

1 OPEN EXECUTIVE SESSION TO CONSIDER AN ORIGINAL BILL
2 ENTITLED "THE PRESCRIPTION DRUG PRICING REDUCTION ACT OF
3 2019"
4 THURSDAY, JULY 25, 2019
5 U.S. Senate,
6 Committee on Finance,
7 Washington, DC.

8 The meeting was convened, pursuant to notice, at
9 9:34 a.m., in room 215, Dirksen Senate Office Building,
10 Hon. Chuck Grassley (chairman of the committee)
11 presiding.

12 Present: Senators Crapo, Roberts, Enzi, Cornyn,
13 Thune, Burr, Portman, Toomey, Scott, Cassidy, Lankford,
14 Daines, Young, Wyden, Stabenow, Cantwell, Menendez,
15 Carper, Cardin, Brown, Bennet, Casey, Warner, Whitehouse,
16 Hassan, and Cortez Masto.

17 Also present: Republican staff: Stuart Portman,
18 Health Policy Staff; and Brett Baker, Health Policy
19 Staff. Democratic staff: Anne Dwyer, Health Policy
20 Staff; and Sean Bishop, Health Policy Staff.
21 Nondesignated staff: Athena Schritz, Hearing Clerk; and
22 Joshua LeVasseur, Chief Clerk and Historian. Witnesses:
23 Phillip Swagel, Director, CBO; Chad Chirico, Chief, Low
24 Income Health Programs and Prescription Drugs Cost
25 Estimates Unit, CBO; and Leo Lex, Deputy Director for
26 Budget Analysis, CBO.
27

1 OPENING STATEMENT OF HON. CHUCK GRASSLEY, A U.S. SENATOR
2 FROM IOWA, CHAIRMAN, COMMITTEE ON FINANCE

3

4 The Chairman. Our meeting will come to order.

5 I want to thank our staff for working so hard, as
6 they have over the last two or three weeks to put things
7 together so we are where we are now.

8 I am going to give my opening statement, and then
9 Senator Wyden is going to give his opening statement, and
10 then I will give some agenda items, and we will have then
11 opening statements from Members. And I think we will do
12 it the same way we do opening statements -- will do it by
13 people as they are coming here in order of attendance.

14 In 2003, when we first passed the Medicare
15 Modernization Act, I was Chairman of the committee and
16 had a big part in putting that program together, and it
17 is one of the things that I am proud of. At that time
18 our goal was to make the first improvements in the
19 Medicare program in nearly 40 years. We wanted to give
20 seniors an affordable option that worked like the health
21 insurance they had in places from where they retired. We
22 wanted to make sure that legislation benefited all
23 seniors, and we put into place a mechanism to keep the
24 price of drugs down.

25 Part D, private insurers negotiate with drug

1 manufacturers to get the best price on drugs so the
2 premiums stay affordable. That has worked well.
3 Premiums in the Part D program have been remarkably
4 stable since the program's inception despite claims from
5 naysayers at that time that premiums would skyrocket.

6 So we should keep what is working and fix what we
7 can improve. In the 15 years since the last major reform
8 of Medicare, we have seen the development of innovative
9 medicines to treat arthritis, cancer, and I will just
10 simply say countless other disorders rather than making a
11 long list. These treatments have been life-saving or
12 life-changing for millions of Americans.

13 But of course they have come with increased cost.
14 This includes increased out-of-pocket costs for
15 beneficiaries, increase taxpayers spending. Now all of
16 us on this committee have heard from our constituents
17 about the high cost of prescription drugs, or we probably
18 would not be here dealing with this legislation. And I
19 am sure the President heard it because 13 months ago he
20 made a commitment to lower the cost of drugs

21 I have heard from Iowans who have left prescriptions
22 at the pharmacy counter or have skipped doses of their
23 medicine to save money. You will all remember in our
24 first hearing that we held this year we heard from a
25 mother whose son reduced his insulin use because he was

1 concerned about the financial burden placed on his family
2 by the cost. You even heard of a person dying as a
3 result of that.

4 So going back to the beginning of this year, not
5 only with what I anticipated doing in this committee,
6 and at that time I met with Ranking Member Wyden on this
7 issue, we both met with Senator Alexander and Senator
8 Murray of the other committee that deals with health
9 issues. We wanted to head in the direction that Senator
10 Alexander's committee proved two weeks ago, where they
11 wanted to go and they had a successful product out of
12 their committee. I hope today we are still headed in
13 that direction and we can have a successful product out
14 of this committee so we can have joint efforts on the
15 floor of the House to accomplish the goals that we sought
16 way back in January.

17 So getting back to the beginning of this year, I
18 said that addressing high drug prices was one of my top
19 priorities. I also said that any effort to tackle such a
20 problem needed to be bipartisan, go through regular
21 order, and be marked up before the August work period.
22 And let me emphasize that bipartisan approach, because
23 everybody whether you are a new member of the senator or
24 an older member of the Senate, you know nothing gets done
25 in this body unless it is bipartisan.

1 So I want to thank the Senators on this committee
2 who I have worked with to craft this bipartisan bill.
3 We have a bill before us that addresses high and rising
4 prescription drug prices, again, emphasizing in a
5 bipartisan manner. At last count, there were over two
6 dozen proposals in the legislation that are supported by
7 at least one Republican and one Democrat on the
8 committee. We have included many of our Member
9 priorities in the bill.

10 Today, we will consider legislation that will
11 improve Medicare Part D by bringing the payment system
12 up-to-date with therapies that are now available. We do
13 this by capping out-of-pocket expenses for seniors and
14 people with disabilities by permanently closing the donut
15 hole by keeping premiums from increasing and using
16 taxpayers' dollars more efficiently.

17 In Part B, we are shifting the perverse incentives
18 towards the use of less expensive but equally effective
19 medications. We also want to manage the cost to the
20 taxpayers. We want more transparency about what goes
21 into the drug price, including information from
22 manufacturers and middlemen such as pharmacy benefit
23 managers.

24 Now getting to the agency that is God around Capitol
25 Hill, CBO. And if you wonder whether CBO is God here on

1 Capitol Hill, just try to get something done when they
2 give you a figure and you got to have 60 votes to
3 override it in the United States Senate. What they say,
4 right or wrong, is very powerful.

5 This is what CBO says, "This bill will save
6 taxpayers more than \$100 billion, lower premiums, lower
7 out-of-pocket expenses for Medicare beneficiaries, and
8 provide peace of mind to millions of seniors who will
9 never have to worry about going bankrupt to pay
10 medication."

11 And I just realized something, my voice is rising.
12 I am yelling. I am not mad at anybody.

13 [Laughter.]

14 The Chairman. Now here is an added benefit --
15 Senator Wyden. You are just being Chuck Grassley.
16 Okay.

17 The Chairman. Okay.

18 Now here is an added benefit, again by the God on
19 Capitol Hill. "It will even help lower costs in the
20 commercial market."

21 Now put that all together. This should be a win for
22 all Americans. To the naysayers who claim our bill
23 contains price controls -- and this is the most vexing
24 problem that Senator Wyden and I had to deal with. He is
25 got people on his side of the aisle who is not satisfied

1 with what we are doing, and I have obviously got people
2 on my side of the aisle that is not satisfied what we are
3 doing. And I think it all boils down to this one issue.

4 But to these naysayers who claim that our bill
5 contains price controls, I want to submit for the record
6 -- and it will be included unless there is an objection -
7 - an analysis by the conservative economist Avik Roy who
8 does a good job of rebutting that argument.

9 [The document appears at the end of the transcript.]

10 The Chairman. Now my second comment is about
11 proposals to tie U.S. drug prices to international
12 prices. I have a couple of serious concerns about the
13 proposal.

14 First of all, we do not know much about what they
15 are or how they work. Secondly, I worry that one
16 unintended consequence could be the loss of innovation.

17 Now this is the moment for the Senate to act. We
18 have jurisdiction over all Medicare and Medicaid. So
19 what we do here today really matters -- really matters --
20 not only politically when you hear about this from our
21 constituents, but to all the people that are affected by
22 these programs, real people.

23 Now before we move on, I am going to ask Senator
24 Wyden if he will pay attention -- special point of
25 thanking Our Ranking Member for his cooperation. He has

1 been a good partner. That said, I want to point out
2 something that the Administration threw at us, kind of a
3 curveball, a couple of weeks ago when they did not
4 finalize a proposed rule. That rule would have ensured
5 that the savings from rebates in the Part D program would
6 be passed through to benefit seniors at the pharmacy
7 counter.

8 It happens that I believe that is a very good idea.

9 So Senator Wyden, I would like to continue to work with
10 you to get a similar policy into our legislation before
11 it becomes law. I would also like to address the unfair
12 clawback practices that affect pharmacist who are trying
13 to take care of their patients.

14 So this is my request, that in the same spirit we
15 worked on so far, I would like to ask if you would agree
16 to work with me on that issue as well.

17 Senator Wyden. Mr. Chairman, I will certainly be
18 working with you on it. And I am going to have some
19 brief remarks on this last point that you made.

20 Colleagues, it involves what is called the point-of-
21 sale rebate. And I will have some remarks with respect
22 to this after the closing of my opening statement.

23 The Chairman. Okay. Now I am just about done with
24 my opening statement, and then go to Senator Wyden.

25 I happen to feel that when 61 percent of the

1 Republicans, in a poll, say that the high cost of
2 medicine is a very important issue to them, and that 61
3 percent even want to go as far as doing away with the
4 non-interference clause. And then we hear from people of
5 all colors about this, that the only option for us to do
6 is to act now. The American people are counting on us.
7 This is the time to decide if we actually want to reduce
8 drug prices for people or just give the problem lip
9 service.

10 I will add one other thing, and that is that we all
11 know around this audience -- not only on this committee,
12 but all the Congress knows this, what a bad situation
13 Medicare Social Security is in. And we all know it takes
14 a bipartisan effort to get anything done in these areas,
15 and we all know something needs to be done. And if we
16 cannot do something just on a small part of this issue
17 with prescription drugs in a bipartisan manner, how are
18 we ever going to get the bipartisan cooperation it takes
19 to deal with the problems that we all know dealing with
20 the longevity of Medicare Social Security.

21 Senator Wyden?

22

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

3

4 Senator Wyden. Thank you, Mr. Chairman.

5 Mr. Chairman I want to begin by expressing my
6 appreciation for our bipartisan work on this issue over a
7 number of years. We blew the whistle on the hepatitis C
8 scandal, where the Sovaldi drug was costing \$1,000 a
9 pill. And this Congress we also passed an important rule
10 to in effect stop Medicaid rip-off, the Right Rebate
11 legislation. And today we have a chance, Mr. Chairman
12 and colleagues, to take another step.

13 Every single time a Senator goes home and goes to
14 the grocery, the cleaners, or town hall meeting, people
15 come up and say they are getting clobbered by the cost of
16 their prescription drugs. Today is an opportunity to do
17 something about it. The proposal before the committee is
18 a helpful step, but there will be a lot more to do.

19 In a moment, I am going to talk about some of what
20 the proposal accomplishes. First, I need to be clear
21 about what comes next in this process. This is
22 bipartisan legislation, which means that if any one of us
23 were to write it on our own, it would look very
24 different.

25 Democrats feel very strongly about giving Medicare

1 the authority to negotiate directly for lower drug
2 prices. Pharma continues to stand in the way. And they
3 have had just about the longest winning streak of any
4 special interest in Washington, D.C.

5 On healthcare more broadly, Democrats believe it is
6 long, long past time to stop the ongoing effort to
7 sabotage the Affordable Care Act and eliminate the
8 protections for pre-existing conditions. Democrats will
9 not vote to begin floor debate on the proposal until it
10 is clear that amendments on two issues: pre-existing
11 conditions and negotiating power in Medicare will get
12 votes on the Senate floor.

13 We are certainly not going to sit quietly by while
14 protections for pre-existing conditions are wiped out.
15 We are not going to sit by while opportunities for
16 seniors to use their bargaining power in Medicare are
17 frittered away.

18 Now on to the specifics of what the proposal does,
19 and these have been confirmed by the Congressional Budget
20 Office. The Proposal saves Medicare \$50 billion with a
21 price hike penalty for drug companies. It does this not
22 by setting prices, but by limiting taxpayer subsidies for
23 arbitrary price hikes. If drugmakers choose to raise
24 prices faster than inflation, they are going to have to
25 pay the difference back to Medicare.

1 Seniors with expensive prescriptions are going to
2 finally have peace of mind because this proposal caps
3 their out-of-pocket expenses in Medicare Part D. In
4 total, it is going to save seniors \$27 billion in out-of-
5 pocket costs. It will be the end of an era when drug
6 prescriptions drove seniors into bankruptcy.

7 The proposal is also going to spur the commercial
8 market to hold costs down. Any attempts by drug
9 companies to set artificially high launch prices will be
10 temporary because the market can catch up to them and the
11 price will come down. The proposal saves a total of 100
12 billion taxpayer dollars in Medicare and Medicaid.

13 Now colleagues what is most important is this is not
14 my opinion. These are the facts according to the
15 Congressional Budget Office.

16 I have already thanked the Chairman for his work. I
17 have appreciated our partnership on this issue. And
18 colleagues let me just wrap up by stating the obvious.
19 We are going to have an enormous amount of work to do on
20 this issue in the days ahead. The entire pharmaceutical
21 supply chain is a mess. It is broken. We are talking
22 about pharmaceutical companies, and we are talking about
23 middlemen. We are talking about insurers. The whole
24 thing is broken.

25 So we are going to have a lot of work to do, and we

1 ought to try to find a common ground. That is what
2 Senator Grassley is trying to do with what I characterize
3 today as a helpful step.

4 One closing comment, the pharmaceutical industry is
5 now trying to douse this proposal with a public-relations
6 tsunami. The pharmaceutical lobby is going to say pretty
7 much western civilization is going to end. It is going
8 to be the end of innovation in America. It is all about
9 price controls, the effort that we are taking is going to
10 destroy jobs, lead to drug shortages. None of that is
11 true.

12 Colleagues what this is all about is deciding who is
13 going to come first. Is it going to be patients and
14 taxpayers, or the pharmaceutical giants who have been
15 celebrating all the billions that they have gotten, and
16 some recently in the tax bill? So this proposal -- as I
17 have indicated -- is a helpful step on a vital issue.

18 And Mr. Chairman, let me just respond to your
19 colloquy, and then you are going to go to the Members
20 opening statements. Because I do believe, and I know you
21 do as well, that the whole supply chain is broken. We
22 have to figure out how to deal with this point-of-sale
23 rebate issue.

24 In 2017, I introduced legislation and a number of
25 Senators here have sponsored what is called the C-THRU

1 bill to not only pull back the curtain on the middlemen,
2 but also to make sure that patients saw the benefit of
3 all the discounts that plans and the pharmaceutical
4 benefit managers negotiate with pharma at the point-of-
5 sale, which is the pharmacy counter. I continue to
6 support a concrete benefit instead of the current system
7 where it is unclear how much pharmacy benefit managers
8 are pocketing for themselves.

9 The Trump Administration proposed something similar
10 last year, but they abandoned it not even two weeks ago
11 at the tail-end of our negotiation.

12 Mr. Chairman, you and I have discussed our mutual
13 interest in seeing what can be done here. The staff --
14 and I want to commend your staff as well as ours, and all
15 the Members who put enormous hours into this, our staffs
16 have already begun thinking about the next steps on this
17 whole issue of the point-of-sale rebate.

18 And Mr. Chairman, I think I speak for both of us
19 when I say that you and I are going to continue talking
20 to Members and look for a way to deal with this issue as
21 the process goes forward.

22 The Chairman. Thank you.

23 Before I call on Members -- and we are going to call
24 them in the order in which you arrived, like we normally
25 do.

1 Go ahead.

2 Senator Wyden. Just for unanimous consent request.

3 The Chairman. Go ahead.

4 Senator Wyden. Mr. Chairman, a couple of Members
5 would like to be added as co-sponsors to amendments. At
6 their request, I ask unanimous consent that Senator Casey
7 be added as a co-sponsor to the Cortez Masto/Hassan
8 Amendment number 7. And that Senator Hassan be added as
9 a co-sponsor to Carper Amendment 3.

10 The Chairman. Okay. Without objection they will
11 be added -- even if there is objection.

12 [Laughter.]

13 The Chairman. Now we will turn to other Members
14 for their opening statements. Because we have very much
15 to cover today, I strongly urge my colleagues to submit
16 any statements for the record, so that we can quickly
17 proceed to the mark. And that is the way Senator Hatch
18 asked you to do it when he was Chairman. So I am asking
19 people to consider doing the same thing. But for any
20 Member who wants to speak at this time, I ask that you
21 please limit your comments to no more than three minutes.

22 And the last time I chaired this committee, which
23 was 2006, we had 20 Members. So we have eight more
24 members now. So that is 24 more minutes that it will
25 normally take.

1 So I think the only fair thing for me to do is when
2 your 3 minutes are up, is to gavel and then call the next
3 person. If that irritates somebody, then tell me now.

4 Would any Member like to speak at this time? So I
5 am going to call on Senator Crapo -- the next one on the
6 list -- if he wants to speak.

7 Senator Crapo. Mr. Chairman, I will, but very
8 briefly.

9 The Chairman. Okay.

10

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

3

4 Senator Crapo. I want to commend both you and
5 Senator Wyden for working on this. There are many
6 provisions in this bill, as you have indicated, that are
7 very helpful. You also indicated that there is one
8 provision that is very difficult.

9 And I just wanted to indicate that the inflation
10 penalty in Part D is one that I have strong concerns
11 about. We worked really hard for years and years to set
12 up the system in Part D so it will be a market-oriented
13 system for pricing on drugs. And it has worked, and it
14 has worked very effectively. Over 80 percent of Medicare
15 beneficiaries are satisfied with their plan and the
16 average premium remains about \$30 a month.

17 And the provisions in this plan -- I know you have
18 indicated that you do not believe that this is undoing it
19 entirely. It is not undoing entirely what we put
20 together for Medicare Part D, but it is beginning in a
21 big way to go down that road to basically undercut the
22 non-interference provisions that we have worked so hard
23 to protect. And I am very concerned about that.

24 I think not only is this a problem in terms of the
25 impact on the market-based foundation of Part D, but it

1 is in my opinion going to result in higher prices for
2 future drugs and cost shifting to patients that is going
3 to be harmful to them.

4 So I think it is it is wrong both on policy as well
5 as on its actual impact on the goal of this legislation.
6 So because of that, I just have to raise concerns. And I
7 will be supporting Senator Toomey's amendment as he
8 brings it today to try to correct this problem.

9 The Chairman. Before you speak, just so everybody
10 understands Mr. Roy, the economist, said everybody had
11 access to -- yesterday -- if they wanted to do it, said
12 that he did not think that this would increase even
13 launch prices. And also remember that we are saying
14 nothing about the price that can be set. So you assume
15 that the company sets the price that they had in
16 developing the drug, plus a profit.

17 All were doing in this instance -- we are not
18 interfering with the price setting. We are just saying
19 how much it can be increased, and we think inflation is a
20 good guide to go by.

21 Senator Cantwell?

22

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

3

4 Thank you, Mr. Chairman. And I want to thank you
5 and the Ranking Member for your hard work on this.

6 I cannot help but thinking about the farm kid from
7 Iowa and the Gray Panther from the Pacific Northwest
8 somehow shaking their proverbial fist at big drug
9 pricing. And so this Member certainly appreciates your
10 David versus Goliath approach in working together in a
11 bipartisan fashion.

12 I also want to say that as a Member of this
13 committee for a long time, I can only remember a couple
14 of times -- maybe only once where -- we not only had a
15 CBO score that said something was going to reduce costs,
16 that there was agreement in a bipartisan fashion to what
17 CBO said. That is almost like agreeing to move the
18 Washington Monument, and agreeing where to move it to.
19 It just does not happen. And so I appreciate the fact
20 that you were able to succeed in getting the CBO score
21 saying that we are going to save the drug-purchasing
22 public money as it relates to Medicare.

23 My constituents understand when you buy in bulk, you
24 get a discount. That is the Costco model. And as a
25 Northwest company, we see that all of the time and wonder

1 why we cannot have the same kinds of access in other
2 areas. So the fact that this provision will help 43
3 million Americans and 830,000 Washingtonians with
4 Medicare Part D, and getting them a better deal than they
5 get today is a huge benefit.

6 This committee's bill takes a meaningful step toward
7 strengthening Medicare's hand in purchasing prescription
8 drugs. And as the CBO score has said, beneficiaries will
9 save \$31 billion as a result at the pharmacy counter and
10 in their premiums. So just as the product manufacturer
11 is not forced to sell to Costco under a discount, this
12 bill is basically saying if you want to sell into the
13 Medicare market, you are going to have to give us this
14 discount.

15 So while I do not think this bill is full price
16 negotiation, I certainly support giving Medicare full
17 negotiation opportunities to drive down costs, as
18 Medicare D pays 80 percent more of what the VA pays for
19 the same brand-name drugs. So if we could achieve that,
20 we would be doing something really phenomenal for the
21 individual seniors and others who are getting so hit and
22 face financial ruin just because of drug pricing.

23 I think the Ranking Member and the Chair for
24 including language in this bill about more information on
25 drug transparency pricing and worked with Senator

1 Lankford on this. I am going to continue to work on this
2 on the Commerce Committee, and also language in here to
3 get us more information about why insulin and other drug
4 shortages are causing and wreaking such havoc in the
5 market for us. We have to come up with better solutions
6 on those problems for our consumers.

7 But again, thank you to Chairman Grassley and
8 Ranking Member Wyden.

9 The Chairman. Also in addition to what she said,
10 this saves the taxpayers \$100 billion.

11 Senator Enzi?

12

1 OPENING STATEMENT OF HON. MICHAEL B. ENZI, A U.S. SENATOR
2 FROM WYOMING

3

4 Senator Enzi. Thank you, Chairman Grassley and
5 Ranking Member Wyden, for all your effort on this
6 legislative package to end the high cost of prescription
7 drugs in our country.

8 I have heard from countless folks back in Wyoming
9 about challenges they face to afford their prescription
10 drugs, and I am concerned about the toll this is taking
11 on American families and on the federal budget. I have
12 been hopeful that we can find some areas of bipartisan
13 agreement on changes to the system that can make
14 prescription drugs more affordable while ensuring that we
15 do not inhibit innovation and the development of new
16 drugs.

17 I have some concerns about the package before us
18 because it is very difficult to vote on a bill when you
19 have only seen 48 hours of the Chairman's Mark, which is
20 just concepts, not legislative language. Physicians in
21 Wyoming have urged me to slow down because patients and
22 providers need more time to understand the policies and
23 how the implementation would affect their lives.

24 I would have liked to have had the benefit of their
25 feedback, and because I agree it is critical to review

1 possible intended and unintended consequences of
2 legislation before voting. I still appreciate all the
3 hard work that is gone into the package and look forward
4 to discussing the proposal before us today.

5 I yield back time.

6 The Chairman. Thank you.

7 Now, Senator Toomey.

8 Senator Toomey. I will pass for now, Mr. Chairman.

9 The Chairman. Okay.

10 Then Senator Cardin.

11

1 OPENING STATEMENT OF HON. BENJAMIN L. CARDIN, A U.S.
2 SENATOR FROM MARYLAND

3

4 Senator Cardin. Well, thank you, Mr. Chairman. I
5 want to thank you and Senator Wyden for the manner in
6 which this bill has come forward in a bipartisan manner
7 involving the impact of the Members of this committee.

8 I just want to make an initial observation in that
9 prescription drug pricing is excessively complex by the
10 manner in which we have set up this system. And it makes
11 it difficult for us to get a handle on the high cost of
12 prescription medicines.

13 But our constituents understand that they are paying
14 too much and that we must do better. And I applaud the
15 effort that has gone into this bill because I think it
16 will make a real difference.

17 The cap on the cost of increasing drugs through the
18 rebate system will deal with the escalating cost of
19 prescription medicines. It will make a difference. The
20 cap on the Part D costs for consumers in the catastrophic
21 area will make a real difference in the lives of millions
22 of seniors.

23 So there is real progress that has been made on this
24 bill. And the transparency to patients, the real-time
25 benefit check, I think will make a real difference to

1 consumers to understand the pricing of different drugs as
2 they need it.

3 I particularly want to thank the Chairman for
4 including in the Chairman's Mark and the modification two
5 issues that I worked, one dealing with drug shortage with
6 Senator Burr that will provide for real help. The
7 provision requires the authority to use alternative
8 payments for drugs and biologics to prevent drug
9 shortages. It also requires the establishment of CMS to
10 determine when they track drugs and biologics that are
11 shortage. I think that is important. It is outrageous
12 in this country that they are a couple hundred drugs that
13 are commonly used that are in drug shortage today.

14 I also thank you for including the provision for
15 reporting fraud and abuse in Part D that I worked with
16 with Senator Cornyn.

17 This is a positive step forward. I hope during the
18 amendment process we can make additional progress. To
19 me, the most important would be to eliminate the
20 prohibition for Medicare to negotiate price. To me that
21 makes no sense at all. I thank Senator Stabenow for her
22 leadership on that. We spend over \$140 billion a year in
23 Medicare prescription drugs. We should use that market
24 force to bring down costs.

25 And lastly, I will offer an amendment to deal with

1 the appeal process under Part D where consumers are
2 denied coverage at the pharmacist. That should be the
3 initial coverage determination because that is when they
4 know they have been denied coverage. They should not
5 have to figure out how and why to go further than that to
6 make their point.

7 Again, I thank the Chairman for the work that has
8 been done, and the Ranking Member, and I look forward to
9 our amendments.

10 The Chairman. Before I call on Senator Cassidy, I
11 want to -- I hope that we follow the rule that every
12 remark has to be out 48 hours ahead of time. And I know
13 that does not sound like much time, but I hope you
14 remember -- at least on my side -- our team leader has
15 had almost every week since last winter -- weekly
16 meetings with the legislative assistance of each Member,
17 and later on, calling meetings of Legislative Directors
18 from time to time.

19 So, I hope that there has been plenty of
20 communication between my staff and the staffs of Members
21 of this committee so that you would be up to date on some
22 of the things that we were thinking about doing.

23 Senator Cassidy?

24 Senator Cassidy. If I can speak later, I will pass
25 for now.

1 The Chairman. Okay.

2 Senator Brown?

3

1 OPENING STATEMENT OF HON. SHERROD BROWN, A U.S. SENATOR
2 FROM OHIO

3

4 Senator Brown. Thank you, Mr. Chairman. I thank
5 you and Ranking Member Wyden.

6 There is some real wins in this bill for Ohio
7 patients and Ohio pharmacies. While today's mark begins
8 to address the challenge of high drug prices, it fails to
9 include a number of policies that many of us on both
10 sides of the aisle have pushed for: giving the Secretary
11 of HHS the authority to negotiate drug prices in
12 Medicare, ending taxpayer subsidies for pharmaceutical
13 advertising, penalizing drug companies who increase the
14 price of their drugs without cause in the commercial
15 market, reducing the exclusivity period for biologics
16 from 12 years to 7 years.

17 Today cannot be the end of the bipartisan
18 conversation on how to address high drug prices. We need
19 to use every tool we have to leverage the federal
20 government's purchasing power to lower prices.

21 That means legislating more. It also means
22 demanding the Administration and future administration's
23 do more. President Trump has shared three big ideas on
24 drug prices requiring the price of drugs to be included
25 in ads, IPI and the rebate rule.

1 One is stuck in court. The other has not been
2 formally proposed, and the third is dead because the
3 President himself killed it. That is not a good way to
4 show you are taking the issue seriously as the President
5 claims he has.

6 We should demand the President reinstate the rebate
7 rule. We should demand he use other tools in his
8 proposal, including in Bayh-Dole to lower drug prices
9 immediately.

10 This Authority is simple. Some call it march in
11 rights in specific situations where taxpayer dollars have
12 helped fund R&D in a product, the government can step in
13 and make the product available in situations where two
14 things: the product is not available to the public on
15 reasonable terms, and action is necessary to alleviate
16 health or safety needs which are not reasonably satisfied
17 by the contractor. HHS can use its authority to do this.

18 How can anybody argue that insulin is of "available
19 to the public on reasonable terms" when we keep reading
20 stories in the news about people who have died because
21 they cannot afford it? This march-in authority, this
22 licensing authority has existed for 40 years in federal
23 law.

24 The government has never used its authority to bring
25 relief to those struggling to afford prescription drugs

1 regardless, [underscore this] regardless how much
2 taxpayer money support of the development of the drug.
3 People have petitioned NIH a half dozen times urging the
4 agency to exercise its march-in rights to lower the cost
5 of a life-saving drug. It has refused to do it each
6 time.

7 President Trump claims that drug pricing is one of
8 his top priorities. Here is an opportunity for him to do
9 something nobody else has done, and do it for the benefit
10 of literally millions of people. I challenge President
11 Trump to end this cycle by using the authority he has --
12 the authority he has -- to lower the cost of taxpayer-
13 funded, life-saving medications and make them available
14 to the public on reasonable terms.

15 Thank you, Mr. Chairman.

16 The Chairman. I will go back up my list because
17 Senator Menendez is here. So Senator Menendez, take your
18 3 minutes.

19

1 OPENING STATEMENT OF HON. ROBERT MENENDEZ, A U.S. SENATOR
2 FROM NEW JERSEY

3

4 Senator Menendez. Thank you, Mr. Chairman and the
5 Ranking Member, for your efforts to address the high
6 prescription drug prices.

7 As I crisscrossed my state last year, I heard from
8 countless constituents who worry about being able to
9 afford their medications that in many cases do not just
10 improve their lives, but keep them alive. Many of these
11 life-changing, life-saving prescription drugs that
12 millions of Americans rely on were discovered, developed,
13 and brought to market by the ingenuity of New Jersey
14 researchers and New Jersey companies. That is right.
15 Among the 9 million New Jerseyans I am so privileged to
16 represent are hundreds of thousands of people who work at
17 the forefront of innovation in medical research and
18 clinical trials.

19 So if there is any state in the country where people
20 ought to be able to afford the medications they need, it
21 is in New Jersey, the medicine chest of the world. That
22 being said, if we are going to take billions of dollars
23 from an industry so important in my state, then it should
24 be going to patients, not to funds that patients will
25 largely never see the benefit of.

1 And quite frankly, I am frustrated to see that for
2 the most part this legislation leaves untouched the role
3 that health insurance companies and pharmacy benefit
4 managers play in this debate over costs even as they make
5 handsome sums of money at the expense of patients and
6 consumers.

7 This money must go to patients. That is why I
8 support a cap on out-of-pocket costs for seniors'
9 prescription drugs and I will continue to work to make
10 that happen.

11 I am a little frustrated, Mr. Chairman, by a late
12 CBO score. When we are making major policy decisions,
13 having had CBO's score in a timely fashion -- not on the
14 eve of a Markup -- I think is only fitting and
15 appropriate. And I would urge both you and the Ranking
16 Member to make sure that we have CBO scores in our hands
17 in a reasonable and fair time to make an analysis about
18 the effect at the end of the day on, in this case,
19 patients, but in any other context, in terms of the
20 legislation we will be voting on.

21 I refuse to believe that innovation and
22 affordability are mutually exclusive goals. And I am
23 going to continue to work to make sure that those goals
24 can be realized.

25 With that, Mr. Chairman, I thank you for the time.

1 The Chairman. Senator Daines?

2

1 OPENING STATEMENT OF HON. STEVE DAINES, A U.S. SENATOR
2 FROM MONTANA

3

4 Senator Daines. Thank you, Mr. Chairman.

5 I get to each of Montana's 56 counties every
6 Congress. I know, Mr. Chairman, you do something similar
7 in Iowa in your 99 county tour. Counties are a little
8 bigger in Montana, but I know we both enjoy Dairy Queens
9 and getting all across our respective states.

10 I get to places like Great Falls, like Libby, like
11 Miles City, like Scobey. One of the concerns I
12 consistently hear from Montanans, from our seniors, from
13 grandma's and grandpa's, from our families, hard-working
14 moms is they are paying too much for the prescription
15 drugs that they need and their lives depend on.

16 These are Montana's who are battling diabetes. They
17 are battling cancer. They are battling arthritis. Folks
18 like Patricia from Helena, Ed from Missoula, Chuck from
19 Polson, Jim and Patty from West Yellowstone who write in
20 about the high cost of prescription drugs and a very real
21 worried that they cannot afford them. Their stories,
22 their concerns, their anxiety, it is very real. And that
23 is why since joining the Senate finance Committee -- it
24 is third Montanan to ever be on this Committee. In fact,
25 it is been one of my top priorities to lower prescription

1 drug costs for Montanans.

2 This is a legislative product, and a result of over
3 six months of bipartisan negotiations. I commend
4 Chairman Grassley, Ranking Member Wyden for their
5 leadership and their commitment to delivering
6 legislation, delivering an outcome, delivering a result
7 for Montana's and the American people that would actually
8 start to address this issue of high cost of prescription
9 drugs.

10 This is more than just talk. It is action. I am
11 proud to have worked here with folks here on this
12 compromise.

13 And though this may not be what you hear on the news
14 -- this does not sell TV ratings. Bipartisan compromise
15 does not sell ratings. But let me say something here
16 today, this committee bipartisan compromise is not dead.
17 We are seeing that today in this Markup.

18 This drug pricing package includes meaningful
19 reforms that will lower prescription drug costs for
20 Montanans. To highlight a few things as we look at what
21 is going on right now with federal spending, this saves
22 Montanans and the American taxpayers more than \$100
23 billion. It lowers Medicare beneficiaries' out-of-pocket
24 costs by \$25 billion. It lowers premiums by \$6 billion.
25 It increases transparency in this very complex drug

1 pricing system.

2 These are significant reforms. I am glad the work
3 that is produced by this committee has the support of
4 President Trump.

5 And lastly, this is about making life a little
6 easier for folks in Montana and across this great nation.
7 It is about keeping our moms, and dads, and families
8 healthy without having to worry about how much it is
9 going to cost or if they can even afford it. It is an
10 important step forward in giving families across Montana
11 and this country relief.

12 Thank you, Mr. Chairman.

13 The Chairman. It will not turn people off on this
14 side of the aisle because he said President Trump
15 supported this effort.

16 [Laughter.]

17 The Chairman. Senator Hassan?

18

1 OPENING STATEMENT OF HON. MAGGIE HASSAN, A U.S. SENATOR
2 FROM NEW HAMPSHIRE

3

4 Senator Hassan. Well, thank you, Mr. Chair. And I
5 want to thank you, Chairman Grassley and Ranking Member
6 Wyden for your work on this important bipartisan package.

7 There is perhaps no issue I hear about more from
8 Granite Staters than the skyrocketing cost of
9 prescription drugs. And the stories are simply
10 outrageous. Albert from Merrimack is a retiree with
11 diabetes who has a Medicare Part D plan and whose out-of-
12 pocket costs have still been over \$5,000 per year. Alex
13 of Nashua was diagnosed with cystic fibrosis 10 days
14 after he was born. And his mother at times has had to
15 choose between paying for Alex's prescriptions and
16 heating their home.

17 While Granite Staters wrestle with agonizing
18 financial choices to afford life-saving medications, big
19 pharmaceutical companies report even higher profits. Yet
20 for far too long, Washington has failed to act. Today we
21 will begin to change that.

22 This bipartisan bill will help control the cost of
23 drugs and lower costs for Medicare beneficiaries by
24 creating an out-of-pocket cap so seniors will not go into
25 bankruptcy because of their prescription drug costs. It

1 will also put downward pressure on the price of
2 medication for all patients.

3 I am also pleased to have worked with my colleagues
4 on both sides of the aisle, Senators Cassidy, Stabenow,
5 Cornyn, Cardin, and Young, to make sure that this bill
6 closes a loophole that has allowed drug companies to
7 overcharge states for drugs in the Medicaid program. And
8 I thank the Chairman and Ranking Member for incorporating
9 my Transparency Study Amendment into this package and
10 look forward to working with you on these issues moving
11 forward.

12 While this bipartisan bill is an important step
13 forward, we have far more work to do. I have offered
14 amendments that would improve this bill by increasing
15 transparency, creating stronger penalties on drug
16 companies that spike the price of their existing drugs,
17 and to ensure beneficiary certainty during benefit
18 redesign. We need to work together to make sure that as
19 this system changes patients can still get the life-
20 saving drugs that they have become accustomed to.

21 I look forward to continuing to work with my
22 colleagues on both sides of the aisle to incorporate
23 these much needed changes and on additional measures to
24 ensure that all Americans can afford critical care and
25 enjoy the quality of life that we all hope so dearly for.

1 Thank you, Mr. Chair.
2 The Chairman. Thank you very much.
3 And now we go to Senator Cortez Masto.
4

1 OPENING STATEMENT OF HON. CATHERINE CORTEZ MASTO, A U.S.
2 SENATOR FROM NEVADA

3

4 Senator Cortez Masto. Thank you. First of all,
5 like my colleagues, Mr. Chairman and Ranking Member, I
6 want to thank you for not only the hearings but for the
7 bipartisan work that has gone into such an important
8 issue not only in Nevada, but across the country.

9 Like my colleagues have said, when I go home to
10 Nevada the high cost of prescription drugs is the number
11 one issue I hear all over. I do not care whether you are
12 Republican, Democrat, Independent, where you are from,
13 this is the number one issue.

14 And what we have the opportunity to do today is an
15 important first step. We have heard it cuts seniors out-
16 of-pocket drug cost by 25 billion and lowers their part D
17 premiums. For the first time, seniors will have the
18 peace of mind of an out-of-pocket cap on their
19 prescription drug costs.

20 Drug companies must chip in for the cost of the
21 Medicare drug program and pay penalties when they hike
22 prices faster than inflation. Those penalties have
23 benefits for families too by putting pressure on drug
24 companies to lay off the price hikes we drive down costs
25 for folks in commercial health plans.

1 In the process, we have saved money for the Medicare
2 program, Medicaid in four states, and I am grateful that
3 we will be able to look under the hood about issues with
4 access to drugs in Indian Country. I also want to
5 recognize, I am grateful that we also have drug
6 manufacturing price transparency. And thank you for
7 providing the MedPAC and MACPAC with access to certain
8 drug payment information, including certain rebate
9 information.

10 But we all know this is an important first step, but
11 it is not the final step. There is more work that needs
12 to be done. I am concerned that we have not moved the
13 needle for many of the families that I have heard from in
14 Nevada on drug prices, the families who get coverage
15 through work or through the exchanges, families whose
16 kids have debilitating asthma or diabetes. And it does
17 not let Medicare leverage its huge market power and
18 negotiate for lower drug prices. And it still leaves too
19 many low-income seniors with high out-of-pocket costs.

20 I have very serious concerns with the provision in
21 the bill that opens the door to contracts that put state
22 Medicaid programs on a mortgage plan for high cost drugs.
23 And we have not even created a system, body, or mechanism
24 that will determine whether the prices that drug
25 companies charge consumers are appropriate. How do we

1 know when \$2 million for a drug is fair?

2 So there is more work to be done. But this is an
3 important first step. And I thank you for the bipartisan
4 support in moving forward.

5 The Chairman. Thank you Senator.

6 I would like to follow up on what she said. More
7 can be done, yes. But I want to get you back to the
8 environment that Senator Alexander, Senator Murray,
9 senator Grassley, and Senator Wyden tried to accomplish
10 in January, that there is the ideal to be done. But we
11 ought to concentrate on what is possible to get done and
12 to get done now.

13 And I think that the product that came out of
14 Senator Alexander's committee that has ideas from 70
15 different Senators in it is pretty good accomplishment on
16 his part. I hope we can have as good of an
17 accomplishment on our part.

18 Senator Wyden did not get everything he wanted. I
19 did not get everything I wanted.

20 The Senator from Texas.

21

1 OPENING STATEMENT OF HON. JOHN CORNYN, A U.S. SENATOR
2 FROM TEXAS

3

4 Senator Cornyn. Thank you, Mr. Chairman.

5 It is a difficult task indeed to come up with
6 policies that will lower out-of-pocket costs for seniors,
7 create cost savings for Medicare and Medicaid, and
8 decrease the high cost of prescription drugs. I support
9 the President's in your efforts to achieve these goals
10 and I believe this package could be a step in that
11 direction.

12 But we also know the uncertainty of this undertaking
13 because of its sheer complexity. It is important we
14 fully understand the impact of these policies on
15 Medicare, Medicaid, and the private insurance market.
16 And while I, like the rest of the members, love a CBO
17 score that tells me something I like to hear, I still
18 remember our colleague Bob Bennett from Utah who famously
19 said the CBO score is always wrong. You just do not know
20 if it is too high or too low, or to quote Yogi Berra, it
21 is tough to make predictions, especially about the
22 future.

23 So I understand there is significant uncertainty
24 whether this policy will lead to higher launch prices, or
25 higher out-of-pocket spinning, or higher premiums. I

1 appreciate the Chairman putting Avik Roy on the phone,
2 but I do know that there is enough money involved in this
3 enterprise that there is all sorts of people with all
4 sorts of points of view and all sorts of agendas. And so
5 I just think that we need to be very careful.

6 Obviously, we need to find an approach that can
7 achieve broad support, and I do not think we are there
8 yet. In other words, while I will support the Chairman
9 and vote to move this bill out of the committee, this
10 bill is not anywhere near ready for action on the floor.

11 The other thing we need to keep in mind is the
12 Judiciary Committee and the HELP Committee has also made
13 a contribution to this effort, and there is significant
14 uncertainty about the interplay of those various
15 committee products. So I think we need to continue
16 refining this proposal to strike the right balance
17 between preventing price increases and preserving a
18 market-based approach that has made Part D a success.

19 So it is important we get this right. It is more
20 important we get it right than we get it done fast. And
21 I think significant input from our Members is still going
22 to be needed following this Markup.

23 So I hope the Chairman and the Ranking Member will
24 commit to continue working with all of us before this
25 package is ready for floor action.

1 The Chairman. I can commit that to you because I
2 have already committed it to two or three other Members
3 of the committee already before you even ask me. And I
4 would also like to emphasize what he said about hopefully
5 certain parts of stuff out of the Judiciary Committee can
6 be mixed up with things that Senator Alexander has done.
7 And you were leader on one of those bills that came out
8 of committee.

9 Senator Cornyn. Mr. Chairman, I guess if I could
10 just sum up in a brief conclusion.

11 The Chairman. Did I interrupt you? I am sorry.

12 Senator Cornyn. No.

13 The Chairman. I did not mean to.

14 Senator Cornyn. I just think -- my concern is that
15 if -- all of us want to lower out-of-pocket costs for
16 prescription drugs, but if there is some unintended
17 consequence, some -- if we are unsuccessful in doing
18 that, we will have failed. And so I just want to make
19 sure we take the time and deliberate on this, and get
20 access to all the information we can so we make the very
21 best decisions.

22 Thank you.

23 The Chairman. Senator Portman?

24

1 OPENING STATEMENT OF HON. ROB PORTMAN, A U.S. SENATOR
2 FROM OHIO

3

4 Senator Portman. Great points by my colleague from
5 Texas, this is complicated. It is not easy. And that is
6 one reason I appreciate you, Mr. Chairman and Senator
7 Wyden in getting us to this point. But we are not done.
8 We have much more to do.

9 I do think as a whole this package will lower drug
10 costs. And it is going to help people with their out-of-
11 pocket expenses, which is what I hear about all the time.
12 So across Ohio people are having a hard time. Some of
13 them have complex medical conditions, and they sort of
14 fall in the middle where they do not have enough help
15 from Medicaid or Medicare and they really cannot afford
16 drugs that they need every day.

17 So I think this will help. Drug prices are too
18 high, and often they are too high for the very people
19 that cannot afford them. So I want to move forward.

20 I think there are a few common sense bipartisan
21 solutions here that are helpful. Having said that we
22 need to do more work, let me talk about a few that I
23 really like.

24 It lowers out-of-pocket costs for seniors in Part D
25 by having this out-of-pocket spending cap, 3,100 bucks.

1 I think that is important for the 2 million Ohioans who
2 rely on Medicare for their health care coverage. This is
3 going to provide more certainty and protect some of those
4 patients with those complex medical conditions.

5 I think this along with restructuring the liability
6 in Part D is going to help to ensure this program works
7 better for those who need it the most. One reason I
8 support the restructuring liability is I think it does
9 take away a current incentive to raise prices by kicking
10 the costs into the catastrophic area where the government
11 picks up the tab. And so I think that is important.

12 I do have one concern about this that I am hearing
13 about, and that is I think we need more study on the
14 impact on very expensive but essential therapies, like
15 psychotherapy drugs. These are not the high margin
16 drugs, and there are a lot of big guys who are not in
17 this business. But those who are in this business have
18 some concerns about the restructuring. And I think there
19 are some ways to deal with that in terms of their
20 manufacture liability. But overall I think it is a
21 really smart approach.

22 The policy that the Ranking Member has championed
23 that deals with price spreading in Medicaid I think is
24 really important. That has been a problem in Ohio, and I
25 am sure in all of your States. PBMs sometimes keep a

1 portion of the amount paid to them by the health plans,
2 prescription drugs instead of passing those along to the
3 pharmacies. And I think that is going to be something
4 positive out of this.

5 On point-of-sale rebates, I agree the rebates need
6 to go to the consumers, need to go to the patients. And
7 I have an amendment, as you know, to offer later on that.
8 We can talk about it a little bit. And I am hopeful that
9 we can get back to that because I think that is
10 important.

11 By the way on the inflationary cap, I do have
12 concerns as was expressed earlier about some of the
13 unintended consequences of that, particularly on R&D and
14 innovation. And also, I wonder why those rebates would
15 not go to consumers rather than, under our current
16 proposal, going to the government. Because again kind of
17 like those point-of-sale rebates, that seems to make more
18 sense to me. We can have that discussion.

19 Finally the package includes the Refund Act, which I
20 have worked on with Senator Durbin and Senator Bennet.
21 This is going to help stop drug manufacturers from
22 producing vials that are too large. It will save
23 billions of dollars a year. A good thing in this bill --
24 and I thank you for including it.

25 And again our work does not end here. But I look

1 forward to having the discussion today, and then helping
2 to move this back and forth.

3 The Chairman. Remind you, I addressed in my
4 opening remarks the point you just made that what can we
5 do to get more rebates to the consumer. And Senator
6 Wyden has agreed to work with us on that.

7 Senator Whitehouse?

8

1 OPENING STATEMENT OF HON. SHELDON WHITEHOUSE, A U.S.
2 SENATOR FROM RHODE ISLAND

3

4 Senator Whitehouse. Thank you Chairman. And thank
5 you also to the Ranking Member.

6 A lot of the problems that we have seen in the
7 pharmaceutical market have not been the product of market
8 behavior, but of monopoly misbehavior. And I am eager to
9 see that we develop a way to actually determine when
10 there is a monopoly and address it as monopolies should
11 be addressed. You are not protecting markets when you
12 are protecting monopolies.

13 I would like to see negotiation by CMS, as Senator
14 Cantwell called it, the Costco rule. I would like to see
15 some form of importation at least by pharmacies who can
16 assure the integrity of the supply chain, perhaps even by
17 States as it appears President Trump hinted at or
18 announced today. I saw early reports.

19 There should be a price index to protect U.S.
20 patients from being the ones who were overcharged by
21 companies who are charging for the same drug lower costs
22 in other countries. So there are a lot of
23 disappointments in where we are. I understand that
24 bipartisanship creates its limitations. I am in the
25 Cornyn squad here of being inclined to vote to move this

1 bill to the floor, but wanting a very clear understanding
2 before we go to the floor that some of these issues that
3 I just mentioned will be addressed because this is too
4 important a problem for us to simply reach the goal of
5 bipartisanship and then stop. We have to reach the goal
6 of bipartisanship and then keep pushing until we see real
7 change in these very difficult markets, which I think are
8 corroded with monopoly misbehavior.

9 I was on the HELP Committee when we started looking
10 at this problem. And the HELP committee has some good
11 work on this. I am on the Judiciary Committee along with
12 the Chairman, and we have some good material on this.
13 Between what is in this bill, what is in the Judiciary
14 package, what is in the HELP package and some of the
15 ideas that I mentioned, I think we can actually put
16 together a really, really consequential piece of
17 legislation. This is not that piece of legislation.

18 But as the Ranking Member has said, it is a good
19 start. It does not claim to be more than that. And I
20 appreciate the bipartisan work that went into it.

21 Senator Wyden. Mr. Chairman, if I could just
22 respond to Senator Whitehouse who is very knowledgeable
23 on this and is focused particularly on making sure that
24 the consumer has more market power. That is really the
25 driver that is behind all of the positions were taking.

1 And your work on the Judiciary Committee is particularly
2 helpful as well.

3 We pointed out that with respect to the patents
4 which have been wildly abused -- these monopolistic
5 companies guard their patents like Gollum guards his
6 ring. It is just outrageous.

7 So we will keep working with you on it.

8 Senator Whitehouse. Yeah, and just to be clear --
9 I have a few seconds left.

10 I am not just talking about misuse of official
11 monopolies that are conferred through the patent system.
12 I am talking about the kind of companies that come in buy
13 a pharmaceutical company when it has a de facto monopoly,
14 when it has no competition, jump the price up 200, 500,
15 1000 percent, scare off any competition because they know
16 they can drop it back down and price them back out again,
17 and just continue to ride monopolistic behavior.

18 And there is no place in the federal government
19 right now that hunts that down, calls it out, and is able
20 to address that. It is just a huge gap. And this
21 monopolistic misbehavior has no defense in market theory,
22 in conservative theory, in consumer theory, and
23 progressive theory anywhere. It is just mischief, and it
24 is got to stop.

25 The Chairman. I agree with you on importation, but

1 that is not within the jurisdiction of our committee

2 Senator Carper?

3

1 OPENING STATEMENT OF HON. THOMAS R. CARPER, A U.S.
2 SENATOR FROM DELAWARE

3

4 Senator Carper. Thanks, Mr. Chairman.

5 I want to join my colleagues in commending you, and
6 Senator Wyden, and your staffs, and our staffs for
7 working together to get us to this point in time.

8 It is been said that bipartisan solutions are always
9 the lasting ones. Think about that. Bipartisan
10 solutions are always the lasting ones. And I am pleased
11 that at least that is where we are starting here, and my
12 hope is that that is the way that we will finish.

13 The Preamble of the Constitution of our country
14 begins with these words, "We the people of the United
15 States, in Order to form a more perfect Union." It does
16 not say in order to form a perfect union. It says "a
17 more perfect Union." Their idea was that what we do
18 would be making progress year after year, generation
19 after generation toward perfection.

20 Medicare was a big step down that road to
21 perfection. It was not perfect. We added Medicare Part
22 D. It helped a lot. It was not perfect. And today we
23 have an opportunity to improve on that, and we need to.

24 Some of my colleagues may remember when we were
25 debating in this room tax reform. There were four

1 questions I would always ask of every tax reform proposal
2 that was suggested to us: 1) Is it fair? 2) Does it
3 promote economic development or retard it? 3) Does it
4 make the tax system more complex or less? 4) How does it
5 affect the budget and budget deficits? Those are my four
6 frames, which I looked at every tax reform proposal. And
7 I put together four or five frames, questions that I ask
8 when people come to me with different ideas on what to do
9 about pharmaceutical pricing.

10 I am told description drugs represent one dollar out
11 of every five that Medicare beneficiaries spend, one out
12 of every five. We have, I think, the most expensive
13 pharmaceuticals in the world. So there is something we
14 need to -- but I ask these five questions.

15 One of those is when an idea is suggested to me, is
16 it fair? Does it help people who need help the most?

17 The second is with respect to transparency. This is
18 complex stuff. I have had a hard time getting my brain
19 around it. My colleagues have as well. But does what we
20 are doing today and the approach that we are going to
21 take -- does it make this situation more complex, or
22 maybe less?

23 The third and importantly, does it allow market
24 forces to continue to work where they work? And where
25 they are not working, does it provide reasonable

1 alternatives to help right a wrong?

2 Four, impact on deficits -- impact on deficits. We
3 are about to take up a spending plan for the next two
4 years. It will make a bad situation worse, and we have
5 an opportunity here today with this compromise to
6 actually reduce budget deficits, and we should seize that
7 day.

8 And lastly, do the actions that we take with this
9 legislation -- whatever we adopt -- continue to preserve
10 the incentives for the research that is needed to come up
11 with even more needed drugs?

12 Last word, Winston Churchill -- Winston Churchill
13 famously said, "You can always count on America do the
14 right thing in the end after trying everything else."
15 And we are going to try to do the right thing today. And
16 in the end when we finish up weeks from now, months from
17 now, we are going to try to do it then as well.

18 Thank you.

19 The Chairman. I do not have time to explain it,
20 but I would like to talk to you about how we are actually
21 making Part D simpler, not more complicated.

22 Senators Thune, Scott, Young, Lankford, Burr,
23 Stabenow, and Casey.

24

1 OPENING STATEMENT OF HON. JOHN THUNE, A U.S. SENATOR FROM
2 TEXAS

3

4 Senator Thune. Thank you, Mr. Chairman.

5 I would start by saying I think we all want to
6 address the cost of prescription drugs and lower out-of-
7 pocket costs for seniors. That is something that we all
8 hear out there, and no doubt we want to be able to do it
9 in a bipartisan fashion. As a former committee Chairman,
10 I know that just as well as anyone.

11 And there are significant provisions in this
12 legislation that will make meaningful progress toward
13 lowering drug costs, like the Part D benefit
14 modernization. And I think you would find broad support
15 on both sides of the aisle for many of the provisions
16 that are included in the Mark. And I would point out
17 that according to the CBO study 80 percent of the cost-
18 sharing savings are as a result of the Part D benefit
19 redesign.

20 There are notable improvements in transparency of a
21 complicated and often opaque drug pricing process which I
22 commend. The promotion of real-time benefit tools will
23 aid in helping inform consumers of cheaper drug options.
24 I have long supported efforts to tackle a critically
25 important issue to pharmacists that this bill in part

1 addresses, and that is the DIR fees.

2 But a part of the legislation, the inflationary
3 rebate policy in Part D would unravel one of the
4 foundational pieces of a successful conservative health
5 care policy, and that is free market competition. There
6 are really a couple of ways that you can reduce prices,
7 and one is a free market where competitive actors act in
8 a way that tries to bring more options available to
9 consumers out there, and that puts downward pressure on
10 prices. And I think that is what has made the Part D
11 model so effective and so successful and one that has
12 found broad satisfaction among consumers. It gives them
13 more options, and it creates more competitive actors, and
14 it helps put downward pressure on prices.

15 And as has been mentioned earlier, Senator Toomey
16 will offer an amendment to strike this particular
17 provision in the bill, which I will support. But I would
18 tell you, Mr. Chairman, that many of these other policies
19 -- including some that I just mentioned -- I think if
20 this particular amendment offered by Senator Toomey, if
21 that provision is stripped out, I think you would have a
22 big bipartisan margin on this bill coming out of here.

23 I think many of us have concerns and a lot of
24 heartburn about what that does to the Part D program.
25 And I believe inevitably it will lead to cost shifting.

1 We have seen that in so many other areas of health care
2 where the government steps on the scale, providers cost
3 shift to other payers. And I think we will see that
4 here.

5 So I think this Part D policy is -- I find it
6 objectionable. I hope we can support Senator Toomey's
7 Amendment, and then I would like to see us report out a
8 bill that I think does do what many of us want to see
9 happen in a strong bipartisan fashion.

10 Thank you.

11 The Chairman. It could get us a unanimous vote in
12 this committee, but it would also leave the taxpayers
13 with a \$50 billion more cost.

14 Senator Scott?

15

1 OPENING STATEMENT OF HON. TIM SCOTT, A U.S. SENATOR FROM
2 SOUTH CAROLINA

3

4 Senator Scott. Thank you, Mr. Chairman.

5 Let me just be simple and clear and associate myself
6 first with Senator Thune's comment, second to say to you
7 and Ranking Member Wyden thank you very much for your
8 hard work, for your efforts. There is no doubt in my
9 mind that you all have produced a package that you think
10 is the most effective package in addressing what is
11 indeed the biggest issue at home, which are the price of
12 drugs. There is no doubt that you have kept your focus
13 on the ball.

14 I will say that as I have worked through this
15 process, Senator Thune's comments are consistent with
16 mine. The amendment that will be offered by Senator
17 Toomey is one that I would support. I think it makes the
18 bill stronger, not weaker.

19 Ultimately, it comes down to something quite simple.
20 As we all seek to have a positive impact on the price of
21 drugs, I think this legislation ultimately will do three
22 things. One, which I think is quite positive, is it will
23 cap the spending from the out-of-pocket perspective for
24 seniors, which is very positive. Second, is I think it
25 will ultimately stifle innovation. Third, it will

1 ultimately increase the list prices, which finally means
2 that while we may celebrate in the short-term reduction
3 in prices, I think in the long-term we will see the exact
4 opposite.

5 The Chairman. Senator Lankford?

6

1 OPENING STATEMENT OF HON. JAMES LANKFORD, A U.S. SENATOR
2 FROM OKLAHOMA

3

4 Senator Lankford. Mr. Chairman, thank you for the
5 incredible work on this. This is a -- you have grabbed
6 the bull by the horns, and you and the Ranking Member are
7 taking it for a ride.

8 Dealing with pharmaceutical prices and trying to be
9 able to get a lower price to consumers and a better price
10 for the taxpayers is an incredibly complicated process.
11 We have had hearings in this room dealing from everything
12 from the bottle, all the way through the how it is
13 manufactured, all the way to the very hidden in the
14 middle of the pharmacy benefit managers that most people
15 did not even know they existed before we started this
16 series of hearings to something as complicated as what is
17 called DIR fees that damage a lot of our specialty rural
18 pharmacies that are out there all the way to the final
19 price the consumer pays.

20 We have done an extensive set of hearings. I think
21 it is been exceptionally beneficial. You have been very
22 open in being able to take on amendments early on the
23 process, and I appreciate that very much.

24 Senator Cantwell and I have a transparency proposal
25 that we have made. The committee has accepted that. We

1 have talked through several things on DIR fees. The
2 committee has been very open to be able to accept those
3 and include other ideas.

4 So you have not been closed in this process, to say
5 the least. You have been very open on it.

6 We have all expressed that we would love to have the
7 information earlier, or the final product to be able to
8 read through that. But throughout the course of this
9 process, you have been very open. I we have quite a few
10 amendments that are still coming today as well.

11 Senator Menendez and I, and Senator Danes and Cardin
12 all have an amendment as well on tiering, and trying to
13 be able to deal with tearing which is an issue that we
14 have dealt with on generic branded tiers. So grateful
15 for all of that dialogue as well and look forward to
16 getting a chance to get this done.

17 The two big pieces of this, as well as the
18 transparency and other elements, deal with the redesign
19 of the program. There is wide support for the redesign
20 of the program, which is much needed and saves the
21 taxpayer a tremendous amount of money and consumers are
22 tremendous amount of money.

23 The question still comes back to the inflation caps.
24 And I cannot get away from two issues. One is we have
25 economist on both sides saying the inflation caps will

1 cause the list prices to go up, and inflation caps will
2 not cause the list prices to go up. And we have battling
3 economists on that, and we have got to figure out which
4 way we are going to go.

5 But I cannot get away from a decision that
6 Oklahomans made in 2012 when we voted as a state to cap
7 our property tax increases because we were tired of our
8 property taxes going up all the time. That cap, though,
9 has become the floor. And every year I can assure you my
10 property taxes will go up three percent every year
11 regardless of what happens because there is a cap on how
12 much it can go up. So it always will go up by that
13 amount.

14 Not every drug goes up every year, thankfully. But
15 my concern is if we put a cap, every drug will go up by
16 that amount every year because they can. And I want us
17 to spend more time debating that in the days ahead, and I
18 look forward to that dialogue.

19 The Chairman. Okay.

20 Now, Senator Stabenow.

21

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

3

4 Senator Stabenow. Thank you very much, Mr.
5 Chairman, and I thank you and the Ranking Member for
6 working together.

7 Health care is personal, not political, for every
8 American. That includes the prescription medications
9 people need to stay healthy and to stay alive. And
10 unfortunately it is getting harder and harder to do that
11 to stay healthy and stay alive.

12 Between 2008 and 2016, prices on the most popular
13 brand name drugs rose 208 percent in the United States.
14 I know that the incomes of Michigan families did not go
15 up 208 percent. Certainly, the incomes of our seniors
16 did not go up 208 percent.

17 And unfortunately while we are here talking about
18 how we address this, the Trump Administration is ripping
19 apart the entire health care System, supporting a court
20 case doing sabotage that includes reopening the Part D
21 coverage gap called the doughnut hole, and eliminating
22 coverage of prescription drugs as an essential benefit.
23 I do not know how that fits with the discussion that we
24 are having today.

25 We all know we pay the highest prices in the world.

1 And we could actually cut prices today. That is what I
2 am excited about. We could actually do that. It is not
3 in the bill at this point, but I will be offering an
4 amendment with colleagues that would actually do that.

5 This bill does take positive steps. I am pleased to
6 have worked with the Chairman and Ranking Member as well
7 as Senator Peters on his legislation to require drug
8 companies to keep price increases below the rate of
9 inflation or pay a penalty.

10 And I have long-advocated for an out-of-pocket cap
11 for seniors. And that is a good reform. I am pleased
12 there are savings in the bill. That Medicare Part D
13 rebate provides, for example, would save taxpayers \$5
14 billion a year over 10 years.

15 But let us be real. Between the enactment of the
16 Republican tax cut in January 2019, a little over a year,
17 pharmaceutical companies received a big enough tax cut
18 that they could spend \$73 billion in a year to give to
19 their CEOs and their investors.

20 This legislation slows down price increases, which
21 is good. But imagine the savings to taxpayers and
22 patients if we actually cut prices. The good news is we
23 have a chance to do that in a very simple way,
24 uncomplicated way today. We can do what everyone says
25 that they want to do. And that is why, along with the

1 majority of my Democratic colleagues we will be offering
2 an amendment based on legislation of Senator Klobuchar's
3 to let Medicare negotiate lower drug prices just like
4 every other plan does.

5 This is the way to actually cut prescription drug
6 prices, and I hope my colleagues will support the
7 amendment.

8 The Chairman. Senator Casey?

9

1 OPENING STATEMENT OF HON. ROBERT P. CASEY, JR., A U.S.
2 SENATOR FROM PENNSYLVANIA

3

4 Senator Casey. Thank you, Mr. Chairman. I want to
5 thank Chairman Grassley, Ranking Member Wyden for your
6 work to produce a bipartisan package for today's Markup.

7 Throughout the process, the individuals and the
8 families who cannot afford the medications they need have
9 been my focus, and I know the focus of many here. I met
10 a woman from southwestern Pennsylvania who sometimes pays
11 as much as \$500 a month for multiple medications to
12 manage bleeding ulcers, high blood pressure, and more. I
13 will support this package because it takes steps to help
14 people like this individual I met, and to help seniors
15 who pay many more thousands of dollars a year on
16 prescription drugs.

17 For example, in our state 60,000 Pennsylvanians
18 faced catastrophic prescription drug costs just in 2017.
19 These seniors and people with disabilities who have face
20 lower costs, would have already been helped had this
21 package been made part of our law prior to this.

22 This bill, of course, is not enough. The rising
23 cost of prescription drugs is not happening in isolation.
24 It is part of a larger challenge many Americans face
25 every day trying to make ends meet. The simple way to say

1 it is flat wages and high costs.

2 For too many families the cost of prescription drugs
3 is like a bag of rocks thrown on their shoulders every
4 single day in addition to the other bags of rocks they
5 are carrying around, whether it is high health care
6 costs, high cost for college, high cost for childcare,
7 and the like. Families are crushed by these costs, and
8 they do deserve more than this package.

9 Indeed we must do more. We must ensure that those
10 with meager savings and little more than their social
11 security check can afford their medications. And I
12 believe we should make sure that the savings secured
13 through this package are invested in the right places.
14 These savings should be used to strengthen Medicaid and
15 Medicare.

16 I have filed amendments to expand low-income
17 protections for seniors and to protect families with
18 Medicaid from needing to spend down into abject poverty.
19 These are just two examples of the kinds of investments
20 we need to make.

21 Today this committee has made a small but necessary
22 first step. But it does fall short of the leap -- the
23 leap to truly lift this crushing bag of rocks weighing
24 down American families.

25 Finally, Mr. Chairman, I want to say despite this

1 bipartisanship today that Senator Stabenow referred to,
2 Republicans in Congress and the Administration are
3 supporting a lawsuit that would destroy the Affordable
4 Care Act with no replacement to ensure protections for
5 pre-existing conditions, not to mention a guarantee of
6 coverage for at least the 20 million Americans who got
7 their coverage through the Affordable Care Act.

8 With that, Mr. Chairman, I want to ask consent to
9 make part of the record a chart entitled *Medicare Part D*
10 *Enrollees Without Low-income Subsidies With Drug Spending*
11 *Above the Catastrophic Threshold in 2017, By State By the*
12 *Kaiser Family Foundation.*

13 The Chairman. Without objection, it will be
14 included. And with regard to --

15 Senator Casey. Thank you.

16 -- preexisting conditions, we would very much as a
17 Majority Party like to get a bill up that will guarantee,
18 regardless of the court cases, that pre-existing
19 conditions will always be protected. That is our Party
20 position.

21 [The chart appears in the appendix.]

22 The Chairman. Senator Toomey. Oh, no. I am
23 sorry. Senator Warner.

24 [Off mic.]

25 The Chairman. Okay.

1 Now that is the last one. We passed over a couple
2 of people. Do you want to speak now, Senator Toomey and
3 Senator Cassidy?

4 Senator Toomey. Mr. Chairman, I will just make my
5 comments when I introduce my amendment.

6 The Chairman. Okay.

7 Senator Cassidy?

8

1 OPENING STATEMENT OF HON. BILL CASSIDY, A U.S. SENATOR
2 FROM LOUISIANA

3

4 Senator Cassidy. Yes, I will speak. Thank you.

5 I approach this problem, Mr. Chairman as a doctor
6 representing patients, as a Senator representing
7 taxpayers. As a doctor, I know we need pharma to
8 innovate. But I also know that if drugs are
9 unaffordable, it is as if the innovation never occurred.

10 How do we control costs? My colleagues on the other
11 side of the aisle support direct negotiation. I oppose
12 that. The federal government would be both setting the
13 rules and also the negotiator. I think that is unfair.
14 It would give absolute power to the government. And
15 absolute power corrupts absolutely.

16 Now, there is also the inflation cap. I reject that
17 it is price setting. It really limits subsidies. But
18 for the sake of argument, let us ask does Medicare set
19 prices? Of course Medicare sets prices. Every doctor,
20 every hospital tells you that Medicare sets their price.

21 What about drugs? This committee sets prices --
22 340b, which has tremendous support, Medicaid best price.
23 That is setting prices. Section 103 of this bill tells
24 biosimilars you are either getting that price or this
25 price. To pretend we do not set prices is a pretense.

1 Now, what about the inflation caps benefits? I
2 would argue it does have benefits. Under the Medicare
3 Part D protected categories, manufacturers have absolute
4 power over pricing -- absolute power, because we the
5 taxpayer must pay for whatever they offer. And just like
6 absolute power corrupts the federal government, so
7 absolute power corrupts that pricing.

8 Latuda -- this is an article from Secretary Azar and
9 Seema Verma on cms.gov speaking of Latuda. Latuda's
10 prices increased by 19 percent every year from 2013 to
11 2017, 19 percent. That is not innovation. That is
12 shareholder benefit. That is taxpayers as a captive
13 payer paying monopolistic pricing. That is not free
14 market.

15 Now, I am a conservative who is for free markets. I
16 reject monopolistic pricing exploiting a captive payer
17 who is a taxpayer. So as a doctor representing patients,
18 as a Senator representing taxpayers who firmly believes
19 that we have to have a market which works, not a market
20 in which the taxpayer and patients are exploited, I think
21 we should unanimously support inflation caps.

22 I yield back.

23 The Chairman. We are now ready for the
24 walkthrough. The committee has before it --

25 Senator Brown. Mr. Chairman, could I make one more

1 comment really quickly over here?

2 The Chairman. Go ahead.

3 Senator Brown. Yeah, I thank you. And I always
4 appreciate the comity of this committee -- comity with a
5 "t."

6 I was intrigued by what Senator Casey said about the
7 court case and how virtually every Republican on this
8 committee has opposed the Affordable Care Act. And then
9 I appreciated your rejoinder, Mr. Chairman, that the
10 Republican Party position is to keep the protections for
11 pre-existing condition.

12 And you know that is not true. And I know that is
13 not true. There is simply no way to protect pre-existing
14 condition without all the things that go with it. So I
15 just wanted to put that on the table, Mr. Chairman.

16 Senator Cornyn. Mr. Chairman?

17 The Chairman. Now we are turning to Senator
18 Cornyn.

19 Senator Cornyn. This is such a transparent ruse.
20 It is a lie that Republicans do not support coverage for
21 pre-existing conditions. It is a lie. But you know the
22 theory of the big lies, if you tell them often enough and
23 loud enough, some people will believe it. And it is true
24 that Democrats benefited in 2018 by perpetuating that
25 lie.

1 But we have a responsibility to call it out for what
2 it is. And I would just point out, you know, after being
3 told if you like your policy, you can keep your policy.
4 If you like your doctor, you can keep your doctor, and
5 touting the great benefits of the Affordable Care Act,
6 most of the Democratic Presidential candidates want to
7 eliminate private insurance -- eliminate it for 180
8 million people who get it through their job. And they
9 want to bankrupt Medicare, which is already on a path to
10 insolvency.

11 So thank you for giving me a chance to say a word.
12 But this is really a --

13 [Simultaneous speech.]

14 The Chairman. Okay, I want to get --

15 Senator Casey. Mr. Chairman?

16 The Chairman. Can you do it in one minute --

17 Senator Casey. Yes.

18 The Chairman. -- because I want to get back to
19 business.

20 Senator Casey. It is not a lie when you support
21 the lawsuit. If you support the lawsuit without a
22 replacement, I am still -- what happened in 2017 --

23 [Simultaneous speech.]

24 Senator Cornyn. We have a replacement, Senator.
25 And you know it.

1 Senator Casey. -- and 2018 -- 2017 and 2018, you
2 had a Republican President, Republican Senate, Republican
3 House. No replacement bill was passed. How the hell can
4 you say support protections when you had all the power
5 and a bill did not pass that would replace the Affordable
6 Care Act?

7 I am still waiting for the replacement. You have
8 had 8 years of bellyaching about it, and you have not
9 done a damn thing about it.

10 The Chairman. Okay. Now we are ready.

11 I am sorry I commented what our position was after
12 Senator Casey talked. We wasted 4 minutes.

13 The committee has before it a Chairman's Mark, the
14 Prescription Drug Pricing Reduction Act, along with the
15 Chairman's modification developed by a bipartisan staff,
16 which is hereby incorporated into the Mark.

17 Today we have with us a lot of experts in this area
18 that are going to answer your questions. Brett Baker
19 Stuart Portman, Sean Bishop, and Anne Dwyer, all health
20 policy staff for the Senate Finance Committee are sitting
21 before us to walk through the modification to the Mark
22 and answer any questions.

23 In addition, we also have at the table from the
24 Congressional Budget Office Director Phillip Swagel and
25 Chad Chirico and Leo Lex. We also have representatives

1 from the Senate Legislative Council.

2 Mr. Baker, would you please get us started with the
3 modifications?

4 Mr. Baker. Thank you, Mr. Chairman.

5 The Chairman. And please talk loud and get the
6 microphone close to you.

7 Mr. Baker. Certainly, sir. Thank you.

8 And the first modification of the Mark is to Section
9 105 of the Chairman's Mark. It is to accept Menendez-
10 Carper 3 Amendment, and that is specifically on page 6 of
11 the Mark in the last sentence on that page. Add the
12 following after the first sentence: "The payment will not
13 exceed the total amount for the reference biologic." The
14 modification ensures that the biosimilar would not be
15 paid more than the brand reference product during the
16 five-year period in which the biosimilar gets a higher
17 add-on payment.

18 The second modification is to Section 108 on page 10
19 of the Mark. In the first paragraph on that page modify
20 the second sentence to strike "may" and insert "shall."
21 That will require the Secretary to provide an additional
22 allowance for unused drug product for drugs with unique
23 circumstances.

24 The next modification is to accept Cassidy 2. And
25 then on page 12 of the Mark after Section 112 insert the

1 following: "Section 113, Study of Average Sales Price."
2 This provision would require GAO to study the difference
3 between commercial and Medicare prices reported for ASP.

4 The next modification is to add Section 114,
5 "Authority to Use Alternative Payment for Drugs and
6 Biologicals to Prevent Drug Shortages." And on page 12
7 of the Mark insert the following, the same section
8 heading as 114. This provision would authorize the
9 Secretary of Health and Human Services to pay higher
10 rates than would otherwise be paid under the payment
11 methodology under Medicare Part B for drugs that are
12 currently in shortage and are on the FDA shortage list,
13 or for drugs that have a declining number of
14 manufacturers that may result in a shortage in the
15 future.

16 The provision also requires the establishment of a
17 mechanism that hospitals would use to report to CMS the
18 use of drugs in shortage in the hospital inpatient
19 setting.

20 The next modification is to Section 123. On page 18
21 of the Mark before the last sentence in the first full
22 paragraph under provision add the following sentence:
23 "Data released under this provision may represent
24 transactions that occurred two years prior to the plan
25 year in which data is released." This modification would

1 prohibit against inadvertent release of information that
2 could potentially reveal negotiated drug prices.

3 The next modification is to Section 125. On page 21
4 of the Mark in the first sentence of the first full
5 paragraph, following "electronic transmission of" but
6 before "formulary and benefit information" insert
7 "eligibility." And further on page 21 in the second
8 sentence of the first full paragraph following "formulary
9 of such plan," but before "pharmacy options" insert
10 "information relating to cost sharing."

11 These modifications ensure that the tools provide
12 the information that is most helpful to patients.

13 The Chairman. Are you done sir?

14 Mr. Baker. I can be sir.

15 The Chairman. Yeah.

16 [Laughter.]

17 The Chairman. No proceed, please.

18 Mr. Baker. Oh, okay. We will move quickly.

19 To modify Section 129 -- and this would add a new
20 section -- I am sorry. Yes, would add a new section,
21 create a new section. "Prohibit branding on Part D
22 Benefit Cards." So this would prohibit Part D plan
23 sponsors from including any pharmacy branding information
24 on cards to beneficiaries that may be misleading.

25 The next modification is to accept Cornyn-Cardin

1 Number 1. This would add a Section 130 to the Mark that
2 would implement a recommendation from the Office of
3 Inspector General to require all Medicare Part D plan
4 sponsors to report suspected fraud, waste, and abuse
5 information to CMS.

6 The next modification, accept Cassidy-Brown-
7 Lankford-Menendez-Daines Number 8. On page 25 of the
8 Mark insert the following after Section 130, a new
9 Section 131 to establish pharmacy quality metrics in
10 Medicare Part D.

11 The next modification would be to accept Cassidy-
12 Menendez Number 6 as modified. And on page 25 of the
13 Mark insert the following after Section 131, which would
14 be a new Section 132 that would require star rating
15 measures to ensure biosimilar uptake in Medicare Part D.

16 The next the next modification is to accept Portman-
17 Carper Number 2 as modified. And so this would add a new
18 Section 133 after section 132, and it is a study and
19 report on the influence of pharmaceutical manufacturer
20 Distribution on prescribing behavior.

21 The next modification is in Subsection C, the
22 Miscellaneous Provisions. It would modify Section 141 on
23 page 27 of the Mark, substitute the fourth paragraph with
24 "HHS would be prohibited from publicly posting any
25 proprietary manufacturer information."

1 The following modification is to remove Section 142
2 that appeared in the Mark and its entirety.

3 The next modification is accept Cantwell-Lankford
4 Number 3. And this would create a new Section 142 that
5 would strengthen and expand pharmacy benefit manager
6 transparency requirements. At least some of the
7 Senators had spoken of this provision earlier.

8 The following modification would be to accept Casey
9 Number 2. And this would add a new Section 143, and it
10 would codify and build on an internet dashboard that
11 provides information that is relevant to patients and
12 others related to Medicare Part B, Part D, and Medicaid
13 drug spending.

14 The next modification is to accept Burr-Bennet-
15 Carper-Scott-Brown-Cassidy Number 1. And this would
16 create a new Section 144 that would require more
17 coordination between the Centers for Medicare and
18 Medicaid services in the FDA.

19 The following modification is to accept Carper
20 Number 1 as modified. And this is with Senator Isakson.
21 This would create a new Section 145 that would ensure
22 that patient representation is on local Medicare coverage
23 decisions that are made by the local and state
24 contractors.

25 The following modification is to accept Hassan-

1 Whitehouse Number 4 as modified. This is a GAO study on
2 increases in Medicare spending due to pharmaceutical
3 manufacturer contributions to copay and patient
4 assistance organizations.

5 And then the next modification is Toomey-Enzi Number
6 16. And it would create a new Section 147. It would
7 require the Medicare Payment Advisory Commission to
8 submit to Congress a report on the potential of shifting
9 coverage of certain Medicare Part B drugs to Medicare
10 Part D.

11 And with that, I will stop and turn it over to my
12 colleague, Stuart Portman.

13 The Chairman. The modification is hereby
14 incorporated into the Mark.

15 Before we go to questions on the Mark, to the people
16 that are experts before us, I am going to ask Senator
17 Crapo to call on the Members so I can take a four-minute
18 to do something else.

19 Thank you, Senator Crapo.

20 So it is time for the questions now.

21 Senator Crapo [presiding]. Are there any questions
22 from Senators?

23 [No response.]

24 The Chairman. Well if there is not, I better not
25 go then.

1 Okay. Let us go on to the amendments.

2 So we will recognize Senators to offer amendments.

3 I should allow a sufficient period of time for debate.

4 But I hope you can keep it as short as you can.

5 And Senator Toomey, if you do not feel insulted if I

6 leave while you are offering the main amendment to our

7 Mark, I am still going to go, but if --

8 Senator Toomey. Mr. Chairman, I assure you I am no

9 longer easily offended.

10 [Laughter.]

11 Should I take that as being recognized?

12 Senator Crapo [presiding]. You are recognized.

13 Senator Toomey. Thank you very much, Mr.

14 Chairman. And before you leave I do want to commend you

15 and thank you for the very hard work that you and Senator

16 Wyden have done on this -- very, very thoughtful and

17 constructive, and I appreciate that.

18 I would like to ask unanimous consent to add Senator

19 Lankford as a co-sponsor of this Toomey-Roberts Amendment

20 Number 1.

21 Senator Crapo. Without objection.

22 Senator Toomey. Thank you very much. And I want

23 to introduce this with just a little bit of context, Mr.

24 Chairman, and I am referring to the really unique, among

25 federal programs, the unique design of Medicare Part D.

1 And what I am referring to is the fact that it is based
2 on competition.

3 Plans in Part D have to compete for the business of
4 senior citizens. And one of the ways they do that is
5 they pit drug companies against each other forcing lower
6 prices for our seniors and for the government, and that
7 is integral to the design of Medicare Part D. It always
8 was. And the fact is it works. The evidence is very,
9 very clear.

10 The cost of this program have come in under budget,
11 under projection. From 2006 to 2013 spending on this
12 program was 50 percent lower than what CBO originally
13 projected, five, zero. It consistently receives very
14 high marks for our beneficiaries' satisfaction.

15 And 2019 marks the second consecutive year that
16 average Part D premiums have actually decreased. The
17 cost of the premium is going down. This was achieved
18 without government interference in negotiations, or price
19 settings, or regulating increase in prices. It was
20 achieved because of competition, and it is proven that
21 competition can work.

22 Now, I think we have all acknowledged that the Part
23 D benefit design has a problem, and the problem is there
24 is a relatively small, but certainly not insignificant
25 percentage of beneficiaries who experience catastrophic

1 unlimited out-of-pocket costs. And we all believe, I
2 think, that something has to be done about that. And
3 this bill does that.

4 We redesigned the benefit structure so that there
5 will be nobody in Medicare Part D with an uncapped
6 unlimited financial liability such as we have today.
7 That extremely expensive risk is gone because we end that
8 problem by redesigning the benefit. We put a cap at
9 \$3,100, and lower income seniors will not get close to
10 \$3,100 because they get a subsidy.

11 So that brings me to the heart of my amendment which
12 is Section 128. Section 128 imports a price control
13 mechanism from Medicaid really. And the way I think
14 about it is it is a 100% tax or penalty, depending on
15 which you prefer, on any price increase that is greater
16 than ordinary inflation.

17 Now, I am sure that is a good intention, but I think
18 it is a bad idea. And so my amendment simply strikes
19 this provision,

20 Here is why I think it is a bad idea. First of all,
21 what problem are we fixing here? We have eliminated,
22 through another provision in this bill, the catastrophic
23 cost risk to all seniors. That is gone by virtue of
24 another provision in the bill.

25 We have a program in which costs are coming in below

1 projection, and now have declining prices in the form of
2 premiums. Medicaid, itself, which has this mechanism has
3 no competition mechanism. There are no formularies.
4 There is no ability for plans to pit manufacturers
5 against each other as Medicare Part D does and uses.

6 Further, I think it is very likely that this would
7 be ineffective. Manufacturers will have other ways of
8 circumventing this intended price cap, including higher
9 launch prices and lower rebates. And those workarounds,
10 if you will, on the part of Manufacturers are inevitably
11 going to be harmful to prescription drug consumers
12 outside of Medicare without providing a benefit to
13 Medicare beneficiaries.

14 And where does this lead? Let me remind my
15 colleagues. In 1990, Congress built a very small rebate
16 into the Medicaid drug program. That is how it started.

17 Today in this underlying bill, the bill contemplates
18 modifying the cap on that rebate such that there are
19 scenarios in which a drug manufacturer could be forced to
20 actually pay the government to have a consumer use their
21 drugs. That is where this has gone.

22 My colleague from Louisiana who is very, very
23 knowledgeable, very passionate about this and I
24 appreciate his inputs. He has observed that there are
25 other circumstances in which Medicare sets prices. It is

1 true. It is also true that as a general matter we have
2 been trying to get away from that, trying to get away
3 from the fee-for-service model in which the government
4 sets prices and move, for instance, in the direction of
5 bundled payments, which dramatically reduces the
6 government's setting of prices. And we have tried to
7 introduce competition where we can.

8 Let me also acknowledge that competition is not
9 always possible, not for all drugs because sometimes you
10 get a breakthrough, a major new innovation. And a new
11 medicine is the only treatment, the only therapy. And we
12 need these new innovations. We all know that.

13 But let me also point out that that phenomenon has
14 been in existence for quite some time, and despite that,
15 we have got a program that is under budget and declining
16 in premiums.

17 So Mr. Chairman, it is my view that we should not
18 use this sledgehammer of a universal Part D price control
19 imported from Medicaid to deal with that relatively
20 narrow problem and to disrupt a model that is working
21 very, very well. And so I ask for a roll call vote.

22 Senator Wyden. Mr. Chairman, I would like to
23 respond to Senator Toomey before we go to any votes.

24 The Chairman. Yes, respond, and I am going to
25 respond too.

1 Senator Wyden. Very good.

2 So Senator Toomey has gone back to this question of
3 how this is somehow a price control. So let me ask the
4 CBO Director who is over on the end of the table. Mr.
5 Director, is the inflation rebate in Medicare Part D a
6 form of price controls?

7 Mr. Swagel. As we analyze it, we would say no --
8 that the inflation rebate provides an incentive and is a
9 factor that will affect prices, but it does not control
10 prices.

11 Senator Wyden. So, and the reason that the
12 Director makes that judgment, colleagues, is the cap here
13 does not set prices. It limits subsidies, and that is a
14 crucial distinction.

15 I am somebody who has always felt the private sector
16 should have a significant role in the delivery of health
17 care in America. So as we got into this, we said we are
18 not going to set prices, but we are going to limit
19 subsidies. And there is a very sharp difference between
20 the two.

21 I would also just like to note for the record that
22 as somebody who was supportive of Part D over the years,
23 there has not been any break on the price accelerator.
24 List prices for 100 brand name drugs that seniors take
25 every day increased over 200 percent between 2006 and

1 2017. Inflation increased only 25 percent over the same
2 period.

3 So as somebody who supports a role for the private
4 sector in health care, somebody who believes that we
5 ought to be limiting subsidies and not getting in the
6 business of trying to set prices on everything, I would
7 urge my colleagues strongly to oppose the Toomey
8 amendment, a vote to strip this critical provision out of
9 the Chairman's Mark.

10 It is just one thing folks. It keeps the pharma
11 status quo in America. It would be a big mistake. I
12 urge my colleagues strongly to vote no.

13 Senator Cornyn. Mr. Chairman? Mr. Chairman, could
14 I?

15 The Chairman. Yes, Senator Cornyn.

16 Senator Cornyn. If I can just speak to this, and
17 first ask the CBO Director if this reduces the subsidy,
18 it is a subsidy by the federal government?

19 Mr. Swagel. I am sorry. An inflation rebate
20 reduces the subsidy by the federal government. Is that
21 the --

22 Senator Cornyn. And so whose pocket? Where is
23 that cost shifted?

24 Mr. Swagel. Okay, very good.

25 So the inflation rebate, as we analyze it, will have

1 different effects. The main effect in reducing federal
2 spending will come on the existing drugs for which there
3 are not substantial rebates.

4 Senator Cornyn. Right, but does the premium that
5 somebody pays for their health insurance premium go up?
6 In other words, it has got to go somewhere. It does not
7 just go poof.

8 Mr. Swagel. No. So the price increases for those
9 drugs would be more moderated, would be slower.

10 Senator Cornyn. So that price would be borne by
11 the manufacturer?

12 Mr. Swagel. So then the premiums would go down,
13 both the premiums paid by the beneficiary, and also the
14 federal government spending would go down because the
15 federal government picks up roughly 80 percent of the
16 premiums for the Medicare Part D.

17 Senator Cornyn. Well forgive me for being so slow
18 to understand. But if you cut the subsidy, does not
19 somebody else's cost have to go up, whether it is the
20 premium somebody pays for health coverage, or their out-
21 of-pocket costs, or -- explain that to me.

22 Mr. Swagel. Yes, of course. So in this case, the
23 out-of-pocket spending would go down. The premiums would
24 go down. The federal spending would go --

25 Senator Cornyn. Everything goes down, you are

1 saying?

2 Mr. Swagel. But -- I apologize. I am doing a
3 roundabout way of getting exactly to your question. In
4 the instance you are focused on, the drug manufacturer,
5 they would see lower price increases than they might have
6 seen without this provision.

7 Senator Cornyn. So they would have to eat that
8 cost.

9 Mr. Swagel. We would see them -- as you put it --
10 eating some of that cost, and they might change their
11 overall pricing as well. There would be some mix of
12 those two.

13 Senator Cornyn. Mr. Chairman, I think there is --
14 to my mind -- sufficient uncertainty on how this would
15 actually work in reality. I would ask to be a unanimous
16 consent to be co-sponsor to the Toomey Amendment, and I
17 would urge its adoption.

18 The Chairman. Yeah.

19 There is a couple things that I want you to remember
20 about Part D. I wrote it. So you ought to know that I
21 want to protect it. I hope you also know that I have
22 great respect for the Senator from Pennsylvania, and it
23 happens that he and I agree on a subsidy limitation that
24 I have been trying to get into farm bills for the last 10
25 years and been successful in the Senate, but not

1 successful in the House of Representatives, and that is
2 the overall cap on subsidies that big farmers get from
3 the farm program.

4 However on this amendment, he and I disagree. When
5 we wrote Part D, we wanted a market-based affordable
6 option for prescription drugs for seniors and people with
7 disability. We struck the right balance in 2003.

8 However, in 2019, the taxpayers are picking up 75
9 percent of the expenditures in part D. So it is not
10 fiscally responsible to ignore this 75 percent. It is
11 time to keep what works and change what does not work.
12 This part D inflationary rebate that is included in our
13 bill is a market-based reform that shifts the
14 responsibility of managing catastrophic drug costs from
15 taxpayers to private insurers as well as manufacturers.

16 The pharmaceutical lobby calls this inflationary
17 rebate or price control, when in fact it controls
18 subsidies to manufacturers, not to prices. I oppose the
19 amendment.

20 I call on Senator Stabenow.

21 Senator Stabenow. Thank you, Mr. Chairman.

22 I oppose the amendment as well. And before a brief
23 statement about that, I want to just go back to the
24 beginning and thank you and the Ranking Member for the
25 work that is been done in committee. I do not in any way

1 underestimate the hearings that were done. That had not
2 been done a long time with pharma CEOs and PBMs, and I
3 think this has been a very important process. So I want
4 to thank you for that.

5 I just want to say that if my friend from
6 Pennsylvania thinks the process is working, I do not know
7 who he is talking to. He is not talking to anybody in
8 Michigan.

9 And according to the AARP, the average price of
10 brand-name drugs that seniors often take rose at four
11 times the rate of inflation in 2017 alone. I do not call
12 that working. People in Michigan, actually, if we want
13 to talk price controls, they would love somebody to help
14 control the prices. I would vote no.

15 The Chairman. Shall we vote?

16 Senator Wyden. Please.

17 Senator Daines. Mr. Chairman, can I quickly?

18 The Chairman. Yes.

19 Senator Daines. CBO Director, my colleague
20 mentioned competition and the role of competition. In
21 the protected classes, is there any -- what power does
22 the purchaser have to drive down cost in the protected
23 classes?

24 Mr. Swagel. It is exactly as you said before, the
25 protected classes remove the power of the insurer to

1 drive down prices.

2 Senator Daines. So there is no competition in the
3 protected classes, no ability for the purchaser to drive
4 those costs down?

5 Mr. Swagel. That is correct.

6 Senator Daines. And have we seen accelerated rates
7 of inflation in those protected classes in which there is
8 monopoly power and no ability to leverage those costs
9 down?

10 Mr. Swagel. I do not have the figures in front of
11 me, but the broad answer is yes.

12 Senator Daines. Is that -- by the way, you are an
13 economist. Is that the definition of a free market? It
14 does not sound like it.

15 Mr. Swagel. It is a complicated answer, but there
16 is a lack of power on the part of the insurers to hold
17 down costs as you put it.

18 Senator Daines. And then I will say that I think
19 my colleague and I, though, have common ground. If you
20 wish to have a secondary amendment which would eliminate
21 protected classes, I would support his bill. But the
22 degree to which his bill feeds into protected classes,
23 those sellers who have no competition and no ability for
24 the purchaser, the taxpayer, or the patient to drive down
25 the cost, therefore they can raise their cost 19 percent

1 per year compounded, that is not a free market. That is
2 exploiting the taxpayer.

3 So if he is willing to eliminate protected classes,
4 I would be for his amendment.

5 The Chairman. The Clerk will call the roll.

6 The Clerk. Mr. Crapo?

7 Senator Crapo. Aye.

8 The Clerk. Mr. Roberts?

9 The Chairman. Aye by proxy.

10 The Clerk. Mr. Enzi?

11 Senator Enzi. Aye.

12 The Clerk. Mr. Cornyn?

13 The Chairman. Aye by proxy.

14 The Clerk. Mr. Thune?

15 Senator Thune. Aye.

16 The Clerk. Mr. Burr?

17 The Chairman. Aye by proxy.

18 The Clerk. Mr. Isakson?

19 The Chairman. Aye by proxy.

20 The Clerk. Mr. Portman.

21 The Chairman. Aye.

22 The Clerk. Mr. Toomey?

23 Senator Toomey. Aye.

24 The Clerk. Mr. Scott?

25 The Chairman. Aye by proxy.

1 The Clerk. Mr. Cassidy?
2 Senator Cassidy. No.
3 The Clerk. Mr. Lankford?
4 Senator Lankford. Aye.
5 The Clerk. Mr. Daines?
6 Senator Daines. Aye.
7 The Clerk. Mr. Young?
8 Senator Young. Aye.
9 The Clerk. Mr. Wyden?
10 Senator Wyden. No.
11 The Clerk. Ms. Stabenow?
12 Senator Stabenow. No.
13 The Clerk. Ms. Cantwell?
14 Senator Cantwell. No.
15 The Clerk. Mr. Menendez?
16 Senator Menendez. Aye.
17 The Clerk. Mr. Carper?
18 Senator Carper. No.
19 The Clerk. Mr. Cardin?
20 Senator Cardin. No.
21 The Clerk. Mr. Brown?
22 Senator Brown. No.
23 The Clerk. Mr. Bennet?
24 Senator Wyden. No by proxy.
25 The Clerk. Mr. Casey?

1 Senator Casey. No.

2 The Clerk. Mr. Warner?

3 Senator Warner. No.

4 The Clerk. Mr. Whitehouse?

5 Senator Whitehouse. No.

6 The Clerk. Ms. Hassan?

7 Senator Hassan. No.

8 The Clerk. Ms. Cortez Masto?

9 Senator Cortez Masto. No.

10 The Clerk. Mr. Chairman?

11 The Chairman. No.

12 Can you announce the totals?

13 The Clerk. Mr. Chairman, the final tally is 14
14 ayes, 14 nays.

15 The Chairman. The amendment lost.

16 Next Amendment? And we are ready -- Senator
17 Stabenow.

18 Senator Stabenow. Thank you very much, Mr.
19 Chairman. And I want to thank colleagues who are co-
20 sponsoring this amendment to let Medicare negotiate.

21 Let me take you back to the debate we had on the
22 Republican tax cut. When the Republican majority on the
23 committee wrote your tax bill, you did not think it was
24 enough to just cap the rate of tax increases for Pharma
25 or for wealthy individuals. You gave them a tax cut.

1 They wanted a tax cut. And the people of our country
2 want a cut in the prices they are paying for prescription
3 drugs.

4 Now, unfortunately, pharma did not take that big tax
5 cut and lower prices for Americans. They gave their CEOs
6 and their investors \$73 billion, in a little more than a
7 year.

8 And insulin, like Novolog, did not go down. It
9 still costs over \$19,000 a year. In fact, insulin has
10 tripled in price -- tripled in the last 15 years. And
11 Humira's price was not lowered. It still costs about
12 \$50,000 a year.

13 Now the bill takes a step by slowing the future
14 increases above \$50,000. But \$50,000 is too high. The
15 good news is we have a Chairman and Ranking Member who
16 both care about this issue. And today we can actually do
17 something that will cut prices if we have the will to do
18 it, something that is supported overwhelmingly by the
19 American people.

20 Currently Medicare is prohibited, as we know, from
21 harnessing the bargaining power of 53 million American
22 seniors to bring down prescription drug costs. That did
23 not make sense when Medicare Part D became law in 2003,
24 and it certainly does not make sense today.

25 We know that negotiation works. The VA negotiates

1 prices for our veterans, and saves 40 percent -- 40
2 percent compared to what is done with Medicare.
3 According to a recent AARP analysis, Medicare could have
4 saved \$14.4 billion on just 50 drugs if it paid the same
5 price as the VA. And by the way, I want to thank the
6 AARP for supporting our amendment today.

7 Looking at this bill, the Medicare Part D inflation
8 cap in this bill saves about \$50 billion over the next 10
9 years. With negotiation, Medicare could save more than
10 \$140 billion for Americans and taxpayers over 10 years on
11 just those 50 drugs.

12 Now why is this so hard to pass? In 2018, there
13 were 1451 lobbyist for the pharmaceutical and health
14 product industry, almost 15 for every 1 of us. And I am
15 sure with the drug bill going on, all the debate, I am
16 sure it is much higher now.

17 Their job is to stop competition and keep prices
18 high, and they do a very good job of it. They won in
19 2003 when they put language in to stop Medicare from
20 being able to negotiate.

21 Sixteen years later, please do not let them win
22 again. It is time to --

23 The Chairman. Senator Menendez --

24 Senator Stabenow. -- put people before profits --

25 The Chairman. I'm sorry.

1 Senator Stabenow. Mr. Chairman, that is all right.
2 It is time to put people over profits.

3 Mr. Chairman and Mr. Ranking Member, Stabenow
4 Amendment Number 1 is as straightforward as it gets. It
5 simply allows the Secretary of Health and Human Services
6 to leverage the bargaining power of Medicare Part D
7 enrollees to lower prescription drug prices. I would
8 urge a yes vote.

9 Thank you, Mr. Chairman.

10 The Chairman. Senator Menendez.

11 Senator Menendez. Thank you, Mr. Chairman.

12 I appreciate what my colleague is seeking to do, but
13 I -- can I ask CBO a question on this? Is that part of
14 the process?

15 The Chairman. Yes, you may.

16 Senator Menendez. Yeah.

17 To Dr. Swagel, there is a letter dated May 17th,
18 2019, made out to the Chairman re negotiation over drug
19 prices in Medicare. Are you familiar with that letter?

20 Mr. Swagel. I am.

21 Senator Menendez. Okay. And is it fair to say, to
22 synthesize the letter, that what you say about
23 negotiation is that it is only likely to be effective if
24 it is accompanied by some source of pressure on drug
25 manufacturers to secure price concessions. For example,

1 authority to establish a formulary. Is that a fair
2 statement of what you said in the law?

3 Mr. Swagel. Yes, that is correct.

4 Senator Menendez. So in other words, a national
5 formulary which is what people can or cannot get access
6 to would be necessary in order for drug prices to come
7 down, particularly for the consumer. Is that a fair
8 statement?

9 Mr. Swagel. A formulary of some sort. Yes.

10 Senator Menendez. So that is a fair statement. So
11 the problem is that this amendment does not create such a
12 formulary and we have not had a national debate with
13 seniors in this country about what a formulary would be
14 and what the consequences of what you can and cannot get
15 are. And therefore, if at the end of the day our
16 exercise is to reduce prices for consumers, not just for
17 the government, and to do so, you need a formulary which
18 is a prohibition on what you can or cannot get, then I
19 think that deserves a national conversation with seniors
20 and for that reason, I will be opposing the amendment.

21 The Chairman. I want to associate myself with what
22 Senator Menendez just said. I was going to make those
23 points in my remark. I thank you very much, and I
24 associate myself with what you said about the formulary.

25 Senator Stabenow?

1 Senator Stabenow. Thank you, Mr. Chairman. I
2 just wanted to indicate this is the first step in
3 allowing the Secretary to negotiate. There will be a lot
4 of opportunity for public comment as they put together
5 the structure. I would just indicate there is not an
6 insurance plan in America or in anyone that is involved
7 in offering prescription drug medicines that does not
8 have certain rules.

9 A formula is one tool. There are other tools.
10 There are those in plans that incentivize generics.
11 There are a variety of ways to address doing this. There
12 is no plan that just basically operates with no
13 parameters or rules.

14 And so step one is to allow the authority. Step two
15 is then public rules process that the public will have a
16 lot of opportunity to be involved in. I assume it would
17 take time to do that, to figure out the best way to make
18 sure people have the medicine that they need.

19 And so, this to me is not the argument that I would
20 find persuasive. I thank you, Mr. Chairman.

21 Senator Enzi. Mr. Chairman?

22 The Chairman. Senator Enzi?

23 Senator Enzi. Mr. Chairman, we have already tried
24 that. The veterans have that kind of a program where
25 there are negotiated prices, which means if there are

1 several drugs, one is the winner. Others are not
2 available then to the veterans. So they were really
3 relieved when we did Part D. And many veterans got on to
4 Part D to get their medications because they could get
5 what their doctor and they thought were most appropriate.

6 That is also what Canada does to drive down their
7 prices. They negotiate the drug prices. They eliminate
8 some of the drugs that are available so they -- we will
9 get Canadians that come to the United States to pick up
10 some of the things that they think they prefer and need,
11 and their doctors think they need.

12 So I think it is an experiment that is already
13 failed, and I hope we do not approve it.

14 The Chairman. Senator Cardin?

15 Senator Cardin. Mr. Chairman, I thank Senator
16 Stabenow. I co-sponsor and strongly support the
17 amendment.

18 Please read what the amendment does. It eliminates
19 the prohibition in law for Medicare to be able to
20 negotiate. Can you imagine any plan manager or any
21 sponsor of a plan accepting the responsibility without
22 the ability to decide how to manage the negotiations on
23 price? That makes no sense at all.

24 We had two hearings on the PBMs, and we were all
25 kind of glazed at how they operate. As a result, there

1 have been numerous amendments filed by my colleagues for
2 more transparency on how the pharmaceutical, the benefit
3 managers operate their plans.

4 Well, give Medicare the ability to organize this in
5 a way that is in the best interest of the taxpayers of
6 this country because so much is subsidized by taxpayers,
7 but also the consumers. It is just counter-intuitive to
8 say you cannot negotiate with the full force that you
9 have.

10 If you are if you are a company trying to buy a
11 product, are you going to divide it into 10 or 15
12 different commodities to do the negotiations? Are you
13 going to negotiate collectively in order to get the best
14 price? That is all we are asking.

15 The Chairman. I think we will have three remarks
16 and then we will vote on this. I am going to -- you, and
17 then Whitehouse.

18 Senator Hassan. Mr. Chairman I also wanted to be
19 recognized if I could in order.

20 The Chairman. Okay, we will do that.

21 First of all, this issue that Senator Stabenow
22 brings up is not going to go away. There is two focal
23 points besides Senator Stabenow.

24 Number one, the House of Representatives announced,
25 I think this week, that when they come out with a plan in

1 September, it is going to be the focal point of the House
2 of Representatives. The President campaigned on exactly
3 this issue. Now thank God the President has not
4 advocated that lately, but who knows what he is going to
5 do?

6 So I kind of see what Senator Wyden and I have
7 worked out here as kind of a middle and sensible,
8 particularly common sense approach that maybe a lot of
9 people will be looking for if they want to get anything
10 done at all because I do not think that you are going to
11 get 60 votes in the United States Senate for what Senator
12 Stabenow wants to do.

13 So there is a lot of good bipartisan bicameral
14 support. This is one policy, however, out there that I
15 do not agree with. That is repealing the non-
16 interference laws.

17 I would like to explain why Congress kept government
18 out of the business of negotiating drug prices six years
19 ago as the principal architect of Part D. For the first
20 time ever, Congress added outpatient prescription drug
21 benefits to the Medicare. Adding a prescription drug
22 benefit for seniors was the right thing to do. But it
23 needed to be done in the right way, right for seniors and
24 right for the American taxpayers. By that, I mean
25 allowing forces of free enterprise and competition to

1 drive costs down and drive value up.

2 Part D has worked so I believe that the non-
3 interference laws make Part D work. So let us keep what
4 is working and fix what can be improved.

5 And I expressed my view of agreement with Senator
6 Menendez on the letter that he was -- do you realize that
7 all the programs I have been involved in in Part D, it is
8 the only one that has come in under budget. For those
9 first 10 years, 39 years under budget. It is working.

10 The Chairman. Senator Brown?

11 Senator Brown. Thanks, Mr. Chairman.

12 I speak in support of Stabenow Amendment. We all do
13 roundtables and town halls and we to various degrees
14 follow the Lincoln dictum of going out getting our public
15 opinion baths. And I do not know that I have ever met
16 anybody except for a drug company executive or a lobbyist
17 for the drug companies that Senator Stabenow talked -- or
18 a Member of Congress. I do not think I have met anybody
19 that thinks that direct negotiations on consumers behalf
20 is not a good thing. Everybody -- it is just hard to
21 find anybody out there in the public that thinks this
22 amendment is a bad idea. I mean, it is just total
23 commonsense.

24 The Chairman. Can I interrupt you?

25 Senator Brown. Certainly, Mr. Chairman. You

1 always may.

2 The Chairman. I have explained it this way. It
3 comes up in my town meetings. I kind of say you can have
4 the government negotiate, but you are going to limit
5 formulary. And I think that makes a difference.

6 If the public understands that the government is
7 going to tell you what you can buy or not buy regardless
8 of what your doctor thinks.

9 Senator Brown. Particularly, if you could have a
10 death panel making the decision, Mr. Chairman.

11 I just -- I do not get it on this amendment. It has
12 got overwhelming public support. It will clearly bring
13 prices down. It works for the VA. It works for -- it
14 works in other countries. It is agreed on among the
15 public however you explain it. It is perhaps the best
16 way to get prices down.

17 I had offered an amendment that would go further
18 than Senator Stabenow's not just to renegotiate, but to
19 negotiate with an added backstop of competitive
20 licensing. I think we could even go that far. I am very
21 happy, though, with Senator Stabenow's Amendment.

22 My competitive licensing bill would prevent a
23 formulary -- would prevent that kind of formulary. So
24 this amendment -- it is what our constituents want. It
25 will work. I ask for support of my colleagues.

1 The Chairman. Senator Hassan, and then Senator
2 Wyden, and then we will vote.

3 Senator Hassan. Thank you, Mr. Chair.

4 I want to thank Senator Stabenow for introducing
5 this amendment and indicate my support of it, and echo
6 something that Senator Brown was just saying towards the
7 end of his comments, which is that the supporters of this
8 amendment want Medicare to have the bargaining power on
9 behalf of the American taxpayers and American patients
10 that will help us lower the cost of life-saving
11 prescription drugs.

12 Some of my colleagues on the other side of the aisle
13 have indicated their concern about the limitations of
14 formularies. I have to say that I think it is a false
15 choice to say that our only options here are no
16 negotiations or a formulary that is highly restrictive.
17 We are Americans and when we put our minds to things, we
18 usually can find a third way forward that addresses these
19 concerns.

20 So I am very grateful to all the work that you and
21 the Ranking Member have done on this bipartisan package,
22 which takes very important steps forward. But I do think
23 without negotiating power for Medicare, this package is
24 lacking the single most impactful thing we could do in
25 terms of lowering prescription drug prices. That is why

1 I am supporting it but I would look forward to working
2 with Members of both parties to see if we can talk about
3 a negotiating system that also provides consumer and
4 patient choice, and I think there are ways to do that.

5 Thank you, Mr. Chair.

6 The Chairman. Senator Wyden?

7 Senator Wyden. Thank you, Mr. Chairman.

8 I want to speak in behalf of the Stabenow Amendment.

9 She has brought so much energy and passion to this
10 cause, and I so appreciate it and give my sense of where
11 I think things are to my colleagues.

12 I have made it clear that I believe the changes in
13 the Mark which are bipartisan are a helpful start to
14 reign in pharma and lower costs. But I think we also
15 have to recognize what the driving principle behind the
16 Stabenow Amendment is all about. And that is that
17 Medicare negotiating authority is a vital part of giving
18 consumers and taxpayers in America control over their
19 pharmaceutical costs.

20 Now, I already went through the fact that prices are
21 still going up in Part D, and until Medicare can leverage
22 the bargaining power of 43 million seniors to get the
23 best possible deal for the older people and for
24 taxpayers, our work is unfinished. I would urge
25 colleagues to support the Stabenow Amendment.

1 The Chairman. The clerk will call the roll.
2 The Clerk. Mr. Crapo?
3 Senator Crapo. No.
4 The Clerk. Mr. Roberts?
5 The Chairman. No by proxy.
6 The Clerk. Mr. Enzi?
7 Senator Enzi. No.
8 The Clerk. Mr. Cornyn?
9 The Chairman. No by proxy.
10 The Clerk. Mr. Thune?
11 Senator Thune. No.
12 The Clerk. Mr. Burr?
13 The Chairman. No by proxy.
14 The Clerk. Mr. Isakson?
15 The Chairman. No by proxy.
16 The Clerk. Mr. Portman?
17 The Chairman. No.
18 The Clerk. Mr. Toomey?
19 Senator Toomey. No.
20 The Clerk. Mr. Scott?
21 The Chairman. No by proxy.
22 The Clerk. Mr. Cassidy?
23 Senator Cassidy. No.
24 The Clerk. Mr. Lankford?
25 Senator Lankford. No.

1 The Clerk. Mr. Daines?
2 Senator Daines. No.
3 The Clerk. Mr. Young?
4 The Chairman. No by proxy.
5 The Clerk. Mr. Wyden?
6 Senator Wyden. Aye.
7 The Clerk. Ms. Stabenow?
8 Senator Stabenow. Aye.
9 The Clerk. Ms. Cantwell?
10 Senator Cantwell. Aye.
11 The Clerk. Mr. Menendez?
12 Senator Wyden. No by proxy.
13 The Clerk. Mr. Carper?
14 Senator Wyden. Aye by proxy.
15 The Clerk. Mr. Cardin?
16 Senator Cardin. Aye.
17 The Clerk. Mr. Brown.
18 Senator Brown. Aye.
19 The Clerk. Mr. Bennet?
20 Senator Wyden. Aye by proxy.
21 The Clerk. Mr. Casey?
22 Senator Casey. Aye.
23 The Clerk. Mr. Warner?
24 Senator Warner. Aye.
25 The Clerk. Mr. Whitehouse?

1 Senator Wyden. Aye by proxy.

2 The Clerk. Ms. Hassan?

3 Senator Hassan. Aye.

4 The Clerk. Ms. Cortez Masto?

5 Senator Cortez Masto. Aye.

6 The Clerk. Mr. Chairman?

7 The Chairman. No.

8 Announce the vote when you are ready.

9 The Clerk. Mr. Chairman, the final tally is 12
10 ayes, 16 nays.

11 The Chairman. Give it again, please.

12 The Clerk. I am sorry: 12 ayes, 16 nays.

13 The Chairman. The amendment lost.

14 Any other amendments?

15 [No response.]

16 The Chairman. Then we are ready for --

17 Okay, Senator Toomey.

18 Senator Toomey. Mr. Chairman, I think I can go
19 through this quickly.

20 We just had a big debate and a vote, and my previous
21 amendment lost on a tie with respect to striking the
22 inflation cap on Part D prices.

23 Toomey Amendment Number 4 is a little different. It
24 would prevent the Part D inflationary rebate from taking
25 effect unless and until the Secretary of Health and Human

1 Services certifies that the implementation of that
2 feature will neither increase launch prices for future
3 drugs or result in higher beneficiary cost sharing due to
4 those higher prices.

5 So clearly the intent of this legislation is not to
6 increase drug prices. It seems to me perfectly
7 reasonable to build into the legislation a guardrail.
8 Let us not impose this pricing mechanism from Medicaid
9 until we know and it is certified that it will not
10 increase launch prices.

11 And I ask for a recorded vote.

12 Senator Wyden. Has my colleague finished his
13 statement?

14 Senator Toomey. I have.

15 Senator Wyden. Okay. I just want to ask a couple
16 of basic kind of questions, and then I am going to have a
17 short statement on the Toomey Amendment.

18 Ms. Bishop, if I could, does the inflation rebate
19 interfere with negotiations between PBMs and
20 manufacturers?

21 Ms. Bishop. No. The way that the inflation rebate
22 is structured is separate from plan and PBM negotiations.

23 It is a mechanism. You can think about it as a backstop
24 to the negotiations that would be undertaken between the
25 plans and the PBM.

1 A backstop is something that works sort of on the
2 backend, obviously. So the plans and the PBMs have all
3 of the authority that they have today to negotiate
4 prices.

5 If they negotiate well, if they keep the prices
6 below inflation, then the backstop never kicks in. If
7 they do not, if they cannot keep the prices below
8 inflation, then the penalty would be applied.

9 So it is something that happens in a stacking order.
10 First a negotiation, then the penalty if the negotiations
11 do not work to keep prices below.

12 Senator Wyden. All right, I would like at this
13 point, Mr. Chairman, to make a point of order that the
14 amendment is non-germane. Therefore, it is out of order
15 under Rule 2 of the committee rules.

16 The Chairman. I agree with the Ranking Member that
17 the amendment is not germane as to out of order.

18 Senator Toomey. Mr. Chairman?

19 The Chairman. Yes.

20 Senator Toomey. I just want to briefly comment.

21 The reason -- everybody should know the reason it is
22 out of order and not germane is because CBO believes that
23 this amendment would cost money. It would diminish the
24 savings. Why would it diminish the savings? Because CBO
25 believes that the HHS Director will never be able to

1 certify that implementation of this inflation penalty
2 will not result in higher launches of drug prices.

3 So really what we are demonstrating by refusing to
4 allow a vote on this by ruling it out of order is exactly
5 the point we are making, that this inflation price cap is
6 going to result in higher drug prices in other places.

7 The Chairman. Senator Cardin.

8 Senator Cardin. Mr. Chairman, I am going to offer
9 Cardin-Cornyn Amendment --

10 Senator Wyden. We have to vote, Senator Cardin.

11 Senator Cardin. Oh, I am sorry.

12 The Chairman. He did not appeal the Chair.

13 Senator Wyden. It is ruled out of order.

14 The Chairman. Yeah. He did not --

15 Senator Cardin?

16 Senator Cardin. Thank you. That is what I thought
17 it was ruled.

18 I am going to offer Cardin-Cornyn Amendment Number
19 2. Mr. Chairman, I will not be requesting a vote, and I
20 will withdraw. But I have got to express my real
21 disappointment that this was not included in the revised
22 Mark. When I left last night, I thought it was included,
23 quite frankly. And we have had a wonderful relationship
24 with staff on these amendments. And I want to explain my
25 disappointment.

1 And I first want to thank my Republican colleagues
2 that support this. We have strong bipartisan support for
3 this amendment on the committee.

4 Senator Cornyn has been the leader on the Republican
5 side. But I also want to thank Senator Portman, Senator
6 Scott, and Senator Daines for their input and support.

7 What this amendment does is allow for the initial
8 determination on a denial to be made when the consumer is
9 denied coverage when they are at the pharmacist and are
10 ready to pick up their prescription then are told that
11 there is a denial. Under current practice, that consumer
12 subscriber needs to figure out why it was denied and take
13 that information and go through an administrative process
14 before they get to the initial determination, which means
15 they are not going to get their drugs. Pure and simple.

16 This committee understood that, and in 2014 every
17 Member that was then on the Finance Committee wrote a
18 letter to CMS about this concern to get it fixed. And
19 Mr. Chairman, I am going to ask consent that that letter
20 of 2014 be included in our record.

21 The Chairman. Without objection, so ordered.

22 Senator Cardin. So this is a commonsense
23 correction to a problem that we all have recognized. And
24 I understand things sometimes do not get covered that
25 should be covered in a Mark. I have confidence of our

1 leadership on this committee, but I just have to explain
2 I was disappointed that this was not included. And I
3 hope we will have an opportunity to correct that as this
4 process goes.

5 Senator Wyden. Mr. Chairman, if I can just very
6 quickly respond to Senator Cardin.

7 Not only do I agree with this. I mean this kind of
8 goes back to my Gray Panther roots. This is about the
9 rights of older people. We will work with you on it. As
10 you know, I was very pleased that we were able to get
11 your Shortage Amendment, the Real-time Amendment in
12 there.

13 You always understand these issues. And we will
14 work closely with you. And I think we can get some
15 version of it.

16 Senator Cardin. And I am sorry I disappointed
17 Senator Cornyn on this issue because he is been a strong
18 supporter on this. And I appreciate your help Senator
19 Cornyn.

20 The Chairman. Senator Warner?

21 Senator Warner. Mr. Chairman, I want to bring up
22 Warner-Carper-Bennett Amendment Number 2. I am not going
23 to be asking for a vote, but I want to speak to it, and I
24 also want to speak very briefly to Cortez Masto-Warner-
25 Hassan Number 8 as they both deal --

1 The Chairman. Proceed.

2 Senator Warner. Thank you. I appreciate the good
3 work you have both done.

4 I actually do believe that some of the issues that
5 Senator Toomey raised on his previous amendment have some
6 validity. I think the inflationary cap is a good tool,
7 but -- and that will take -- and it will limit price
8 increases on already existing formulary drugs or one-off
9 drug, but because of this inflationary cap, as new drugs
10 come to market, there will be pressure for the drug
11 companies because they will not be able to go forward and
12 raise their prices over a period of time to launch price
13 at a much higher price.

14 But I think that is something we need to take on,
15 and I would hope the Chairman and the Ranking Member
16 would work with me and others on this issue.

17 One of the things that we have in our circumstances
18 right now is there is absolutely no limitation at all on
19 launch prices for any drugs. And remarkably, we have no
20 system at all, as well, to ever evaluate the efficacy of
21 new drugs that come to market. So what Warner-Carper-
22 Bennet Amendment Number 2 would do is it would put in
23 place a procedure -- a procedure that is used in other
24 industrial nations that would allow -- and other Members
25 on the Republican side have talk with this. And again, I

1 hope we continue to work on this issue that would allow a
2 drug manufacturer to put out a launch price, but within
3 some period of time, six months, a year, there would then
4 be a review were an independent body would look at the
5 efficacy of that drug and put a price on it.

6 If the drug company then decided they did not like
7 that price point, there would be an arbitration process.
8 Other industrial nations have used this without a loss of
9 other drugs coming to market, without any decrease in
10 drugs coming to the market.

11 I think what we have taken a great step forward here
12 in this bill, but if we do not grapple with the launch
13 price issue, the savings we get on the inflationary cap
14 may come back to bite us on the new launch prices. So I
15 hope, Mr. Chairman, that we would work on this issue on a
16 going-forward basis.

17 And then I would simply add one other comment, and
18 that is that the Cortez Masto-Warner-Hassan Number 8. It
19 looks well at this launch price issue, and it simply says
20 -- and I was disappointed this was not included in the
21 Chairman's Mark because it said even if you do not want
22 to go as far as what I have suggested, and Senator
23 Bennet, and Senator Carper, it would say we ought to have
24 GAO study the launch price issue because I do think by
25 the good work that the inflation caps are putting in

1 place in this legislation, we are going to create a new
2 impetus for drug companies to offer much higher launch
3 prices. And would hope we would have at least had a GAO
4 study on that.

5 So I am not going to ask for a vote on my amendment,
6 but I would hope the Chairman and Ranking Member would
7 work with me on this issue.

8 The Chairman. Yes, we will.

9 Senator Lankford?

10 Senator Lankford. Mr. Chairman, I am also offering
11 an amendment. I am going to withdraw it, but I do hope
12 we can work on it between now and the floor. This is
13 something that Senator Menendez, and I, and Senator
14 Cardin, and Daines have worked on and that deals with
15 tiering of brands and generics.

16 This is something that came up in the hearings that
17 I had the opportunity to be able to ask some of the drug
18 companies about and they sheepishly said we do not know
19 what you are talking about on tiering, but in reality
20 tiering is a very significant issue.

21 When new generics are put on branded tiers, that
22 drives up the cost for people on Medicare Part D. To
23 give you an example of this, in a recent study Part D
24 plans had the generic drugs placed in the lowest cost-
25 sharing tier, preferred generic only 14 percent of the

1 time in 2016 to 2019. There is an area where they are
2 continuing to place specialty generic medicines on one
3 formulary for specialty drugs, again driving up the cost
4 for seniors based on where they selected.

5 This is how significant this issue is. A recent
6 study that was done found that if we change this tiering
7 issue and said the generics have to go on the generic
8 tier, it would save consumers \$22 billion in out-of-
9 pocket costs.

10 Now understand this has been something that we
11 raised, that there has not been time for CBO to be able
12 to finish the scoring on, and we are going through that
13 process. But with a \$22 billion out-of-pocket savings
14 for consumers, we think this is exceptionally important
15 to be able to bring to the final product, and we hope to
16 be able to move this conversation, and to get CBOs final
17 scoring on it so we can actually get this done for the
18 final piece.

19 So with that, I would withdraw it and hope to get it
20 including the final.

21 The Chairman. Yeah, and you asked us to work with
22 you and --

23 Senator Lankford. Yes, sir. We have.

24 The Chairman. Senator Roberts for 20 seconds, and
25 then Senator Young.

1 Senator Wyden. After Senator Roberts, if we could
2 go to Senator Brown, and then Senator Young.

3 The Chairman. No. I have got to call on Senator
4 Young before Senator Brown.

5 Senator Brown. It is all right.

6 The Chairman. Senator, go ahead for 20 seconds,
7 Roberts.

8 Senator Roberts. Twenty seconds.

9 The Chairman. That is what you told me you wanted.

10 Senator Roberts. I have never done that in my
11 life.

12 I have four amendments. I am going to withdraw
13 them, but I want to especially mention the orphan drug
14 industry, the requirement in Section 141, the drug
15 manufacturers submit a justification for a new drug for
16 launch prices above a threshold.

17 I am worried that we are going to have a public
18 shaming list that dissuades pharmaceutical companies to
19 bring up orphan drugs to market they are in the special
20 class.

21 Thank you.

22 The Chairman. Thank you.

23 Senator Young, and then Senator Brown.

24 Senator Young. Well, Mr. Chairman, I too want to
25 offer my sort of laudatory comments towards you and your

1 leadership on this whole endeavor. It is really
2 important.

3 There has been six months of bipartisan
4 negotiations. That encourages me. I commend all the
5 staff and stakeholders who have been party to those
6 conversations. I commend our President as well for
7 elevating this issue, and making it a priority, and for
8 having his team engage on this issue.

9 But I do want to publicly indicate that I have -- to
10 put it mildly -- concerns about the process. In the
11 Chairman's defense, he is following the precedent of this
12 committee. And I am a new Member of this committee.

13 But the process surrounding today's Markup, we were
14 given 48 hours to review what is a very complex issue. I
15 have not had the opportunity to read all this. Then we
16 have got the amendments. You know, there is a lot of
17 stuff here.

18 And I promised Hoosiers I would make a thoughtful
19 and informed decision as it relates to matters of great
20 consequence. This certainly falls in that category.

21 So I could not fully digest all this. Some of my
22 colleagues are really quick studies and no doubt
23 penetrated much of it, and they are building on a base of
24 knowledge that maybe I do not enter this discussion with.
25 Although I did spend four years -- I would note -- on the

1 Ways and Means Committee, and the process was different.
2 And I would suggest that perhaps we could learn from
3 that.

4 Secondly, this markup is about concept, this is a
5 concept bill, again per precedent. It is not actual
6 legislative text. I think that will surprise a lot of
7 members of government, to say nothing of members of the
8 public. This is how we do business, not an indictment
9 and on our leadership -- not an indictment. They are
10 following precedent of this committee, and we need to
11 empower them to adopt different rules if we want to
12 affect change. That is why I feel the need to vocalize
13 this important structural and procedural issue. Bad
14 process oftentimes leads to a bad work product.

15 This has not been fully analyzed by the
16 Congressional Budget Office, so we are just speculating
17 about the impact this is going to have on out-of-pocket
18 costs for consumers, which is really what this whole
19 endeavor is about. So because of this lack of
20 information, it is questionable to me, just in in full
21 disclosure, exactly what the impact will be.

22 The Part D cost-sharing changes are an important
23 first step as I see it to reducing costs for seniors. It
24 is a small step. It helps a very small group of seniors,
25 and that is not enough to get me to a yes. We need to be

1 helping millions more of our seniors in the Medicare Part
2 D program who really need help with rising prescription
3 drug costs. And that has been articulated by so many of
4 my colleagues on both sides of the aisle here today.

5 So it is difficult to go into this Markup so
6 uninformed of the real-life impact of these proposals
7 while recognizing that we might be missing a really
8 valuable opportunity to come up with a better work
9 product because our leaders have been handy-cuffed by
10 this precedent of this committee.

11 So I am a tentative know today, but if you will give
12 me a bit more time, I can explain how we can get to "yes"
13 in the course of my time, and it will be very short. I
14 promise to keep it brief, Mr. Chairman.

15 So I do have some substantive -- I have some
16 substantive concerns that I would like to engage in a
17 colloquy with the Chairman about because I think we can
18 do better in coming weeks as we look to -- shall we say --
19 - sand and polish this conceptual draft. And so I am
20 prepared to vote yes today to keep the process moving
21 forward. So it would be a provisional yes for final
22 passage if the following two things are addressed, and
23 they have been at least alluded to by my colleagues.

24 So one pertains to the catastrophic phase of the
25 benefit. I think we need to spread the rebate across the

1 entire benefit design so it does not disproportionately
2 fall on those who serve patients, seniors, and other
3 Americans with rare diseases. That is the first issue.
4 I like a commitment for the Chairman to address in coming
5 weeks as we look to improve this model that we are voting
6 on today.

7 The Chairman. Well, you can count on me and I
8 think -- I had a conversation with Senator Wyden on this.
9 We are willing to work with you on that issue.

10 Senator Young. That is fantastic. If I was not
11 privy to that back and forth, it is because I was down
12 voting on the world's worst famine since the 1950s in the
13 country of Yemen.

14 So the second issue pertains to rebates, the rebate
15 pass-through. I want the savings that the government is
16 realizing from this, which is, and I think we have
17 counted a \$100 billion figure. Maybe it is more. Maybe
18 it is less. But those need to be spread broadly across
19 the Part D program so they can specifically get at my
20 concerns about making sure that all seniors are able to
21 enjoy lower out-of-cost prescription drug costs, as
22 opposed to using that revenue to be spent on other
23 important priorities of this committee or elsewhere.

24 The Chairman. I have talked to the Ranking Member
25 about that. You also have the advantage that the

1 Administration is working on exactly the same thing you
2 are talking about. Now I do not know what the
3 Administration wants to do interacting with us. But at
4 least there is interest in the Administration on the
5 point that you want to accomplish.

6 Senator Young. I am very encouraged. I am not
7 surprised by the Chairman's flexibility and desire to
8 make continuous improvements on this.

9 Thank you for indulging me on this and that is
10 enough to earn my support here today.

11 The Chairman. Senator Brown?

12 Senator Brown. Yeah, thank you, Mr. Chairman.

13 A piece of advice to my friend Todd Young, to come
14 in here and question the Chairman and the process and say
15 that the Ways and Means Committee did it better than
16 Finance might mean that Senator Young is going to be
17 sitting at the children's table for a few more years.

18 [Laughter.]

19 Senator Brown. Anyway --

20 Senator Young. It will be a hell of a lot more
21 powerful children's table --

22 Senator Brown. Perhaps.

23 Senator Young. Yeah, thank you.

24 Senator Brown. I would like to call up, and then I
25 will call and withdraw, but I have a question for the

1 Chair and the Ranking Member.

2 I call up Brown Amendment Number 10, co-sponsored by
3 Senators Cassidy, and Carper, and Lankford, and Hassan,
4 and Daines. The Amendment is based on a bipartisan bill
5 I introduced yesterday with Senators Kennedy and Tester -
6 -

7 The Chairman. Can we pay attention to Senator
8 Brown, please?

9 Senator Brown. Thank you, Mr. Chairman.

10 We introduced with Senators Cassidy, Tester, Kennedy
11 and Cassidy the Fair Relief Act. This amendment would
12 place a temporary freeze on DIR fee clawbacks, helping to
13 lower cost at the pharmacy counter for patients while
14 providing certainty to community pharmacies in Ohio and
15 elsewhere.

16 It would requires CMS to develop standardized
17 pharmacy quality metrics strength and PBM transparency
18 measures, something we all want to do as we learn more
19 and establish reporting and auditing system. I
20 appreciate the inclusion of the standardized quality
21 program part of our amendment into the revised Mark. I
22 am still concerned we fail to address the issue of DIR
23 fees and PBM clawbacks as part of the package.

24 We also have not done anything to require PBMs
25 provide the negotiated price at the point-of-sale on this

1 committee Mark. This amendment would make these
2 improvements. You addressed it, Mr. Chairman, as did
3 Senator Wyden in your opening remarks. Fixing clawbacks
4 is a huge priority for so many of us on this committee on
5 both sides of the aisle.

6 My question does to the Chairman and the Ranking
7 Member, can we clarify we have a commitment from both of
8 you to continue working with all of us until we find a
9 way to provide real relief to community and specialty
10 pharmacists, and patients at the counter and DIR, not
11 just rebates, and do this as soon as possible?

12 The Chairman. The answer is yes. And let me agree
13 with you that it is utterly irresponsible for
14 particularly these community pharmacist to get a bill at
15 the end of the year that they got to pay back a bunch of
16 money.

17 Senator Wyden. Absolutely. I was just in several
18 in rural Oregon. On the front lines of rural health care
19 you really have the community pharmacists. They are the
20 one who know the seniors. Absolutely essential do what
21 Senator Brown is talking about.

22 Senator Brown. I withdraw Amendment 10.

23 The Chairman. Okay.

24 I have to go to Toomey, and then Hassan, and then
25 Portman, if I can remember how I just said that.

1 Go ahead.

2 Senator Toomey. And I am happy to report this is
3 the last recorded vote I am going to be asking for among
4 amendments today.

5 But thank you, Mr. Chairman, I would like to ask
6 unanimous consent to include Senator Lankford as a co-
7 sponsor, and this is an amendment that would prohibit the
8 finalizing an implementation of the International Price
9 Index Model for Part B drugs that has been proposed.

10 Look, I think it is a fact our constituents
11 subsidized drug consumption of people from other
12 countries. And the President has been quite right to
13 focus on this as a problem because it is a problem, and
14 it is not fair.

15 I suspect that there is wide agreement that we have
16 got to find a way to deal with this issue of foreign
17 freeloading off our higher prescription drug prices.
18 That being said, I do not think that the proposed
19 International Price Index ought to be the solution to
20 this problem.

21 First of all, the effect of this model, the proposed
22 International Price Index Model is to import the foreign
23 price controls of countries that restrict access to
24 drugs. And let us be clear who some of these countries
25 are. More than half of the proposed reference countries

1 have GDPs that are less than 5 percent of America's GDP.
2 It includes countries like the Czech Republic, Portugal,
3 Greece, Slovakia.

4 These countries simply do not have comparable health
5 care systems. They certainly do not have anything like
6 the innovative research and development and discovery in
7 the life sciences and prescription drug space that we do.

8 It is their goal to get their drug prices to converge as
9 closely as possible to the marginal cost of production
10 without any regard for all of the research and
11 development, which is a necessary precondition for every
12 new drug.

13 I am also very doubtful that this mechanism would
14 actually achieve the price parity between the U.S. and
15 foreign countries that we would all prefer to see. It is
16 unlikely, I think that this program would spur systemic
17 changes in the way foreign countries price their drugs.
18 It is hard for me to believe that former Soviet Bloc
19 countries have either the resources or the will to raise
20 the prices that they pay for pharmaceuticals. So I think
21 manufacturers would simply stop selling in those places,
22 and that would eliminate the effect of this of this
23 index.

24 Look, I think we do need to address this. I think
25 the way to address this problem is through trade

1 negotiations. This should be a very high priority of
2 this Administration, and I hope it will be.

3 Mr. Chairman, you have made it clear repeatedly that
4 you are at least a skeptic about the International Price
5 Index, and while we are doing other constructive things
6 in this legislation like redesigning the Medicare benefit
7 structure and Part D that will lower costs for consumers,
8 I do not think this is a good idea, and so I would ask
9 for a recorded vote.

10 Senator Wyden. Mr. Chairman, as I understand it,
11 we will both have very quick comments on the Toomey
12 Amendment, then we will vote on the Toomey Amendment, and
13 we will go to final passage. Is that acceptable to you,
14 Mr. Chairman?

15 The Chairman. It is --

16 Senator Cornyn. No. I do not believe you
17 recognized some other Senators before we go to final
18 passage, briefly.

19 The Chairman. Okay, then if there is objection,
20 then we will proceed that way.

21 Let me first of all speak that Senator Toomey has
22 correctly stated my concern about the policy that he
23 wants to have in his amendment. I have stated that in
24 regard to suggested rulemaking by the Administration, but
25 I am going to still oppose his amendment at this point

1 because I just think that I do not want to get this issue
2 wrapped up with all the other stuff we are trying to
3 accomplish here.

4 Senator Wyden. Mr. Chairman, just very quickly.
5 When we had our hearing with the manufacturers, I asked
6 the pharma CEOs if they made a profit, a significant
7 profit in Western industrialized nations that pay far
8 less for their medicine. They said yes.

9 So this is a very, very serious problem. I support
10 our country getting the best deal. I will be voting
11 against Toomey Amendment.

12 Senator Cassidy. Mr. President?

13 The Chairman. Yeah, go ahead.

14 Senator Cassidy. I will say that probably I may
15 have been the first to start talking about the sort of
16 IPIs on my website. It does not lower health care costs,
17 but I will be supporting my fellow Senator on this. I
18 say this because the last rule as I saw constructive was
19 self-referential. It referenced countries that
20 referenced us, which we referenced back. So it is going
21 to be a spiral downward as is currently constructed.

22 I also think that there is some other ideas that I
23 think would be a little bit more effective at controlling
24 that initial launch price. I am interested in working
25 with my colleagues on that. So I will support it.

1 The Chairman. The Clerk will call the roll.
2 The Clerk. Mr. Crapo?
3 Senator Crapo. Aye.
4 The Clerk. Mr. Roberts?
5 The Chairman. Aye by proxy.
6 The Clerk. Mr. Enzi?
7 Senator Enzi. Aye.
8 The Clerk. Mr. Cornyn?
9 The Chairman. Aye by proxy.
10 The Clerk. Mr. Thune?
11 Senator Thune. Aye.
12 The Clerk. Mr. Burr?
13 The Chairman. No by proxy.
14 The Clerk. Mr. Isakson?
15 The Chairman. Aye by proxy.
16 The Clerk. Mr. Portman.
17 The Chairman. Aye by proxy.
18 The Clerk. Mr. Toomey?
19 Senator Toomey. Aye.
20 The Clerk. Mr. Scott?
21 The Chairman. Aye by proxy.
22 The Clerk. Mr. Cassidy?
23 Senator Cassidy. Aye.
24 The Clerk. Mr. Lankford?
25 Senator Lankford. Aye.

1 The Clerk. Mr. Daines?
2 Senator Daines. Aye.
3 The Clerk. Mr. Young?
4 Senator Young. Aye.
5 The Clerk. Mr. Wyden?
6 Senator Wyden. No.
7 The Clerk. Ms. Stabenow?
8 Senator Stabenow. No.
9 The Clerk. Ms. Cantwell?
10 Senator Cantwell. No.
11 The Clerk. Mr. Menendez?
12 Senator Wyden. No by proxy.
13 The Clerk. Mr. Carper?
14 Senator Carper. Aye.
15 The Clerk. Mr. Cardin?
16 Senator Cardin. No.
17 The Clerk. Mr. Brown.
18 Senator Brown. No.
19 The Clerk. Mr. Bennet?
20 Senator Bennet. No.
21 The Clerk. Mr. Casey?
22 Senator Casey. No.
23 The Clerk. Mr. Warner?
24 Senator Warner. No.
25 The Clerk. Mr. Whitehouse?

1 Senator Whitehouse. No.

2 The Clerk. Ms. Hassan?

3 Senator Hassan. No.

4 The Clerk. Ms. Cortez Masto?

5 Senator Cortez Masto. No.

6 The Clerk. Mr. Chairman?

7 The Chairman. No.

8 The Clerk. Mr. Chairman, the final tally is 14
9 ayes, 14 nays.

10 The Chairman. The amendment lost on a tie vote.

11 I think this is your -- Senator Hassan, Senator
12 Cornyn -- do you have an amendment?

13 Senator Hassan. I just wanted to offer and
14 amendments and speak briefly to two of them.

15 The Chairman. The way my staff has it lined up, I
16 will call on Cornyn and then Hassan.

17 Senator Cornyn. I would defer to Senator Hassan.
18 Senator Hassan. Thank you, Senator Cornyn.

19 I just wanted to, first of all, thank you, Mr. Chair
20 for including Hassan Number 4 in the Mark-up. I will
21 offer and withdraw Hassan 1, 2, 3, 5, 6, 7, 8, 9, and 10.

22 I did want to speak to Hassan Number 7 which would
23 be mandatory reporting of charitable contributions by
24 opioid manufacturers. We have all read the stories of
25 opioid manufacturers using deceptive and appalling

1 marketing tactics to increase opioid prescribing. And
2 these tactics have fueled the epidemic that is
3 devastating communities around our country.

4 We have seen the activities of these charitable
5 organizations from building museums to sponsoring events
6 and paying advocacy organizations. Thanks to the open
7 payments database championed by Chairman Grassley, we
8 know how much money opioid manufacturers give to
9 prescribers, and researchers have begun to use that
10 information to look at how this money may have influenced
11 prescribing over the years.

12 We also know, thanks to the oversight work of
13 Chairman Grassley and Ranking Member Wyden, that there
14 are conflicts of interest between some advocacy
15 organizations, pain associations, and opioid
16 manufacturers. Yet, we have no way to determine
17 consistently and specifically where those conflicts of
18 interest exists.

19 Requiring these financial relationships to be
20 disclosed is a commonsense step to help root out these
21 conflicts. This amendment which Senator Whitehouse has
22 joined me on would be an important addition to the
23 comprehensive approach that this committee and this body
24 has taken to combat the opioid crisis. I am hopeful it
25 can be included in this package before it moves to the

1 senate floor.

2 And on Amendment 10, which I offered with Senators
3 Cortez Masto and Brown, ensuring beneficiaries certainty
4 in Part D during the benefit redesign, that is simply an
5 amendment intended to make sure that as we transition
6 under the terms of this bill that insurers do not abuse
7 utilization management in a way that would impact
8 beneficiaries who already have prescriptions that have
9 been pre-authorized. We want those pre authorizations to
10 stay in effect during benefit redesign to ensure
11 stability and certainty for people who need these life-
12 saving drugs.

13 Thank you very much, Mr. Chair.

14 The Chairman. Okay, thank you.

15 Now Senator Cornyn, and -- you have an amendment
16 too?

17 [Response of mic.]

18 The Chairman. Okay.

19 Senator Cornyn.

20 Senator Cornyn. Thank you, Mr. Chairman. I will
21 try to be brief, and I am not going to ask for a vote on
22 the amendment.

23 But I do want to point out that the Chairman's Mark
24 includes a redesign of Medicare Part D that would cap
25 out-of-pocket costs for beneficiaries, but pour more

1 liability on the drug manufacturers during catastrophic
2 coverage. This will benefit seniors, no doubt, but I
3 have heard some concerns that the redesign may cause
4 access issues for patients with severe mental illness.

5 According to the National Alliance for Mental
6 illness, the majority of Medicare beneficiaries with
7 serious mental illness or low-income subsidy and dual-
8 eligible who are not subject to the coverage gap and have
9 durable protections from high cost-sharing, the shift in
10 manufacturer liability will be applied across both the
11 low-income subsidy and non-low income subsidy
12 populations. And there are concerns that this change
13 will have a disproportionate impact on particular
14 therapeutic areas with heavy prescribing to low-income
15 subsidy and dual-eligible individuals. This includes
16 antipsychotics where most of the innovation is done by
17 smaller more specialized company.

18 So the Cornyn-Portman-Menendez Amendment would
19 authorize the Secretary to modify a manufacturers'
20 liability in the catastrophic phase if the current
21 manufacturers' liability of 20 percent would threaten
22 access to treatments for people with serious mental
23 illness or other disabilities. This would preserve
24 access to this vulnerable population and ensure that we
25 are not negatively impacting innovation.

1 As I said, Mr. Chairman, I do not intend to offer
2 the amendment, but I did want to lay that down as a
3 marker and take you up on your offer to continue to have
4 a conversation before this bill comes to the floor to
5 address this concern.

6 The Chairman. Before I go to Senator Portman, this
7 is what I would like to do. I would like -- because
8 people are getting anxious to get out of here. I would
9 like to have a vote on final passage, and then I and
10 Senator Wyden will stay around to get into the record
11 everything anybody wants to say on their amendment for
12 withdrawal.

13 Is there any objection to going to final passage?

14 [No response.]

15 The Chairman. The clerk will call the roll.

16 The Clerk. Mr. Crapo?

17 Senator Crapo. No.

18 The Clerk. Mr. Roberts?

19 The Chairman. No by proxy.

20 The Clerk. Mr. Enzi?

21 Senator Enzi. No.

22 The Clerk. Mr. Cornyn?

23 The Chairman. Aye by proxy.

24 The Clerk. Mr. Thune?

25 Senator Thune. No.

1 The Clerk. Mr. Burr?
2 The Chairman. No by proxy.
3 The Clerk. Mr. Isakson?
4 The Chairman. No by proxy.
5 The Clerk. Mr. Portman.
6 The Chairman. Aye by proxy.
7 The Clerk. Mr. Toomey?
8 Senator Toomey. No.
9 The Clerk. Mr. Scott?
10 The Chairman. No by proxy.
11 The Clerk. Mr. Cassidy?
12 Senator Cassidy. Aye.
13 The Clerk. Mr. Lankford?
14 Senator Lankford. No.
15 The Clerk. Mr. Daines?
16 Senator Daines. Aye.
17 The Clerk. Mr. Young?
18 Senator Young. Aye.
19 The Clerk. Mr. Wyden?
20 Senator Wyden. Aye.
21 The Clerk. Ms. Stabenow?
22 Senator Stabenow. Aye.
23 The Clerk. Ms. Cantwell?
24 Senator Cantwell. Aye.
25 The Clerk. Mr. Menendez?

1 Senator Menendez. Aye.
2 The Clerk. Mr. Carper?
3 Senator Carper. Aye.
4 The Clerk. Mr. Cardin?
5 Senator Cardin. Aye.
6 The Clerk. Mr. Brown?
7 Senator Brown. Aye.
8 The Clerk. Mr. Bennet?
9 Senator Bennet. Aye.
10 The Clerk. Mr. Casey?
11 Senator Casey. Aye.
12 The Clerk. Mr. Warner?
13 Senator Warner. Aye.
14 The Clerk. Mr. Whitehouse?
15 Senator Whitehouse. Aye.
16 The Clerk. Ms. Hassan?
17 Senator Hassan. Aye.
18 The Clerk. Ms. Cortez Masto?
19 Senator Cortez Masto. Aye.
20 The Clerk. Mr. Chairman?
21 The Chairman. Aye.
22 Senator Scott wants to vote as in person.
23 What is your vote?
24 Senator Scott. Thank you, sir. No, sir.
25 The Clerk. Mr. Chairman, the final tally is 19

1 ayes and 9 nays.

2 The Chairman. The bill will be reported to the
3 floor.

4 Senator Portman?

5 Senator Portman. Thank you, Chairman.

6 As I said during my opening comments, I do have some
7 concerns about aspects of the legislation. But I think
8 it is also important to move something forward and
9 therefore voted aye.

10 The Chairman. If people are going to leave, can
11 they leave quietly so we can hear Senator Portman.

12 Senator Portman. One of the concerns I raised in
13 the opening was what Senator Cornyn just talked about.
14 And I support his Amendment strongly because there are
15 some companies that tend to be smaller companies that
16 have very expensive drugs, particularly with regard to
17 people who have mental health illnesses. And I think
18 there is a potential concern about that catastrophic
19 level on the reorganization. So thanks to Senator Cornyn
20 for working with me, Senator Menendez, and others on
21 that.

22 I also want to thank you for including Portman 2 in
23 the Mark. This comes out of work Senator Carper and I
24 did with regard to Evzio, which is a miracle drug that
25 reverses the effects of opioid addiction, opioid

1 overdoses. But the cost had gone up dramatically. It
2 was because of these third-party reimbursement hubs, and
3 we have now addressed that in this amendment, and I
4 appreciate you including that.

5 And Senator Carper may want to talk about that
6 later, but it was a scandal. And I think this is one
7 example where we can do it -- it might be a relatively
8 narrow issue, but can really help.

9 Finally, I want to offer and then withdraw an
10 amendment with regard to the rebates. We talked about
11 this earlier, and I think there is agreement, at least
12 among you and the Ranking Member, Mr. Chairman, that we
13 should get these rebates back to consumers.

14 The Administration had attempted to do that, and
15 there were a couple problems. One, legislation is
16 required probably to do what they wanted to do in terms
17 of the 100 percent. Second, there were a lot of
18 questions about the increase, particularly in premiums,
19 and the cost to the government. But I think CBO would
20 agree that the premium issue is the one that really
21 created a bigger problem.

22 So here is my recommendation. Instead of 100
23 percent, let us start with 20 percent. Let us do 20
24 percent in our legislation. When we get to the floor, we
25 have a chance to talk about this more back to the

1 consumer. Let us get started on this. That would be a
2 minimum threshold. It would also give the Administration
3 the tools they need legislatively to be able to do this
4 and not raise premiums. And I think there is an
5 opportunity here if we are to adopt this amendment on the
6 floor to make a huge difference in terms of lowering out-
7 of-pocket costs, which is the big issue that I hear back
8 home.

9 So that is the amendment. I know it is not germane
10 today, but I also know that it is one that you have an
11 interest in as does the Ranking Member, and I hope we can
12 move forward on a sensible practical way to get some of
13 these rebate savings back down to consumers.

14 The Chairman. Thank you very much.

15 Now, Senator Burr.

16 Senator Thune. Mr. Chairman, I ask unanimous
17 consent to be recorded as a no in person.

18 The Chairman. Senator can be because it does not
19 change the results of the vote. You will be recorded
20 that way.

21 The Chairman. Senator Carper, and then you Senator
22 Brown.

23 Senator Carper. Yeah, I want to just comment very
24 briefly on the comments from Senator Portman. I always
25 enjoy working with Senator Portman and his team and

1 appreciate very much the work that we have done together
2 on this point.

3 Mr. Chairman, I remember -- I do not know if it was
4 a bipartisan teleconference call, or it was just
5 Secretary Azar talking with Democrats. I just do not
6 remember.

7 But I remember about a year ago being on a
8 conference call with the Secretary of Health and Human
9 Services, and he shared with us, all the Senators on the
10 call, an overview of maybe 30 ideas that they had come up
11 with within the Department of Health and Human Services
12 to get better health care results for less money.

13 And one of the only ideas that he seemed to be
14 especially taken with was with respect to
15 pharmaceuticals. It was an issue involving point-of-
16 sales rebates -- point-of-sale rebates from drug
17 companies to patients. And he described his 30 ideas as
18 a lot of singles, some doubles, a couple of triples, and
19 one or two homeruns. He thought this one was a homerun.

20 And I think it is in an idea -- I am told that you
21 have some interest in, the Majority, as does the Minority
22 led by Senator Wyden. But according to Secretary Azar,
23 passing drug company rebates to patients at the pharmacy
24 counter is one of the best ways we can bring down out-of-
25 pocket costs for seniors.

1 And this change would also inject some badly needed
2 transparency into our convoluted drug pricing system, and
3 I would urge us to keep working at this idea between now
4 and the time the bill comes to the floor, point-of-sale
5 rebates to directly lower drug costs for seniors at the
6 pharmacy counter. That is one.

7 Second issue I would like to mention deals with
8 insulin price. There is a piece of legislation,
9 bipartisan legislation whose sponsors include Senator
10 Shaheen, myself, I think Senator Collins. And it is
11 called the Insulin Price Reduction Act. I like
12 harnessing market forces, and I like using market forces
13 where they work. Where they do not work, I like to find
14 something that does work.

15 But for more than 30 million Americans living with
16 diabetes, insulin is as we know life-saving and essential
17 to remaining healthy. Last week, as I said, I joined
18 Senator Shaheen, Collins, and Cramer in introducing a
19 bill. It was called the Insulin Price Reduction Act to
20 ensure that insulin is affordable for all Americans with
21 diabetes and their families.

22 This bipartisan bill rolls back over a decade of
23 list price increases for insulin, decreasing prices for
24 the most popular insulins by about 75 percent. And I
25 would just say to our Chair and Ranking Member, I believe

1 you share the priority of lowering the price of insulin
2 and other drugs at the pharmacy counter for patients.

3 I hope we can continue to work with you, the
4 sponsors of our bills, to ensure that insulin is
5 affordable for the millions of Americans who are
6 dependent on this drug. Thank you.

7 The Chairman. Before I go to Brown and then
8 Cassidy, I have got to ask your consent that the staff be
9 granted authority to make technical, conforming, and
10 budgetary changes. And without objection, it is so
11 ordered.

12 Senator Brown and then Cassidy.

13 Senator Brown. Thank you, Mr. Chairman.

14 I will be brief. I know that Senator Cassey and
15 others want to move too. I want to raise Brown Amendment
16 2 based on my Stop Price Gouging Act legislation I
17 introduced earlier this year with Senator Gillibrand of
18 New York.

19 While the Chairman's Mark is a good bipartisan bill,
20 it is not a substitute for other measures like government
21 price negotiation, as we discussed, ending price spikes
22 for everyone, curbing drug corporations monopoly power,
23 as Senator Whitehouse talked about. Brown Amendment 2
24 takes the Chairman's Mark a step further and creates a
25 penalty for companies that engage in price gouging, not

1 just in Medicare and Medicaid, but across the entire U.S.
2 prescription drug market.

3 The amendment is simple. It would require drug
4 companies to report increases in drug prices, and to
5 justify the increase.

6 Second, it would penalize drug companies that engage
7 in unjustified price increases with financial penalties
8 proportionate to the price spike. The purpose of
9 medicine is to help people, not to line the pockets of
10 drug company big pharma executives. Too many hardworking
11 Americans still struggle to afford the medicine they need
12 as we know. Often, the culprit is price gouging by some
13 of the largest pharmaceutical companies. It has to stop.

14 My Amendment would end this predatory practice.

15 And Mr. Chair, I will withdraw the amendment, but
16 hope that it can precipitate more discussion.

17 The Chairman. Thank you.

18 Now, Senator Cassidy.

19 Senator Cassidy. Mr. Chairman, I speak to Cassidy
20 Number 5. It is about value-based pricing. We are
21 trying to find ways to make new drugs more affordable,
22 and this amendment would allow for a cost-neutral
23 demonstration from CMS allowing commercial value-based
24 arrangements, exempting them from Medicaid best price
25 requirements.

1 I understand that it is the other side of the aisle
2 that does not want this amendment. So I enter for the
3 record a statement from John Gruber, so-called architect
4 of the Affordable Care Act. "We are about to enter an
5 era of unprecedented treatment for rare disease and
6 unprecedented prices. To ensure access to all who need
7 it, it is critical that we develop innovative new pricing
8 models that spread payments and share risk between drug
9 manufacturers and payers. This proposal is an important
10 step forward in that direction."

11 That was also a statement from Mark Trusheim, a free
12 market MIT Economist. So with a commitment from the
13 Chairman to work on ensuring we can pay for life-saving
14 therapies in the future, I withdraw and move to Cassidy
15 Number 1

16 Right now, Medicare Part B payers do not have the
17 same incentive to negotiate low prices because they are
18 more fully reimbursed by Medicare. And these claims
19 inflate the average sales price or ASP. Cassidy Number 1
20 would require manufacturers to rebate to Medicare the
21 difference between their prices negotiated in Medicare
22 and in the commercial market, giving taxpayer and
23 patients full access to the prices achieved with tools
24 used in the free market.

25 I will also note this was brought to me

1 constructively by a pharmaceutical CEO who felt like this
2 would be an alternative to some of the other things we
3 are speaking of. So, I appreciate the Chairman's
4 including Cassidy Number 2 in the mark to study this
5 issue, and respectively remove this amendment and go to
6 my last which is Cassidy Number 3, which I am kind of
7 scratching my head why it is not included.

8 This is a claims modifier from the OIG report. I
9 have got two OIG reports. The one from 2016 said that,
10 "we found that methods that operate on the claim level
11 can improve accuracy in identifying 340b drug claims, and
12 therefore help states correctly collect rebates." But it
13 also noted, "while CMS agrees with the importance of
14 claims levels message, the statute does not allow it."
15 So it falls to Congress.

16 OIG is saying that you are not supposed to take both
17 340b discount and Medicaid best price. Thirty-seven
18 percent of the claims are taking both of these
19 deductions. That is wrong. It is against the law. We
20 need to help hospitals be legal. I am not blaming them.
21 I am just saying it is confusing.

22 This modifier would click whether or not it is 340b
23 or whether it is Medicaid best price, but it would not
24 double dip. And I can go further, but I think that is
25 the bottom line. And again, I have two OIG reports

1 suggesting it.

2 So I guess I would say this is a very simple
3 amendment. It takes a top recommendation from OIG to
4 limit waste, fraud, and abuse by giving hospitals the
5 tools they need to avoid inadvertent duplicate discounts.
6 And I hope it can be reconsidered as we move to the
7 floor.

8 With that, I withdraw.

9 The Chairman. I missed the point whether or not
10 you were asking consent for something be included in the
11 record.

12 Senator Cassidy. Yes, that was on the previous
13 one, a quote from both Jonathan Gruber and Mark Trusheim,
14 two MIT economists.

15 The Chairman. Without objection, it will be so
16 ordered.

17 [The document appears at the end of the transcript.]

18 The Chairman. Senator Casey?

19 Senator Casey. Thank you, Mr. Chairman.

20 I will talk about Casey Amendment Number 1 co-
21 sponsored by Cortez Masto, Brown, Stabenow, and I would
22 have not asked for a vote. I will just talk about it.

23 I want to thank you first and foremost before I get
24 to the amendment itself. I want to thank both Chairman
25 Grassley, Ranking Member Wyden not only for the work on

1 this bill, but also for including two of my priorities in
2 the Mark.

3 As part of the package, I partnered with Senator
4 Daines to ensure low-income people with Medicare can
5 access the medications they need as they transition into
6 Medicare.

7 And the second matter, worked with Senator Collins
8 to bring greater transparency to what Medicare and
9 Medicaid spend on prescription drugs as well as consumers
10 must pay out of pocket. So thanks for that work.

11 I have also -- as I have already expressed, the
12 package does not do enough to lower crushing health care
13 costs for constituents. But we are grateful for the work
14 that has been done.

15 I have filed an amendment that would take this
16 package further especially on one issue. Earlier this
17 year, I introduced a bill to strengthen a little-known
18 program called Extra Help. This aptly named program
19 provides extra help with covering premiums, co-payments,
20 and coinsurance costs for the lowest income seniors and
21 people with disabilities. This existing program simply
22 does not go far enough.

23 Extra Help is fraught with Administrative
24 complexity, which I will not go into today. Even with
25 the programs help, some of the participants face

1 coinsurance rates that prevent them from accessing needed
2 medications.

3 So I am not asking for a vote. But I hope the
4 committee will address this program's shortcomings at a
5 later date.

6 Thank you both.

7 The Chairman. Thank you.

8 I want to close now by thanking all my colleagues
9 for their attendance today, and particularly staff that
10 works day, and night, and weekends to move us forward.

11 I think the bill we just voted out of committee, it
12 was an important step towards addressing the problem of
13 high-cost prescription drugs.

14 I look forward to continuing to work together, and
15 passing these important reforms into law.

16 With that, this hearing is adjourned.

17 [Whereupon, at 12:33 p.m., the meeting was
18 adjourned.]

I N D E X

	<u>PAGE</u>
<u>STATEMENT OF:</u>	
THE HONORABLE CHUCK GRASSLEY A United States Senator from the State of Iowa	2
THE HONORABLE RON WYDEN A United States Senator from the State of Oregon	10
THE HONORABLE MIKE CRAPO A United States Senator from the State of Idaho	17
THE HONORABLE MARIA CANTWELL A United States Senator from the State of Washington	19
THE HONORABLE MICHAEL B. ENZI A United States Senator from the State of Wyoming	22
THE HONORABLE BENJAMIN L. CARDIN A United States Senator from the State of Maryland	24
THE HONORABLE SHERROD BROWN A United States Senator from the State of Ohio	28
THE HONORABLE ROBERT MENENDEZ A United States Senator from the State of New Jersey	31
THE HONORABLE SENATOR STEVE DAINES A United States Senator from the State of Montana	34
THE HONORABLE MAGGIE HASSAN A United States Senator from the State of New Hampshire	37
THE HONORABLE CATHERINE CORTEZ MASTO A United States Senator from the State of Nevada	40

I N D E X

	<u>PAGE</u>
<u>STATEMENT OF:</u>	
THE HONORABLE JOHN CORNYN A United States Senator from the State of Texas	43
THE HONORABLE ROB PORTMAN A United States Senator from the State of Ohio	46
THE HONORABLE SHELDON WHITEHOUSE A United States Senator from the State of Rhode Island	50
THE HONORABLE THOMAS R. CARPER A United States Senator from the State of Delaware	54
THE HONORABLE JOHN THUNE A United States Senator from the State of South Dakota	57
THE HONORABLE TIM SCOTT A United States Senator from the State of South Carolina	60
THE HONORABLE JAMES LANKFORD A United States Senator from the State of Oklahoma	62
THE HONORABLE DEBBIE STABENOW A United States Senator from the State of Michigan	65
THE HONORABLE ROBERT P. CASEY, Jr. A United States Senator from the State of Pennsylvania	68
THE HONORABLE BILL CASSIDY A United States Senator from the State of Louisiana	72

Inside the Pharmaceutical Lobby's Campaign for More Government Subsidies Through Medicare Part D



Avik Roy *Forbes* Staff
The Apothecary Contributor Group
Policy
Commentary from Forbes' Policy Editor



Senate Finance Committee ranking member Sen. Ron Wyden, D-Ore., left, sitting next to committee chairman Sen. Chuck Grassley, R-Iowa, right, speaks during a hearing. (AP Photo/Susan Walsh) ASSOCIATED PRESS

Senate health care leaders have developed a bipartisan, fiscally responsible way to reduce the cost of the Medicare prescription drug benefit, also known as Medicare Part D. But pharmaceutical companies, in a furious lobbying effort, are trying to blow up the deal by demanding that taxpayers spend tens of billions on drug industry subsidies.

Lowering drug costs for seniors and taxpayers

As I discussed last month, behind closed doors the Senate Finance Committee has been considering a bipartisan package to restructure Medicare's prescription drug benefit.

The proposed legislation would cap seniors' out-of-pocket costs in the Part D program at a fixed level, perhaps \$2,500 a year. The problem is that capping out-of-pocket costs in this way would give drug companies an incentive to jack up their prices, because seniors would no longer notice any price increases above \$2,500; taxpayers would be forced to pay for the increases in the form of greater Part D subsidies.

Hence, the proposal also caps the growth of government subsidies to drug manufactures at consumer inflation (CPI). Drug companies would be free to raise their prices faster than inflation, but they would have to return to the taxpayer any subsidies they received above inflation.

The legislation would also mirror a market-based reform from the Center for Medicare and Medicaid Innovation, by shifting responsibility for managing catastrophic drug costs from Medicare to private insurers.

The net effect of the Senate proposal would be a win for both seniors and taxpayers. Seniors would benefit from a cap on their out-of-pocket costs, and taxpayers would benefit from a reduction in the growth of Medicare subsidies to drug companies.

Naturally, the drug industry is up in arms about that last part, and is aggressively lobbying behind the scenes to remove the taxpayer protection feature of the bill.

Controlling subsidies, not prices

The go-to argument for the drug lobby is that limiting government subsidy growth to inflation is a “price control.” But it’s nothing of the sort, as subsidies are not prices. Under the Senate Finance proposal, drug companies would continue to be able to set whatever prices they wish for their products. But growth in *subsidies* to drug companies would be limited to consumer inflation.

That would provide drug companies with a strong incentive to focus on developing new, innovative drugs instead of taking advantage of government-sanctioned monopolies to raise prices on older drugs.

In 2016, of the ten Part D drugs with the biggest Medicare spend, only three had been on the market for fewer than 12 years: that is to say, those three are relatively recent innovations. The other seven drugs had been on the market for an average of 16 years.

And that 16-year average actually underestimates the age of these drugs. GlaxoSmithKline’s Advair, for example, has been on the U.S. market since 2000, for treatment of asthma and chronic obstructive pulmonary disease. But Advair is simply a combination of two older, off-patent GSK drugs called Flonase and Serevent, which were first approved by the FDA in 1988.

I guess you could call that “innovation,” but it’s a pretty incremental form of innovation. By comparison, the best-selling cell phone in 1988 was the Motorola DynaTAC, the brick-sized cell-phone made famous by Gordon Gekko in the movie *Wall Street*. The DynaTAC was genuinely innovative in 1988. But no one would expect taxpayers to subsidize billions in DynaTAC purchases today, at 10 to 20 times the price of the 1988 version. Think about the amount of innovation that occurred in cell phones between the DynaTAC and the iPhone Xs Max, and compare that to the amount of innovation in Advair over that period—it’s not even close.

The good news is that generic versions of Advair are finally being approved by the FDA, after years of bureaucratic holdups. But in the meantime, taxpayers spent tens of billions of dollars subsidizing a British corporation, GlaxoSmithKline, which took advantage of its monopoly status in the U.S. to raise prices over

and over again. In 2001, Advair cost about \$150 a year. In 2013, the average Medicare enrollee spent \$1,482 on Advair, roughly 10 times the 2001 price. By 2017, Medicare patients were paying \$2,091: a 41 percent increase from 2013.

Nothing about Advair changed in the intervening periods: not its cost to manufacture, nor its cost to ship the drug to wholesalers. Advair wasn't 14 times more beneficial to patients in 2017 than it was in 2001. The cost of pharmaceutical innovation didn't increase by 14 times from 2001 to 2017. Speaking of R&D, GSK spends 2.5 times more on marketing and overhead than on R&D; in 2012, it paid \$3 billion in fines to U.S. governmental entities for inducing illegal overspending on its drugs, including Advair. Pharmacy benefit managers captured some of Advair's price hikes through rebates, but only a minority.

Again, the Senate proposal wouldn't prohibit GlaxoSmithKline from increasing the price of a future drug by 1300%. But there's no reason why the government should subsidize GSK for doing so.

Drug price inflation vs. launch prices

One argument the drug lobby is making is that if Medicare ties subsidy growth to consumer inflation, pharmaceutical manufacturers will respond by increasing launch prices, and the end result will be the same amount of Medicare spending. This is unsupported by actual experience with drug company pricing strategies.

Think about the Advair example above. If GSK had launched Advair in 2001 at 14 times the combined price of Flonase and Serevent—the drugs that are administered in Advair—no one would have paid that price. Consumers paying out-of-pocket wouldn't have paid it. Private insurers wouldn't have paid it. They would have stuck with Flonase and Serevent, even if using those drugs separately was mildly less convenient.

Drug companies have shareholders, and their CEOs are obliged to maximize shareholder value at all times. They already do launch their drugs at the highest possible prices they can. What limits launch prices is the ability of insurers to say no: to say that they won't cover a drug whose price far exceeds its value to patients.

Insurers in the Medicare Part D program have the ability to say no in this way, except in six “protected classes,” where they are forced by law to pay for drugs regardless of their value to the patient or the market. (Advair is not a member of a protected class; the drug has simply benefited from its government-enforced monopoly status. Along with protected classes, Medicare Part D requires that participating plans cover two drugs in each therapeutic class as defined by the U.S. Pharmacopeia.)

If drug lobbyists truly believed in a market-based Medicare Part D program, they would work to eliminate protected classes. But the “protected classes” rule makes the pharmaceutical industry more money, so you can guess what's happening. The Trump administration proposed liberalizing the “protected classes” rule, but eventually backed down after a flurry of industry lobbying. (The Obama administration also tried liberalizing the protected class rule, with the same non-result.)

Some drug lobbyists are pointing to a Congressional Budget Office report that raises the possibility that “drug manufacturers would be expected to set higher ‘launch’ prices for new drugs” if Congress curbed the growth in drug subsidies, “though the size of that response is uncertain.”

Put simply: no, drug companies won't be able to raise launch prices in order to compensate for a taxpayer inflation rebate, because that would lead to absurd prices that no private plan will be willing to pay, especially in the competitive drug categories that affect most patients. But as an additional

safeguard, the Senate Finance Committee should repeal the protected classes rule, and give plans and taxpayers the freedom they should have to pay only for drugs that create real value for patients.

Without cost control, the reform plan deserves to fail

If the fiscal responsibility provision is taken out of the Senate Finance proposal, with everything else left intact, the bill deserves to fail, as it would then result in a gigantic, tens-of-billions-of-dollars taxpayer-funded giveaway to price-hiking drug companies.

The two leaders of the Senate Finance Committee—Chuck Grassley (R-Iowa) and Ron Wyden (D-Ore.)—have shown impressive fortitude in keeping the deal together to this point. But the ultimate outcome will depend on how much members of the Committee care about keeping money in taxpayers' pockets. We will know soon.

UPDATE: On July 23, the Senate Finance Committee released a summary of the draft legislation, to be marked up by the Committee on July 25. According to the Committee, the Congressional Budget Office estimates that the bill would, over the next decade, reduce federal spending by \$100 billion—\$85 billion in Medicare and \$15 billion in Medicaid—while reducing seniors' out-of-pocket costs by \$27 billion, and Part D premiums by \$5 billion.

**Submitted by Hon. Bill Cassidy, a U.S. Senator From Louisiana
Finance Committee Markup on “The Prescription Drug Pricing Act of 2019”
July 25, 2019**

From an email submitted to Senator Cassidy’s office:

We are about to enter an era of unprecedented treatment for rare disease—at unprecedented prices. To ensure access to all who need it, it is critical that we develop innovative new pricing models that spread payments and share risk between drug manufacturers and payers. This proposal is an important step forward in that direction.

—Jonathan Gruber, Ford Professor of Economics, MIT Mark Trusheim, Strategic Director—NEWDIGS, MIT