. No.

12 The Clerk. Ms. Snowe, no. Mr. Kyl?

13 Senator Kyl. Aye.

14 The Clerk. Mr. Kyl, aye. Mr. Thomas?

15 Senator Grassley. Aye, by proxy.

16 The Clerk. Mr. Thomas, aye, by proxy. Mr. Smith?

17 Senator Smith. Aye.

18 The Clerk. Mr. Smith, aye. Mr. Bunning?

19 Senator Grassley. Aye, by proxy.

20 The Clerk. Mr. Bunning, aye, by proxy. Mr. Crapo?

21 Senator Crapo. Aye.

22 The Clerk. Mr. Crapo, aye. Mr. Roberts?

23 Senator Roberts. Aye.

24 The Clerk. Mr. Roberts, aye. Mr. Chairman?

25 The Chairman. No.

1 The Clerk. The chairman votes no.

2 Mr. Chairman, the tally is 9 ayes, 12 nays.

3 The Chairman. The amendment is not agreed to.

4 Senator Roberts. Mr. Chairman, I have an amendment  
5 that I am not going to ask for a recorded vote. We could  
6 dispense with it and then move to Mr. Grassley's  
7 amendment and Mr. Crapo's amendment, if that would be in  
8 order. Or if you do, I would ask Senator Grassley if he  
9 would--

10 The Chairman. I will defer to the Senator.

11 Senator Roberts. I can either ride drag or ride  
12 point, whatever you want me to do.

13 The Chairman. Senator Grassley.

14 Senator Grassley. I would like to engage CBO now.

15 Senator Roberts. I guess I am drag.

16 Senator Grassley. I would like to engage the  
17 Director of CBO. For all my colleagues on this  
18 committee, this is in regard to amendment number 7.

19 My first question: If Part D negotiations meant  
20 using tools like reference pricing as in the best price  
21 system, do you believe it would lead to higher prices for  
22 other private and public purveyors?

23 Mr. Orszag. To the extent that interventions of that  
24 sort did reduce prices in Medicare, and those sorts of  
25 direct price interventions could produce savings in

1 Medicare, there would likely be upward pressure on  
2 pricing in other programs, including the VA one.

3 I would note, though, that it is not zero sum. You  
4 would not expect full offsetting increases in other  
5 programs.

6 Senator Grassley. So if it leads to higher prices  
7 for other private payers, that means it would cost more  
8 for private insurers and also for small business that  
9 paid for insurance?

10 Mr. Orszag. Again, to the extent that there were  
11 price reductions that occurred in Medicare, there would  
12 be upward pressure on those other payers.

13 Senator Grassley. So for public payers, that would  
14 mean ultimately higher prices for the VA?

15 Mr. Orszag. To the extent that there were price  
16 reductions in Medicare, there would be some upward  
17 pressure on VA prices.

18 Senator Grassley. And would it apply to Medicaid as  
19 well?

20 Mr. Orszag. That is correct.

21 Senator Grassley. I thank you very much.

22 So, Mr. Chairman, I think we need to be concerned  
23 about the unintended consequences Government negotiation  
24 is going to have on the Medicaid program. My amendment  
25 requires the Secretary of HHS to explain how the

1 Secretary would undertake negotiations. It would then  
2 require the GAO to evaluate the impact of Government  
3 negotiations on the Medicaid program. The Part D program  
4 is working. I hope I have made that very clear. I have  
5 not convinced anybody on your side of aisle and two on my  
6 side of the aisle. But I think it has. So the bill is  
7 unnecessary.

8 We all know that to achieve real savings above Part D  
9 is already getting--you have to use real tools to  
10 accomplish that goal. If we actually are thinking about  
11 giving real tools to the Secretary, then we need to  
12 protect our safety net. In our zeal to satisfy seniors,  
13 let us not hurt the poor, the blind, the disabled, and,  
14 most importantly, children. So I encourage everyone to  
15 protect Medicaid by supporting my amendment, and I would  
16 ask for a roll call vote.

17 The Chairman. A roll call vote has been requested.  
18 All those in favor vote aye, those opposed vote no.

19 The Clerk. Mr. Rockefeller?

20 Senator Rockefeller. No.

21 The Clerk. Mr. Rockefeller, no. Mr. Conrad?

22 Senator Conrad. No.

23 The Clerk. Mr. Conrad, no. Mr. Bingaman?

24 The Chairman. No, by proxy.

25 The Clerk. Mr. Bingaman, no, by proxy. Mr. Kerry?

1 The Chairman. No, by proxy.

2 The Clerk. Mr. Kerry, no, by proxy. Mrs. Lincoln?

3 Senator Lincoln. No.

4 The Clerk. Mrs. Lincoln, no. Mr. Wyden?

5 Senator Wyden. No.

6 The Clerk. Mr. Wyden, no. Mr. Schumer?

7 Senator Schumer. No.

8 The Clerk. Mr. Schumer, no. Ms. Stabenow?

9 Senator Stabenow. No.

10 The Clerk. Ms. Stabenow, no. Ms. Cantwell?

11 Senator Cantwell. No.

12 The Clerk. Ms. Cantwell, no. Mr. Salazar?

13 Senator Salazar. No.

14 The Clerk. Mr. Salazar, no. Mr. Grassley?

15 Senator Grassley. Aye.

16 The Clerk. Mr. Grassley, aye. Mr. Hatch?

17 Senator Hatch. Aye.

18 The Clerk. Mr. Hatch, aye. Mr. Lott?

19 Senator Grassley. Aye, by proxy.

20 The Clerk. Mr. Lott, aye, by proxy. Ms. Snowe?

21 Senator Snowe. No.

22 The Clerk. Ms. Snowe, no. Mr. Kyl?

23 Senator Kyl. Aye.

24 The Clerk. Mr. Kyl, aye. Mr. Thomas?

25 Senator Grassley. Aye, by proxy.

1           The Clerk. Mr. Thomas, aye, by proxy. Mr. Smith?  
2           Senator Smith. Aye.  
3           The Clerk. Mr. Smith, aye. Mr. Bunning?  
4           Senator Grassley. No, by proxy.  
5           The Clerk. Mr. Bunning, no, by proxy. Mr. Crapo?  
6           Senator Crapo. Aye.  
7           The Clerk. Mr. Crapo, aye. Mr. Roberts?  
8           Senator Roberts. Aye.  
9           The Clerk. Mr. Roberts, aye. Mr. Chairman?  
10          The Chairman. No.  
11          The Clerk. The chairman votes no.  
12          Mr. Chairman, the tally is 8 ayes, 13 nays.  
13          The Chairman. The amendment is not agreed to.  
14          Senator Crapo. Mr. Chairman?  
15          The Chairman. Senator Kerry, do you want to vote in  
16 person? If you can get Kerry, no. That does not change  
17 the result.  
18          Senator Crapo. Mr. Chairman?  
19          The Chairman. Senator Crapo.  
20          Senator Crapo. Mr. Chairman, I have two amendments  
21 that probably should come now. They are very similar to  
22 that which we just voted on by Senator Grassley in a  
23 different context, if I could just explain. I will  
24 explain both of them, if that is all right, and then  
25 offer them both.



1           Senator Grassley has well pointed out that we need to  
2 study what is going to be the impact on other payers in  
3 the health care system as a result of the exercise of the  
4 authority that is being given in this legislation. And  
5 we have already heard the testimony not only here tonight  
6 but also in other hearings about the fact that there will  
7 be upward pressure on other payers as we see this type of  
8 situation implemented.

9           I know that the legislation before us has a study in  
10 it. The problem with it is that the study requires that  
11 we examine the number and extent of discounts and other  
12 price concessions received under the plan within the  
13 first year. As has already been pointed out tonight,  
14 this authority is not likely to be exercised in the next  
15 year, and so we will be dealing with a study in this  
16 legislation that studies something that still has not  
17 happened yet.

18           We have had a lot of discussion tonight about what  
19 will the Secretary be authorized to do here and what will  
20 the Secretary do with this negotiating authority. And it  
21 has become very clear that we do not know. In the  
22 questioning period, when Senator Grassley was asking his  
23 questions about could the Secretary do this or would the  
24 Secretary be able to do that, the answers consistently  
25 were it is the Secretary's discretion.

1           What my amendment does and what Senator Grassley's  
2           did with regard to Medicaid is that it directs the  
3           Secretary to identify the approach and the plan that the  
4           Secretary would use if this authority were exercised, and  
5           to let us know, in this case let GAO know what the  
6           proposed exercise of this authority would be, and how  
7           they would propose to proceed with this authority. And  
8           then it would direct GAO to study that proposed action  
9           and determine whether there will, in fact, be an impact  
10          on the prices that are paid for prescription drugs by  
11          others. My first amendment requires the study for  
12          private payers; my second amendment requires the study  
13          for the Veterans Administration system.

14          I really believe that--I understand, as I said at the  
15          outset, that we have very big philosophical and  
16          principled differences here over how we should approach  
17          prescription drug pricing and negotiating in this  
18          country. But we certainly should not disagree about the  
19          fact that we should identify as clearly as we can what it  
20          is that we are authorizing in this legislation and then  
21          have an independent, fair study of what impacts that  
22          would have on other payers. And so I would hope that  
23          these studies would be authorized by the committee.

24          The Chairman.     Senator Grassley.

25          Senator Grassley.   Mr. Chairman, I am only going to

1 speak to one of Senator Crapo's amendments. I could  
2 speak to two of them, but time is getting along.

3 We have heard from the other side a great deal about  
4 Government saving money if we negotiate prices under  
5 Medicare prescription drugs. I pointed out so many times  
6 about CBO's disagreement with that, the zero score we  
7 get. So then when you get a zero score from the god on  
8 Capitol Hill, which CBO is--

9 The Chairman. God just returned. God just sat down  
10 over there. [Laughter.]

11 Senator Grassley. So then how do you expect to save  
12 money? Never mind that we have not been given much  
13 information on how to expect the Government negotiations  
14 would work or the effect that this would have on others  
15 in the health care system, meaning both private and  
16 public. This amendment now would finally extract from  
17 the proponents of this bill the details and consequences  
18 of Government negotiation on the part of Part D  
19 prescription drugs. Just saying that Medicare overpays  
20 for prescription drugs, just saying that Government  
21 negotiation is the answer, it is not enough. We cannot  
22 buy into that.

23 We need to know what are the consequences, like the  
24 effect Government negotiations in Medicare will have on  
25 other payers, and we particularly look at all the

1 opposition from the veterans groups to this approach, how  
2 it is going to impact the VA.

3 We all have sympathy for veterans, and making them  
4 pay more because we are trying to do something for a  
5 larger group of people that are already getting 35  
6 percent less for their drugs on the 25 most often used  
7 drug, we already have heard reports that Government  
8 negotiations on Part D will result, in fact, in higher  
9 prices for VA.

10 So are the proponents so certain that this proposal  
11 will not hurt the VA? Are they so certain that this will  
12 not hurt veterans? I think this amendment should be  
13 supported. It is the intellectually honest way to handle  
14 things.

15 Senator Wyden. Mr. Chairman?

16 The Chairman. Senator Wyden.

17 Senator Wyden. To speak in opposition, and I do so  
18 with great reluctance because Senator Crapo is one of my  
19 favorites, and he has been part of our bipartisan effort.  
20 But I am compelled to do because you cannot anticipate  
21 every situation. There may be different situations in  
22 the future where a different Secretary would use the  
23 negotiating authority to get savings that CBO has not  
24 anticipated that nobody has talked about. And this idea  
25 of trying to divine everything now is just in my view not

1 in line with what I think are evolving kind of  
2 circumstances and why so many of us think we ought to  
3 lift the restriction and make sure that Medicare is not  
4 outlied.

5 I oppose this amendment with reluctance because of my  
6 appreciation for my friend.

7 The Chairman. Senator, are you willing to vote them  
8 out en bloc, the two of them together?

9 Senator Crapo. Yes. I would like a roll call vote,  
10 though.

11 The Chairman. Both together.

12 Senator Crapo. Together, yes. Could I just make  
13 one--

14 The Chairman. We will combine them into one vote.

15 Senator Crapo. Combine them into one vote, but let  
16 me just make one very quick rebuttal, and that is, to my  
17 good friend, Mr. Wyden, the response that you gave was  
18 basically that we are not able to study this because it  
19 is too vague, because it is too much discretion in the  
20 Secretary. And I would think that we should at least try  
21 to do something to try to get some focus on some  
22 specifics.

23 The Chairman. The Senator has asked for a roll call  
24 vote.

25 Senator Crapo. I have, yes.

- 1 The Chairman. The clerk will call the roll.
- 2 The Clerk. Mr. Rockefeller?
- 3 Senator Rockefeller. No.
- 4 The Clerk. Mr. Rockefeller, no. Mr. Conrad?
- 5 Senator Conrad. No.
- 6 The Clerk. Mr. Conrad, no. Mr. Bingaman?
- 7 The Chairman. No, by proxy.
- 8 The Clerk. Mr. Bingaman, no, by proxy. Mr. Kerry?
- 9 Senator Kerry. No.
- 10 The Clerk. Mr. Kerry, no. Mrs. Lincoln?
- 11 Senator Lincoln. No.
- 12 The Clerk. Mrs. Lincoln, no. Mr. Wyden?
- 13 Senator Wyden. No.
- 14 The Clerk. Mr. Wyden, no. Mr. Schumer?
- 15 Senator Schumer. No.
- 16 The Clerk. Mr. Schumer, no. Ms. Stabenow?
- 17 Senator Stabenow. No.
- 18 The Clerk. Ms. Stabenow, no. Ms. Cantwell?
- 19 Senator Cantwell. No.
- 20 The Clerk. Ms. Cantwell, no. Mr. Salazar?
- 21 Senator Salazar. No.
- 22 The Clerk. Mr. Salazar, no. Mr. Grassley?
- 23 Senator Grassley. Aye.
- 24 The Clerk. Mr. Grassley, aye. Mr. Hatch?
- 25 Senator Hatch. Aye.

1 The Clerk. Mr. Hatch, aye. Mr. Lott?  
2 Senator Grassley. Aye, by proxy.  
3 The Clerk. Mr. Lott, aye, by proxy. Ms. Snowe?  
4 Senator Snowe. No.  
5 The Clerk. Ms. Snowe, no. Mr. Kyl?  
6 Senator Kyl. Aye.  
7 The Clerk. Mr. Kyl, aye. Mr. Thomas?  
8 Senator Grassley. Aye, by proxy.  
9 The Clerk. Mr. Thomas, aye, by proxy. Mr. Smith?  
10 Senator Smith. Aye.  
11 The Clerk. Mr. Smith, aye. Mr. Bunning?  
12 Senator Grassley. Aye, by proxy.  
13 The Clerk. Mr. Bunning, aye, by proxy. Mr. Crapo?  
14 Senator Crapo. Aye.  
15 The Clerk. Mr. Crapo, aye. Mr. Roberts?  
16 Senator Roberts. Aye.  
17 The Clerk. Mr. Roberts, aye. Mr. Chairman?  
18 The Chairman. No.  
19 The Clerk. The chairman votes no.  
20 Mr. Chairman, the tally is 9 ayes, 12 nays.  
21 The Chairman. The amendment is not agreed to.  
22 Any further amendments?  
23 Senator Roberts. Mr. Chairman?  
24 The Chairman. The Senator from Kansas, Senator  
25 Roberts.

1           Senator Roberts.   We are headed for the last  
2 roundup.

3           The Chairman.   We are getting there.

4           Senator Roberts.   I filed a series of amendments to  
5 the mark that I think are pretty straightforward, but  
6 they all boil down to one simple point.  If my friends  
7 and colleagues on the other side of the aisle do not like  
8 the non-interference language in this current law, then  
9 we ought to change it.  I am confident that they will  
10 like the language in my amendment because the language  
11 comes from bills that they wrote and that they sponsored.

12           My first amendment--and this is the only amendment  
13 that I will introduce--is Roberts number 2.  It simply  
14 restores the non-interference language with language  
15 taken right out of a bill introduced in the 106th, in  
16 fact, cosponsored by 33 Senate Democrats, including the  
17 Chairman, several members of this committee.  And a  
18 unanimous move, Mr. Chairman, I would be even willing  
19 to refer to this amendment as the Baucus-Bingaman-Kerry-  
20 Lincoln-Rockefeller-Schumer-and Roberts amendment.

21           [Laughter.]

22           Now, this is what has been referred to by the  
23 distinguished Senator Kerry as the petard amendment.  I  
24 do not want anybody's imagination, more especially the  
25 Secretary, who has to use his imagination to somehow



1 lower these drug prices, to get this wrong. But a petard  
2 mortar was the demolition weapon fitted to the Churchill  
3 tank. It was a mortar of a 200 mm bore known to its  
4 crews as the "flying dust bin."

5 Now, Senator Kerry, I do not want to hoist anybody on  
6 a bomb, period, and I do not want to embarrass anybody,  
7 and I think maybe that idiom of being hoisted on your own  
8 petard, we should change that to "lance." That could be  
9 terribly uncomfortable, as well as untoward, and so I do  
10 not want to do that either. I think maybe the allegory  
11 would be slipping on your own banana peel.

12 Here is what their language says, here is what my  
13 language says: "Non-interference in administering the  
14 prescription drug benefit program established under this  
15 part, the Secretary may not: one, require a particular  
16 formulary or institute a price structure for benefits;  
17 two, interfere in any way with negotiations between  
18 private entities and drug manufacturers or wholesalers;  
19 or, three, otherwise interfere with the competitive  
20 nature of providing a prescription drug benefit to these  
21 private entities." And it sounds a little bit like the  
22 non-interference language in current law, which my  
23 friends on the other side of the aisle are now so opposed  
24 to.

25 It turns out that the majority did not want the

1 Government to interfere in the private sector  
2 negotiations either at that time. It recognized then, I  
3 think, that the private sector would do a better job. We  
4 all know that the Medicare Part D plan is working, as has  
5 been indicated by virtually everybody on this side of the  
6 aisle. Our premiums are lower. The program's cost is  
7 lower. Seniors are saving an average of \$1,200 per year  
8 on their drug costs, and independent analysis has shown  
9 that 80 percent of the beneficiaries are satisfied with  
10 the plan. The average monthly dollar amount seniors  
11 spend on prescription drugs has fallen 54 percent--that  
12 is astounding--since the enactment of Medicare Part D.  
13 This year, the average beneficiary premium is about \$24  
14 per month, which is 40 percent less than the estimated  
15 last year.

16 Why did I repeat all of that? It just seems to me,  
17 again, I am going to repeat what everybody has said. We  
18 are debating a bill that proposes a solution in search of  
19 a problem.

20 Now, I am not going to ask for a recorded vote for my  
21 "slipping on a banana peel" amendment, but I hope my  
22 colleagues will support my amendment by a resounding aye  
23 to simply restore the non-interference language.

24 Now, I know the argument against this, and I can just  
25 read your argument, then I will read my answer, and then

1 we can just go to a vote. [Laughter.]

2 You are going to state that comparing the non-  
3 interference language in the Democratic bills that I am  
4 referring to--that you wrote and voted for and sponsored--  
5 -do not compare to the non-interference language in the  
6 current law. You are going to say the drug benefit in  
7 the past bills included one negotiated per region, so it  
8 was necessary to include non-interference language.

9 Senator Rockefeller. Correct. [Laughter.]

10 Senator Roberts. Actually, it was Senator Stabenow  
11 that said that, but at any rate--and I listen to Senator  
12 Stabenow, especially about cherries on the Ag Committee.  
13 But all we hear now is how they want to have one  
14 negotiator now, however, for 44 million people in  
15 Medicare. So it is even more important to have the non-  
16 interference clause. Before, you had one negotiator per  
17 region so you included non-interference. Now you want  
18 one negotiator, but you want to get rid of the non-  
19 interference.

20 I do not see the logic in that. Both bills relied on  
21 the private market. Either you want the private market  
22 to work or you do not. So why does it matter if there is  
23 one plan per region or not?

24 I yield back the balance of my time and would--oh, I  
25 am sorry. Mr. Grassley wants a recorded vote? Did you

1 indicate, sir, that that would be your desire?

2 Senator Grassley. I want a recorded vote, yes.

3 Senator Roberts. Bless your heart. I am asking for  
4 a recorded vote. It would be the last one.

5 Senator Grassley. Of the 76 Members of the Senate  
6 that voted for this bill, S. 1, in 2003, eight out of ten  
7 Democratic members on this committee were of that 76 with  
8 this language in it. So I think we ought to know whether  
9 they have really changed their mind or not.

10 The Chairman. Well, I encourage Senators to kind of  
11 not get too involved here. We are going to be talking  
12 about this for a long time. But go ahead, Senator.

13 Senator Rockefeller. Just one point to add. It was  
14 not at that time one PBM per region, as the Senator from  
15 Kansas indicates, but it was one PBM for the entire  
16 country.

17 The Chairman. A recorded vote has been requested.  
18 All those in favor vote aye and those opposed no.

19 The Clerk. Mr. Rockefeller?

20 Senator Rockefeller. No.

21 The Clerk. Mr. Rockefeller, no. Mr. Conrad?

22 Senator Conrad. No.

23 The Clerk. Mr. Conrad, no. Mr. Bingaman?

24 The Chairman. No, by proxy.

25 The Clerk. Mr. Bingaman, no, by proxy. Mr. Kerry?

1 Senator Kerry. No.

2 The Clerk. Mr. Kerry, no. Mrs. Lincoln?

3 Senator Lincoln. No.

4 The Clerk. Mrs. Lincoln, no. Mr. Wyden?

5 Senator Wyden. No.

6 The Clerk. Mr. Wyden, no. Mr. Schumer?

7 Senator Schumer. No.

8 The Clerk. Mr. Schumer, no. Ms. Stabenow?

9 Senator Stabenow. No.

10 The Clerk. Ms. Stabenow, no. Ms. Cantwell?

11 Senator Cantwell. No.

12 The Clerk. Ms. Cantwell, no. Mr. Salazar?

13 Senator Salazar. No.

14 The Clerk. Mr. Salazar, no. Mr. Grassley?

15 Senator Grassley. Aye.

16 The Clerk. Mr. Grassley, aye. Mr. Hatch?

17 Senator Hatch. Aye.

18 The Clerk. Mr. Hatch, aye. Mr. Lott?

19 Senator Grassley. Aye, by proxy.

20 The Clerk. Mr. Lott, aye, by proxy. Ms. Snowe?

21 Senator Snowe. No.

22 The Clerk. Ms. Snowe, no. Mr. Kyl?

23 Senator Kyl. Aye.

24 The Clerk. Mr. Kyl, aye. Mr. Thomas?

25 Senator Grassley. Aye, by proxy.

1 The Clerk. Mr. Thomas, aye, by proxy. Mr. Smith?  
2 Senator Smith. No.  
3 The Clerk. Mr. Smith, no. Mr. Bunning?  
4 Senator Grassley. Aye, by proxy.  
5 The Clerk. Mr. Bunning, aye, by proxy. Mr. Crapo?  
6 Senator Crapo. Aye.  
7 The Clerk. Mr. Crapo, aye. Mr. Roberts?  
8 Senator Roberts. Aye.  
9 The Clerk. Mr. Roberts, aye. Mr. Chairman?  
10 The Chairman. No.  
11 The Clerk. The chairman votes no.  
12 Senator Grassley. Mr. Chairman?  
13 The Chairman. Do you have more?  
14 Senator Grassley. Amendment number 20, and I think  
15 that this one we require a roll call vote on, and then I  
16 will have two that we do not require a roll call vote on  
17 it.  
18 The Chairman. That is progress. You go ahead.  
19 Senator Grassley. You better announce the vote. I  
20 am sorry.  
21 The Chairman. I am sorry.  
22 The Clerk. Mr. Chairman, the tally is 8 ayes, 13  
23 nays.  
24 The Chairman. The amendment is not agreed to.  
25 Senator Grassley. Amendment number 20 gives an

1 opportunity for those who want application of the model  
2 to Medicare. Proponents of Government negotiations keep  
3 saying that this VA system is such a perfect model for  
4 Medicare. Under my amendment, all Medicare beneficiaries  
5 in four demonstration States, including those with  
6 retiree drug coverage, would have their prescription drug  
7 benefits provided under this new style of system.

8 We all know that the VA is a fine system, but it is  
9 one choice of many for veterans because they have the  
10 opportunity also to select Medicare Part D. In fact, the  
11 VA does not recommend that veterans cancel or decline  
12 coverage in Medicare because a veteran may want to  
13 consider the flexibility afforded by enrolling in VA and  
14 Medicare, both of them.

15 For example, veterans enrolled in both programs may  
16 obtain prescription drugs that are not on the VA  
17 formulary if prescribed by a non-VA physician and filled  
18 at the local pharmacies. Under the VA's system, there is  
19 no choice of plans, formularies, hospitals, physicians,  
20 and pharmacies. Personally, I do not believe that this  
21 is the right system for Medicare beneficiaries who value  
22 access and choice. Nevertheless, I am a strong supporter  
23 of States being incubators for ideas.

24 So this amendment allows some of my colleagues an  
25 opportunity to put their rhetoric into reality. This

1 amendment would test the VA model in Medicare.

2 Personally, I will not want Iowa to be used a demo  
3 because--

4 The Chairman. I was going to ask that. I was going  
5 to say, I do not see Iowa listed here. If you agreed to  
6 just a second degree-

7 Senator Grassley. No, no. [Laughter.]

8 The Chairman. This amendment looks suspiciously  
9 mischievous.

10 Senator Grassley. It is very transparently  
11 mischievous, because I think Iowans would rather continue  
12 to enjoy the lower premiums, the lower cost, and the  
13 options, primarily the options to the Medicare drug  
14 benefit as it is currently structured. Still, many have  
15 argued the Government should negotiate for lower prices  
16 through Medicare.

17 So if you want Part D to look more like the VA  
18 system, here is an opportunity to vote for demonstrations  
19 and find out whether or not it works and accomplishes  
20 what you want.

21 Senator Conrad. Mr. Chairman?

22 Senator Grassley. I would ask for a roll call vote.

23 Senator Conrad. Mr. Chairman, can I ask that we  
24 dial the temperature up another 10 degrees? [Laughter.]

25 The Chairman. I think this amendment speaks for



1     itself.

2           Senator Rockefeller. Mr. Chairman, could I suggest  
3     that we take this before the Civil Rights Commission on a  
4     State discrimination basis against at least four that I  
5     can think of, including West Virginia?

6           The Chairman. All right. A roll call has been  
7     requested. The clerk will call the roll.

8           The Clerk. Mr. Rockefeller?

9           Senator Rockefeller. No.

10          The Clerk. Mr. Rockefeller, no. Mr. Conrad?

11          Senator Conrad. No.

12          The Clerk. Mr. Conrad, no. Mr. Bingaman?

13          The Chairman. No, by proxy.

14          The Clerk. Mr. Bingaman, no, by proxy. Mr. Kerry?

15          Senator Kerry. No.

16          The Clerk. Mr. Kerry, no. Mrs. Lincoln?

17          Senator Lincoln. No.

18          The Clerk. Mrs. Lincoln, no. Mr. Wyden?

19          Senator Wyden. No.

20          The Clerk. Mr. Wyden, no. Mr. Schumer?

21          Senator Schumer. No.

22          The Clerk. Mr. Schumer, no. Ms. Stabenow?

23          Senator Stabenow. No.

24          The Clerk. Ms. Stabenow, no. Ms. Cantwell?

25          Senator Cantwell. No.

1 The Clerk. Ms. Cantwell, no. Mr. Salazar?  
2 Senator Salazar. No.  
3 The Clerk. Mr. Salazar, no. Mr. Grassley?  
4 Senator Grassley. Aye.  
5 The Clerk. Mr. Grassley, aye. Mr. Hatch?  
6 Senator Hatch. Aye.  
7 The Clerk. Mr. Hatch, aye. Mr. Lott?  
8 Senator Grassley. Aye, by proxy.  
9 The Clerk. Mr. Lott, aye, by proxy. Ms. Snowe?  
10 Senator Snowe. No.  
11 The Clerk. Ms. Snowe, no. Mr. Kyl?  
12 Senator Kyl. Aye.  
13 The Clerk. Mr. Kyl, aye. Mr. Thomas?  
14 Senator Grassley. Aye, by proxy.  
15 The Clerk. Mr. Thomas, aye, by proxy. Mr. Smith?  
16 Senator Smith. No.  
17 The Clerk. Mr. Smith, no. Mr. Bunning?  
18 Senator Grassley. No, by proxy.  
19 The Clerk. Mr. Bunning, no, by proxy. Mr. Crapo?  
20 Senator Crapo. Aye.  
21 The Clerk. Mr. Crapo, aye. Mr. Roberts?  
22 Senator Roberts. Aye.  
23 The Clerk. Mr. Roberts, aye. Mr. Chairman?  
24 The Chairman. No.  
25 The Clerk. The chairman votes no.

1 Mr. Chairman, the tally is 7 ayes, 14 nays.

2 The Chairman. Picked up. All right. The amendment  
3 is not agreed to.

4 Senator Grassley?

5 Senator Grassley. Amendment number 3, which I am  
6 going to offer and withdraw, this amendment will apply  
7 the Government negotiation model in the chairman's mark  
8 to the Medicaid program. The mark proposes to have the  
9 Secretary negotiate for Medicare drugs. This amendment  
10 would give the same authority to Governors for Medicaid.  
11 This is a very straightforward amendment. If the  
12 Government negotiation is good enough for Medicare, then  
13 it should be good enough for Medicaid.

14 Under current law, States have access to something  
15 called "the best price rebate." By law they get a  
16 mandatory rebate from the manufacturers that is intended  
17 to guaranteeing Medicaid the best price in the  
18 marketplace. Of course, this is price control. It has  
19 led to unfortunate unintended consequences. The drug  
20 rebate program caused VA prices to go up until the law  
21 was changed a year later. We ought to remember that.  
22 The drug rebate caused the best discounts in the  
23 marketplace to disappear. That meant higher prices for  
24 small business and individuals with private health  
25 coverage.

1 I have heard over and over again from the proponents  
2 of this legislation that they do not want price controls;  
3 they want Government negotiation. So we should give  
4 States access to Government negotiation for Medicaid just  
5 like what is proposed today for Medicare. So my  
6 amendment repeals the best price rebate.

7 In place of the rebate program, this amendment would  
8 give Governors the authority to negotiate on behalf of  
9 State Medicaid programs. To be clear, this amendment  
10 gives the Governors the same authority that the Secretary  
11 would have under the chairman's mark. Consistent with  
12 the plan put forward in the chairman's mark for Medicare,  
13 a Governor could not require any particular formulary  
14 under this amendment. If the Secretary cannot, neither  
15 should the Governor. Under this amendment, a Governor  
16 cannot institute a preferred drug list. If the Secretary  
17 cannot, then neither should the Governor. A Governor  
18 cannot institute a price structure for the reimbursement  
19 of covered drugs or any other similar restrictions. If a  
20 Secretary cannot, then neither should a Governor.

21 You may be tempted to argue that what this amendment  
22 proposes is impractical. You might argue it will not  
23 work. But it would give the Governors the same authority  
24 that the Secretary would have to negotiate under the  
25 bill.

1           Mr. Chairman, this debate is about making change in  
2 Medicare benefits that is working. Part D is working  
3 better than we expected. It is working better at holding  
4 down costs than anybody ever believed that it would. It  
5 is working because we use private plans with the  
6 experience and know-how to get better prices for seniors.  
7 It keeps the Government out of the business of  
8 interfering with those negotiations because we know that  
9 the Government is going to get it wrong. The Government  
10 has a terrible track record when it comes to drug  
11 pricing. It was the right discussion and it is working.

12           I told you, Mr. Chairman, privately that I was not  
13 going to ask for a vote on this, but I think that what we  
14 lay out here, if it is such a good idea, we ought to  
15 apply it across the board.

16           The Chairman. If there is no further debate, you  
17 are going to--

18           Senator Grassley. I will withdraw the amendment.

19           The Chairman. The amendment is withdrawn.

20           Any further amendments?

21           Senator Grassley. I would offer amendment number  
22 17. Just before our recess, the Senate approved a  
23 supplemental appropriation bill that included an  
24 amendment that was in our jurisdiction, so I am talking  
25 about this committee's jurisdiction, by the supplemental

1 appropriation bill the Appropriations Committee usurping  
2 jurisdiction of this committee.

3 The amendment, sponsored by Senator Durbin, seeks to  
4 put a 2-year hold on the CMS rule that would limit  
5 Medicaid providers to cost. As a committee, we should  
6 have objected strongly and loudly. The Durbin amendment  
7 is a perfect example of why authorizing an appropriation  
8 bill is discouraged. Why? Because the Durbin amendment  
9 broadly prevents CMS from taking any action related to  
10 this rule or any rule that would affect Medicaid or SCHIP  
11 in a similar manner. Because of the way the Durbin  
12 amendment is written, States could return to financing  
13 schemes when they use Medicaid funds for pork barrel  
14 projects like building stadiums.

15 Mr. Chairman, it is one thing to complain about a CMS  
16 rule. It is another thing entirely to overturn 16 years  
17 of congressional action with this amendment. And let me  
18 talk for a moment about the rule in question. The core  
19 goal of the rule is to limit provider reimbursement to  
20 actual cost. Congress and CMS have spent the last 15  
21 years combating that sort of misbehavior by States. It  
22 makes no sense for Congress to roll back the clock and  
23 allow those crazy practices to come back. If some people  
24 think CMS has gone too far, then we should review their  
25 actions in the Finance Committee. We should call CMS in,

1 make them testify. We should ask tough questions. If we  
2 think there are things that should be done differently,  
3 then we should legislate.

4 So this amendment strikes a balance. It prevents CMS  
5 from implementing the rule for the additional 6 months.  
6 The rule would not be allowed to go into effect until  
7 March 1, 2008. It requires the actual committee of  
8 jurisdiction--that is this committee--to consider this  
9 incredibly complex issue by holding a hearing or even a  
10 number of hearings. It gives us time to take appropriate  
11 action.

12 I am not going to ask for a vote on this amendment,  
13 but I sincerely hope that we can reclaim our committee's  
14 jurisdiction and deal with this in our committee instead  
15 of letting the Appropriations Committee do our work  
16 through truly awful legislation.

17 I withdraw the amendment.

18 Senator Conrad. Mr. Chairman?

19 The Chairman. It is withdrawn. Yes?

20 Senator Conrad. Might I just on this, very briefly,  
21 comment? I agree with Senator Grassley on this. I think  
22 this is an area that should be in the jurisdiction of  
23 this committee, and this is an area where CMS has tried  
24 to prevent what are really abusive practices. We have  
25 seen this in other areas as well where certain States

1 were, in effect, overbilling. Their hospitals would  
2 overbill, and then they would give a kickback to a State.  
3 We have seen that same kind of practice in this area.

4 And so I think Senator Grassley is exactly right on  
5 this issue. This should be in the jurisdiction of this  
6 committee.

7 The Chairman. Clearly, it should. In fact, I was a  
8 little disturbed when I saw Senator Durbin offer that  
9 amendment. It very much should have been the committee.  
10 He did not discuss that with me in advance. We have got  
11 to find a way in this committee to deal with that. Now,  
12 depending what happens with the supplemental, we will  
13 certainly work with him on this issue. But in the  
14 future, I want to make sure that issues like this are  
15 properly before this committee.

16 Senator Grassley. Could I say something? Mr.  
17 Chairman, before we vote, I am sorry we disagree on this  
18 issue, but I think that I can speak for all the members  
19 on my side of the aisle, except for the late hour that  
20 this meeting was called--and I know that is the way  
21 sometimes things work out. And I know the tremendous  
22 pressure that you had to get this done this week. But I  
23 think that I can say for all of us on our side of the  
24 aisle--and I think I can even speak for Senator Smith and  
25 Senator Snowe, even though they are not on my side on



1 this--that you handled this very fairly, and particularly  
2 in the number of amendments that we were able to offer.  
3 And I think it is in the spirit of what I see you trying  
4 to do as a leader, and it gave us the privilege that I  
5 hope I gave you when you were in the minority.

6 The Chairman. Well, thank you very much, Senator.  
7 Spoken very graciously, as is always your case.

8 I also want to thank all the Senators for attending.  
9 It was not clear earlier in the day, even yesterday,  
10 whether we would have such great attendance here on both  
11 sides. I thank everyone. We are the Finance Committee,  
12 and we are very proud to be the Finance Committee, and I  
13 think we generally do a pretty good job in working out  
14 legislation.

15 Senator Kyl. Mr. Chairman, is that the proud, the  
16 few, and the hot? [Laughter.]

17 The Chairman. As I sometimes say, all truth is good  
18 to know, but not all truth is good to say.

19 Senator Grassley. I would like to have a roll call  
20 vote.

21 The Chairman. Yes. If there are no further  
22 amendments, I move that the committee report S. 3, the  
23 Medicare Prescription Drug Price Negotiation Act of 2007  
24 with the committee substitute as modified. A roll call  
25 has been requested, and the clerk will call the roll.

1 The Clerk. Mr. Rockefeller?  
2 Senator Rockefeller. Aye.  
3 The Clerk. Mr. Rockefeller, aye. Mr. Conrad?  
4 Senator Conrad. Aye.  
5 The Clerk. Mr. Conrad, aye. Mr. Bingaman?  
6 The Chairman. Aye, by proxy.  
7 The Clerk. Mr. Bingaman, aye, by proxy. Mr. Kerry?  
8 Senator Kerry. Aye.  
9 The Clerk. Mr. Kerry, aye. Mrs. Lincoln?  
10 Senator Lincoln. Aye.  
11 The Clerk. Mrs. Lincoln, aye. Mr. Wyden?  
12 Senator Wyden. Aye.  
13 The Clerk. Mr. Wyden, aye. Mr. Schumer?  
14 Senator Schumer. Aye.  
15 The Clerk. Mr. Schumer, aye. Ms. Stabenow?  
16 Senator Stabenow. Aye.  
17 The Clerk. Ms. Stabenow, aye. Ms. Cantwell?  
18 Senator Cantwell. Aye.  
19 The Clerk. Ms. Cantwell, aye. Mr. Salazar?  
20 Senator Salazar. Aye.  
21 The Clerk. Mr. Salazar, no. Mr. Grassley?  
22 Senator Grassley. No.  
23 The Clerk. Mr. Grassley, no. Mr. Hatch?  
24 Senator Hatch. No.  
25 The Clerk. Mr. Hatch, no. Mr. Lott?

1 Senator Grassley. No, by proxy.

2 The Clerk. Mr. Lott, no, by proxy. Ms. Snowe?

3 Senator Snowe. Aye.

4 The Clerk. Ms. Snowe, aye. Mr. Kyl?

5 Senator Kyl. No.

6 The Clerk. Mr. Kyl, no. Mr. Thomas?

7 Senator Grassley. No, by proxy.

8 The Clerk. Mr. Thomas, no, by proxy. Mr. Smith?

9 Senator Smith. Aye.

10 The Clerk. Mr. Smith, aye. Mr. Bunning?

11 Senator Grassley. No, by proxy.

12 The Clerk. Mr. Bunning, no, by proxy. Mr. Crapo?

13 Senator Crapo. No.

14 The Clerk. Mr. Crapo, no. Mr. Roberts?

15 Senator Roberts. No.

16 The Clerk. Mr. Roberts, no. Mr. Chairman?

17 The Chairman. Aye.

18 The Clerk. The chairman votes aye.

19 Mr. Chairman, the tally of members present is 12

20 ayes, 5 nays. The final tally, including proxies, is 13

21 ayes, 8 nays.

22 The Chairman. Thank you. The ayes have it. The

23 bill is reported, the committee substitute.

24 I also ask consent that the staff have the authority

25 to make technical and conforming changes. Any objection?

1 [No response.]

2 The Chairman. Without objection, so ordered.

3 Once again, I thank all Senators. I am very proud of  
4 everybody here tonight. Thank you. The committee is  
5 adjourned.

6 [Whereupon, at 9:43 p.m., the committee was  
7 adjourned.]

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**UNITED STATES SENATE  
COMMITTEE ON FINANCE**

**Max Baucus, Chairman**

Thursday, April 12, 2007

219 Dirksen Senate Office Building

**Agenda for Business Meeting**

A substitute to S. 3, the Medicare Prescription Drug Price  
Negotiation Act of 2007

**CHAIRMAN'S MARK  
AMENDMENT TO S. 3 – MEDICARE PRESCRIPTION DRUG PRICE  
NEGOTIATION ACT OF 2007**

**Section 1. Short title.**

*Current Law*

No Provision

*Explanation of Mark*

This bill may be cited as the “Medicare Fair Prescription Drug Price Act of 2007.”

**Section 2. Repeal of Prohibition.**

*Current Law*

Section 1860D-11(i) of the Social Security Act prohibits the Secretary of Health and Human Services (HHS) from interfering with the negotiations between drug manufacturers and pharmacies and prescription drug plan (PDP) sponsors. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 108-173) conference report (108-391) adds that conferees expect PDPs to negotiate price concessions directly with manufacturers. Section 1860D-11(ii) of the Social Security Act prohibits the Secretary of HHS from requiring a particular formulary to institute a price structure for the reimbursement of covered Part D drugs.

*Explanation of Mark*

The Chairman’s Mark would repeal Section 1860D-11(i), thus the Secretary would no longer be prohibited from interfering with the negotiations between drug manufacturers and pharmacies and prescription drug plan (PDP) sponsors. Section 1860D-11(ii) would remain intact, and the Secretary would still be prohibited from requiring a particular formulary to institute a price structure for the reimbursement of covered Part D drugs. Nothing in this Mark does any of the following: (1) prevents a PDP or Medicare Advantage Prescription Drug Plan (MA-PD) from obtaining a discount or reduction in price for a covered Part D drug; (2) affects the Secretary’s authority to ensure appropriate and adequate access to covered Part D drugs under PDPs and MA-PDs, including compliance with existing formulary requirements; or (3) limits access by individuals enrolled in PDPs and MA-PDs to community pharmacies.

The Mark would require the Secretary to submit an annual report on activities conducted to promote and ensure access to fair prices for Part D prescription drugs.

The amendments would take effect on the date of the enactment of the Act.

### **Section 3. Greater Transparency of Part D Prices and Information**

#### *Current Law*

The use and disclosure of most of the information collected by the Centers for Medicare and Medicaid Services (CMS) about PDPs and MA-PDs is restricted by section 1860D–15(f)(2) of the Social Security Act which states, “Information disclosed or obtained pursuant to the provisions of this section may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section.” The section referred to by this statement addresses payment issues under Medicare Part D including the overall subsidy to plans, reinsurance, risk adjustment, risk corridors and other topics.

The law does not currently allow any other parties, including Congressional support agencies or other researchers, to have access to the data. CMS’s interpretation of this statute is that it limits the ability of the agency to use the information for purposes other than those stated in the preceding paragraph, including “for research, internal analysis, oversight, and public health purposes... evaluating the new prescription drug benefit, including its effectiveness and impact on health outcomes, performing Congressionally mandated or other demonstration projects and studies, reporting to Congress and the public regarding expenditures and other statistics involving the new Medicare prescription drug benefit, studying and reporting on the Medicare program as a whole, and creating a research resource for the evaluation of utilization and outcomes associated with the use of prescription drugs.” As a result of this perceived restriction on its use of the data, CMS has issued a proposed rule clarifying the ability of the Secretary to collect the same information under a different authority (section 1857(e)(1) as incorporated into Part D through section 1860D–12(b)(3)(D)), thus allowing the agency to use the data for the purposes described in this paragraph. To date, no final rule has been issued. [Federal Register / Vol. 71, No. 201 / Wednesday, October 18, 2006 / Proposed Rules 61445-61455.]

Some of the information is currently available to the public. For example, the prices of individual drugs covered by each plan can be obtained from CMS web sites if identified individually and entered on web page forms in the process of researching and comparing plans. However, CMS has not made the entire data set of prescription drug prices by plan available to outside parties such as private researchers.

### *Explanation of Mark*

Data collected by the Secretary on PDP and MA-PD plans would be made available to Congressional support agencies to fulfill their duties. The Congressional support agencies are the Congressional Budget Office (CBO), the Congressional Research Service (CRS), the Government Accountability Office (GAO), and the Medicare Payment Advisory Commission (MedPAC).

Upon request, the Secretary would make available to any of the Congressional support agencies the following Part D data: (1) aggregate information on negotiated price concessions, (2) drug claims data, (3) the amount of reinsurance payments paid to plans, and (4) the amount of adjustments of payments to plans as a result of the risk corridors established under MMA. In addition, CBO would be able to obtain non-aggregated data on negotiated rebates, discounts, and other price concessions by drug and by contract or plan in order to permit analyses at the PDP or MA-PD level.

In the course of performing its activities, each of the Congressional support agencies would be prohibited from disclosing the information where such disclosure by the Secretary would be prohibited under applicable Federal law, where such disclosure would result in the disclosure of trade secrets, and where the disclosure, report, or release of the information by the agency would permit the identification of a specific prescription drug plan, MA-PD plan, pharmacy benefit manager, drug manufacturer, drug wholesaler, drug, or individual enrolled in a prescription drug plan or an MA-PD plan.

The Congressional support agencies would be required to adopt and maintain reasonable safeguards to protect against the unauthorized disclosure of data. The Congressional support agencies would be able to disclose the data to another agency or entity only if the agency or entity were under a subcontract with the Congressional support agency to support any analysis conducted by the Congressional support agency and if the subcontractor were subject to the same data disclosure provisions and safeguards as the Congressional support agency. Data provided under this provision would be exempt from disclosure under the Freedom of Information Act.

The CBO would be required to study the effect of market competition on prices for part D drugs. The study would examine the number and extent of discounts and other price concessions received by PDP and MA-PD plans, the relationship between all price concessions and drug utilization, the extent to which the efforts made by the Secretary, as allowed under the Mark, would have an effect upon payers in non-Medicare markets. A report on this study would be due a year after enactment. The Mark also requires CBO to compare discounts and price concessions under Part with those obtained under the Medicaid program.

GAO and MedPAC would also report to Congress on the limitations of the Part D data, made available by the Mark, in evaluating the drug prices under the Medicare Part D program. These reports would be due no later than 180 days after the date of enactment.



The Secretary would also be required to make public the data on the actual prices charged for each covered part D drug by each PDP and MA–PD plan to individuals enrolled in the plan. The data would reflect the prices posted on the Internet website of the Centers for Medicare & Medicaid Services and would be made available in a manner that permits linkage to other data sources. This information would be provided upon request and in an electronic form determined appropriate by the Secretary for a nominal fee based on the cost of preparing and providing the data.

#### **Section 4. Prioritizing Studies of Comparative Clinical Effectiveness of Covered Part D Drugs**

##### *Current Law*

Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) instructed the Agency for Healthcare Research and Quality (AHRQ) to conduct research on outcomes of health care items and services. In order to guide this research, AHRQ developed a list of 10 health conditions that were considered to be a priority for Medicare beneficiaries.

##### *Explanation of Mark*

This Mark would instruct the Secretary of HHS to develop a new prioritized list of comparative clinical effectiveness studies, which would include the comparison of one Part D drug to any drug, biological product, item, or service covered under the Medicare program. The prioritized list would specify the items and services to be evaluated and the general methodology to be used to conduct each study. The Secretary would be required to consider all methodologies available, from systematic reviews to clinical trials.

In addition, the Secretary would be instructed to list studies deemed most critical to advancing value-based purchasing of covered Part D drugs. In doing so, the Secretary would be instructed to take into account certain factors, such as the clinical areas AHRQ has identified as having insufficient clinical evidence, the original list of priority medical conditions developed for AHRQ’s comparative effectiveness studies, clinical areas with the greatest need for information, and advice provided by a new advisory committee.

The Mark would instruct the Secretary to establish an advisory committee to provide advice on setting priorities for comparative clinical effectiveness studies across all agencies of the Department of HHS. Members of the advisory committee would include a diverse range of public and private experts, stakeholders, and interests from medical and pharmaceutical industries, patients and representatives of patients, researchers, and government. The Mark instructs the Secretary to ensure that the committee does not have a majority of members from any one of these groups. Any advice provided to the Secretary by the advisory committee would be required to be made publicly available.

Within one year of the enactment of the Act, the Secretary would be required to submit a report to Congress that would include the prioritized list of comparative clinical effectiveness studies and plans for the conduct of the studies, as well as a summary of the factors the Secretary would be required to take into account in constructing the list. The Secretary would be required to make the report publicly available.

Nothing in this Mark limits the authority of the Secretary to prioritize comparative effectiveness research needs for procedures, devices, diagnostics, or other medical interventions. This Mark also does not limit the authority of the Secretary to conduct any study determined appropriate by the Secretary.

The provision authorizes the appropriation of funds necessary to carry out this section.

#### **Section 5. Authorizing consideration of comparative clinical effectiveness studies in developing and reviewing formularies under the Medicare prescription drug program**

##### *Current Law*

A formulary is a list of preferred drugs for which a Part D drug plan, or other health insurer, has stipulated that it will pay a portion of the costs. A formulary may also specify contingencies for payment. Medicare prescription drug plan sponsors' formularies must be constructed by a pharmacy and therapeutic (P&T) committee, composed of practicing physicians or practicing pharmacists.

Current law provides some guidance for P&T committees on constructing Part D formularies. Medicare Part D drug plans are required to include two drugs in each therapeutic class, except if only one drug is available. The CMS requires coverage of "all or substantially all" drugs for some mental illnesses, including antidepressants, antipsychotics, and anticonvulsants. Anticancer drugs, immunosuppressants, and HIV/AIDS drugs are also included in the "all or substantially all" list of formulary drug classes. Plans can neither change their formularies without CMS approval, nor drop coverage for persons currently using the drug, except at the beginning of the calendar year.

In deciding which drugs in a therapeutic class should be included or excluded in a formulary, a plan's P&T committee is required to base their clinical decisions on the peer-reviewed medical literature (including randomized clinical trials, pharmaco-economic studies, outcomes research data, and other information the committee deems appropriate) and the relative safety and efficacy of drugs.

*Explanation of Mark*

In deciding which drugs in a therapeutic class should be included or excluded from a formulary, the provision would instruct P&T committees to take relevant comparative clinical effectiveness studies into account. The comparative clinical effectiveness studies are to be taken into account in conjunction with the other information already required to be considered, under current law – the peer-reviewed medical literature and the relative safety and efficacy of drugs.

The Mark would leave the other formulary requirements for Part D plans intact.

**MODIFICATION TO CHAIRMAN'S MARK  
AMENDMENT TO S. 3 – MEDICARE PRESCRIPTION DRUG PRICE  
NEGOTIATION ACT OF 2007**

**The Chairman announces the following changes to the mark:**

- 1. Permit the sharing of Medicare part D claims data with States.**
- 2. Require disclosure to Medicare beneficiaries of information about drug costs at point-of-sale.**
- 3. Express the sense of the Senate on the need to revisit the asset test for determination of eligibility for the low-income subsidy.**
- 4. Express the sense of the Senate on the need to address pharmacy issues under the Medicare prescription drug benefit.**
- 5. Prohibit the Secretary from entering into a contract with an outside entity or an Inter-Department Agreement for the purposes of conducting government negotiation for prescription drug prices under part D.**

**Statement of Senator Craig Thomas**  
**Senate Finance Committee Markup of**  
**S.3, the "Medicare Prescription Drug Price Negotiation Act"**  
**Thursday, April 12, 2007**

Today, the Finance Committee is going to mark-up legislation that would remove the non-interference provision included in the 2003 Medicare law. Folks on the other side of the aisle have made a lot of political hay about this so-called "prohibition". However, this rhetoric fails to stand up to the facts.

We all well know that the 2003 law – that both Republicans and Democrats supported – does not prohibit Medicare from negotiating. It simply prevents government bureaucrats from interfering in the negotiations already happening.

Sometimes it helps for people to take a walk down memory lane. I think some folks have forgotten that the provision that is causing so much heartache for Democrats in 2007 was included in the Daschle-Kennedy-Rockefeller and the Gephardt-Dingell-Stark Medicare drug reform bills introduced in 2000. They created the non-interference concept. At that time they believed their idea – which was incorporated into the Medicare Modernization Act (MMA) – was a fine approach. But now they say it prevents Medicare from negotiating?

The fact is that Congress incorporated this bipartisan provision to make sure negotiated Medicare savings resulted from market competition, rather than price fixing. And it is working! Negotiations take place between Medicare prescription drug plans which have years of experience in this area and the drug makers. Competition among plans has lowered costs for the taxpayers and beneficiaries. It has led to lower drug prices. Yet, here we are, with the Finance Committee set to consider legislation that would fundamentally change the Part D benefit – even though it has only been operational for one full year. I have to ask why? Why would Congress "reform" a provision of current law that is clearly working well when there are other areas in Medicare that do need improvement?

The other question is why is this issue important? Why should folks care? The answer is simple. Putting price controls in place will restrict seniors' access to drugs – especially new and innovative drugs. Also, I think it is reasonable to assume costs will be shifted to employer sponsored coverage and working Americans.

We need to understand the consequences of our actions should S. 3 pass the Committee and be referred to the Senate floor for a vote. The Secretary of Health and Human Services told us earlier this week that he does not want this authority. Secretary Leavitt said Part D private plans are negotiating significant savings right now. The Centers for Medicare and Medicaid Services' (CMS) Chief Actuary said the Secretary would be unlikely to achieve deeper discounts than the private Medicare drug plans responding to competitive market forces. Finally, and this is important: even the expert person the

Democratic Majority put in place to head up the Congressional Budget Office (CBO) concluded that striking the non-interference clause would not result in savings or lower drug prices.

In order to achieve even a little bit of savings, several things would have to occur: 1) the government decides which drugs seniors can have, putting government officials between seniors and their doctors; and 2) access to the newest drugs are restricted, putting the lives of million of seniors at risk. It sounds to me like we are moving backwards in our efforts to ensure seniors and the disabled have a wide array of choices and better access to prescription drugs.

Seniors in my state have been calling in to tell me they like their Medicare drug benefit, and they don't want Congress to change it. Why would we want to revert back to a one size fits all approach? Clearly, government price fixing is not the answer. The Medicare law has proven to get seniors the best deal through market competition. I think the Washington Post – not exactly known to be a right wing newspaper – said it best in a November 2, 2006 editorial, *An Election on Drugs*, “A switch to government purchasing of Medicare drugs would choke off this experiment before it had a chance to play out, and it would usher in its own problems. For the moment, the Democrats would do better to invest their health care energy elsewhere.” I couldn't agree more.

## **STATEMENT OF U.S. SENATOR GORDON H. SMITH**

### **“The Medicare Fair Prescription Drug Price Act of 2007”**

**April 12, 2007**

- I want to thank Chairman Baucus for his steady approach to this issue. Helping our seniors obtain more affordable drug prices is something we'd all like to do, most of us simply have varying ideas about how best to do it.
- As is often the case with making policy, sometimes we fail to fully consider the possible consequences our decisions have.
- I am glad the Committee did not rush to pass a bill in the early days of this Congress. I believe we have all benefited from taking a few months to really understand how Medicare Part D purchases drugs now and how costs and access might be affected if we change that system.
- I have supported the concept of Medicare drug price negotiation in the past, but I have always been uncertain as to how such a policy might impact beneficiary access to vital drug therapies as well as innovation in the pharmaceutical industry.
- I approached this markup with some sense of hesitation. I do believe the current system is working for seniors. Over 39 million Medicare beneficiaries are now enrolled in Medicare Part D and many of them are receiving drug coverage for the very first time.
- I also believe that prescription drug plans already negotiate for the drugs they purchase and they generally do a good job. That is reflected at the number of plans that require little to no monthly premium. Plans wouldn't be able to do that if they weren't achieving good prices for their drug purchases on the market.
- However, if there is the possibility that Medicare Part D could achieve additional savings on prescription drugs, then I think we owe it to our seniors to try and capture it.
- I believe Chairman Baucus' mark does just that. It simply repeals the existing provision that prohibits the government from negotiating drug prices on behalf of beneficiaries. It does not require it; it does not impose a heavy hand on the market. It provides a sensible resolution to this matter by allowing the Secretary to exercise his or her discretion in how best to help seniors obtain more affordable drug prices.
- I also appreciate the commitment made to expanding comparative effectiveness research. The Oregon Health Sciences University has done groundbreaking work in this area and I am glad that Medicare's prescription drug plans will be relying more upon that type of evidence in designing their formularies.
- For these reasons, and for the thoughtful approach this Committee has given this issue, I am supporting the Chairman's mark today.

- I would like to make one point in closing. While it is not entirely certain how government price negotiation will impact beneficiary access to critical medications, I have seen enough evidence to suggest that there may be problems down the road.
- That is why I am offering an amendment that would codify the current “all or substantially all” policy that ensures that drug plans provide access to medications in the six protected classes.
- Millions of beneficiaries living with mental illness, HIV/AIDS and cancer rely on the innovative drug treatments in these classes. I believe we need to make the regulatory protection they currently enjoy permanent in law. That way, in the future, if there is ever any issue with limiting formulary choice, we will know beneficiaries will continue to have access to these vital, life-saving drug therapies.
- I hope Chairman Baucus will agree to work with me on developing this policy to include on the floor or in another vehicle that may move later this year.