OPEN EXECUTIVE SESSION TO CONSIDER AN ORIGINAL BILL
ENTITLED “THE PRESCRIPTION DRUG PRICING REDUCTION ACT OF
2019”
THURSDAY, JULY 25, 2019
U.S. Senate,
Committee on Finance,
Washington, DC.

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

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

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

LISA DENNIS COURT REPORTING
The Chairman. Our meeting will come to order.
I want to thank our staff for working so hard, as they have over the last two or three weeks to put things together so we are where we are now.
I am going to give my opening statement, and then Senator Wyden is going to give his opening statement, and then I will give some agenda items, and we will have then opening statements from Members. And I think we will do it the same way we do opening statements -- will do it by people as they are coming here in order of attendance.
In 2003, when we first passed the Medicare Modernization Act, I was Chairman of the committee and had a big part in putting that program together, and it is one of the things that I am proud of. At that time our goal was to make the first improvements in the Medicare program in nearly 40 years. We wanted to give seniors an affordable option that worked like the health insurance they had in places from where they retired. We wanted to make sure that legislation benefited all seniors, and we put into place a mechanism to keep the price of drugs down.

Part D, private insurers negotiate with drug
manufacturers to get the best price on drugs so the
premiums stay affordable. That has worked well.
Premiums in the Part D program have been remarkably
stable since the program’s inception despite claims from
naysayers at that time that premiums would skyrocket.
So we should keep what is working and fix what we
can improve. In the 15 years since the last major reform
of Medicare, we have seen the development of innovative
medicines to treat arthritis, cancer, and I will just
simply say countless other disorders rather than making a
long list. These treatments have been life-saving or
life-changing for millions of Americans.
But of course they have come with increased cost.
This includes increased out-of-pocket costs for
beneficiaries, increase taxpayers spending. Now all of
us on this committee have heard from our constituents
about the high cost of prescription drugs, or we probably
would not be here dealing with this legislation. And I
am sure the President heard it because 13 months ago he
made a commitment to lower the cost of drugs
I have heard from Iowans who have left prescriptions
at the pharmacy counter or have skipped doses of their
medicine to save money. You will all remember in our
first hearing that we held this year we heard from a
mother whose son reduced his insulin use because he was
concerned about the financial burden placed on his family by the cost. You even heard of a person dying as a result of that.

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

So getting back to the beginning of this year, I said that addressing high drug prices was one of my top priorities. I also said that any effort to tackle such a problem needed to be bipartisan, go through regular order, and be marked up before the August work period. And let me emphasize that bipartisan approach, because everybody whether you are a new member of the senator or an older member of the Senate, you know nothing gets done in this body unless it is bipartisan.
So I want to thank the Senators on this committee who I have worked with two craft this bipartisan bill. We have a bill before us that addresses high and rising prescription drug prices, again, emphasizing in a bipartisan manner. At last count, there were over two dozen proposals in the legislation that are supported by at least one Republican and one Democrat on the committee. We have included many of our Member priorities in the bill.

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

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

Now getting to the agency that is God around Capitol Hill, CBO. And if you wonder whether CBO is God here on
Capitol Hill, just try to get something done when they give you a figure and you got to have 60 votes to override it in the United States Senate. What they say, right or wrong, is very powerful.

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

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

[Laughter.]

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

Okay.

The Chairman. Okay.

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

Now put that all together. This should be a win for all Americans. To the naysayers who claim our bill contains price controls -- and this is the most vexing problem that Senator Wyden and I had to deal with. He is got people on his side of the aisle who is not satisfied
with what we are doing, and I have obviously got people on my side of the aisle that is not satisfied what we are doing. And I think it all boils down to this one issue. But to these naysayers who claim that our bill contains price controls, I want to submit for the record -- and it will be included unless there is an objection -- an analysis by the conservative economist Avik Roy who does a good job of rebutting that argument.

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

The Chairman. Now my second comment is about proposals to tie U.S. drug prices to international prices. I have a couple of serious concerns about the proposal. First of all, we do not know much about what they are or how they work. Secondly, I worry that one unintended consequence could be the loss of innovation. Now this is the moment for the Senate to act. We have jurisdiction over all Medicare and Medicaid. So what we do here today really matters -- really matters -- not only politically when you hear about this from our constituents, but to all the people that are affected by these programs, real people.

Now before we move on, I am going to ask Senator Wyden if he will pay attention -- special point of thanking Our Ranking Member for his cooperation. He has
been a good partner. That said, I want to point out something that the Administration threw at us, kind of a curveball, a couple of weeks ago when they did not finalize a proposed rule. That rule would have ensured that the savings from rebates in the Part D program would be passed through to benefit seniors at the pharmacy counter.

It happens that I believe that is a very good idea. So Senator Wyden, I would like to continue to work with you to get a similar policy into our legislation before it becomes law. I would also like to address the unfair clawback practices that affect pharmacist who are trying to take care of their patients.

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

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

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

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

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

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

Senator Wyden?
Senator Wyden. Thank you, Mr. Chairman.

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

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

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

Democrats feel very strongly about giving Medicare
the authority to negotiate directly for lower drug
drugs. Pharma continues to stand in the way. And they
have had just about the longest winning streak of any
special interest in Washington, D.C.

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

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

Now on to the specifics of what the proposal does,
and these have been confirmed by the Congressional Budget
Office. The Proposal saves Medicare $50 billion with a
price hike penalty for drug companies. It does this not
by setting prices, but by limiting taxpayer subsidies for
arbitrary price hikes. If drugmakers choose to raise
prices faster than inflation, they are going to have to
pay the difference back to Medicare.
Seniors with expensive prescriptions are going to finally have peace of mind because this proposal caps their out-of-pocket expenses in Medicare Part D. In total, it is going to save seniors $27 billion in out-of-pocket costs. It will be the end of an era when drug prescriptions drove seniors into bankruptcy.

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

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

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

So we are going to have a lot of work to do, and we
ought to try to find a common ground. That is what Senator Grassley is trying to do with what I characterize today as a helpful step.

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

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

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

In 2017, I introduced legislation and a number of Senators here have sponsored what is called the C-THRU
bill to not only pull back the curtain on the middlemen, but also to make sure that patients saw the benefit of all the discounts that plans and the pharmaceutical benefit managers negotiate with pharma at the point-of-sale, which is the pharmacy counter. I continue to support a concrete benefit instead of the current system where it is unclear how much pharmacy benefit managers are pocketing for themselves.

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

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

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

The Chairman. Thank you.

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

Senator Wyden. Just for unanimous consent request.

The Chairman. Go ahead.

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

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

[Laughter.]

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

And the last time I chaired this committee, which was 2006, we had 20 Members. So we have eight more members now. So that is 24 more minutes that it will normally take.
So I think the only fair thing for me to do is when your 3 minutes are up, is to gavel and then call the next person. If that irritates somebody, then tell me now.

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

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

The Chairman. Okay.
OPENING STATEMENT OF HON. MIKE CRAPO, A U.S. SENATOR FROM IDAHO

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

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

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

I think not only is this a problem in terms of the impact on the market-based foundation of Part D, but it
is in my opinion going to result in higher prices for future drugs and cost shifting to patients that is going to be harmful to them.

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

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

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

Senator Cantwell?
OPENING STATEMENT OF HON. MARIA CANTWELL, A U.S. SENATOR
FROM WASHINGTON

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

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

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

My constituents understand when you buy in bulk, you get a discount. That is the Costco model. And as a Northwest company, we see that all of the time and wonder...
why we cannot have the same kinds of access in other areas. So the fact that this provision will help 43 million Americans and 830,000 Washingtonians with Medicare Part D, and getting them a better deal than they get today is a huge benefit.

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

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

I think the Ranking Member and the Chair for including language in this bill about more information on drug transparency pricing and worked with Senator
Lankford on this. I am going to continue to work on this on the Commerce Committee, and also language in here to get us more information about why insulin and other drug shortages are causing and wreaking such havoc in the market for us. We have to come up with better solutions on those problems for our consumers.

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

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

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

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

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

I would have liked to have had the benefit of their feedback, and because I agree it is critical to review
possible intended and unintended consequences of legislation before voting. I still appreciate all the hard work that is gone into the package and look forward to discussing the proposal before us today.

I yield back time.

The Chairman. Thank you.

Now, Senator Toomey.

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

The Chairman. Okay.

Then Senator Cardin.
OPENING STATEMENT OF HON. BENJAMIN L. CARDIN, A U.S. SENATOR FROM MARYLAND

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

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

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

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

So there is real progress that has been made on this bill. And the transparency to patients, the real-time benefit check, I think will make a real difference to
consumers to understand the pricing of different drugs as they need it.

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

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

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

And lastly, I will offer an amendment to deal with
the appeal process under Part D where consumers are
denied coverage at the pharmacist. That should be the
initial coverage determination because that is when they
know they have been denied coverage. They should not
have to figure out how and why to go further than that to
make their point.

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

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

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

Senator Cassidy?

Senator Cassidy. If I can speak later, I will pass
for now.
1 The Chairman. Okay.

2 Senator Brown?
Senator Brown. Thank you, Mr. Chairman. I thank you and Ranking Member Wyden.

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

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

That means legislating more. It also means demanding the Administration and future administration’s do more. President Trump has shared three big ideas on drug prices requiring the price of drugs to be included in ads, IPI and the rebate rule.
One is stuck in court. The other has not been formally proposed, and the third is dead because the President himself killed it. That is not a good way to show you are taking the issue seriously as the President claims he has.

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

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

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

The government has never used its authority to bring relief to those struggling to afford prescription drugs.
regardless, [underscore this] regardless how much taxpayer money support of the development of the drug. People have petitioned NIH a half dozen times urging the agency to exercise its march-in rights to lower the cost of a life-saving drug. It has refused to do it each time.

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

Thank you, Mr. Chairman.

The Chairman. I will go back up my list because Senator Menendez is here. So Senator Menendez, take your 3 minutes.
OPENING STATEMENT OF HON. ROBERT MENENDEZ, A U.S. SENATOR
FROM NEW JERSEY

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

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

So if there is any state in the country where people ought to be able to afford the medications they need, it is in New Jersey, the medicine chest of the world. That being said, if we are going to take billions of dollars from an industry so important in my state, then it should be going to patients, not to funds that patients will largely never see the benefit of.
And quite frankly, I am frustrated to see that for the most part this legislation leaves untouched the role that health insurance companies and pharmacy benefit managers play in this debate over costs even as they make handsome sums of money at the expense of patients and consumers.

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

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

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

With that, Mr. Chairman, I thank you for the time.
The Chairman. Senator Daines?
OPENING STATEMENT OF HON. STEVE DAINES, A U.S. SENATOR FROM MONTANA

Senator Daines. Thank you, Mr. Chairman.

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

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

These are Montana’s who are battling diabetes. They are battling cancer. They are battling arthritis. Folks like Patricia from Helena, Ed from Missoula, Chuck from Polson, Jim and Patty from West Yellowstone who write in about the high cost of prescription drugs and a very real worried that they cannot afford them. Their stories, their concerns, their anxiety, it is very real. And that is why since joining the Senate finance Committee -- it is third Montanan to ever be on this Committee. In fact, it is been one of my top priorities to lower prescription
drug costs for Montanans. This is a legislative product, and a result of over six months of bipartisan negotiations. I commend Chairman Grassley, Ranking Member Wyden for their leadership and their commitment to delivering legislation, delivering an outcome, delivering a result for Montana’s and the American people that would actually start to address this issue of high cost of prescription drugs.

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

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

This drug pricing package includes meaningful reforms that will lower prescription drug costs for Montanans. To highlight a few things as we look at what is going on right now with federal spending, this saves Montanans and the American taxpayers more than $100 billion. It lowers Medicare beneficiaries’ out-of-pocket costs by $25 billion. It lowers premiums by $6 billion. It increases transparency in this very complex drug
pricing system. These are significant reforms. I am glad the work that is produced by this committee has the support of President Trump.

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

Thank you, Mr. Chairman.

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

[Laughter.]

The Chairman. Senator Hassan?
OPENING STATEMENT OF HON. MAGGIE HASSAN, A U.S. SENATOR
FROM NEW HAMPSHIRE

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

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

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

This bipartisan bill will help control the cost of
drugs and lower costs for Medicare beneficiaries by
creating an out-of-pocket cap so seniors will not go into
bankruptcy because of their prescription drug costs. It
will also put downward pressure on the price of medication for all patients. I am also pleased to have worked with my colleagues on both sides of the aisle, Senators Cassidy, Stabenow, Cornyn, Cardin, and Young, to make sure that this bill closes a loophole that has allowed drug companies to overcharge states for drugs in the Medicaid program. And I thank the Chairman and Ranking Member for incorporating my Transparency Study Amendment into this package and look forward to working with you on these issues moving forward.

While this bipartisan bill is an important step forward, we have far more work to do. I have offered amendments that would improve this bill by increasing transparency, creating stronger penalties on drug companies that spike the price of their existing drugs, and to ensure beneficiary certainty during benefit redesign. We need to work together to make sure that as this system changes patients can still get the life-saving drugs that they have become accustomed to. I look forward to continuing to work with my colleagues on both sides of the aisle to incorporate these much needed changes and on additional measures to ensure that all Americans can afford critical care and enjoy the quality of life that we all hope so dearly for.
Thank you, Mr. Chair.

The Chairman. Thank you very much.

And now we go to Senator Cortez Masto.
OPENING STATEMENT OF HON. CATHERINE CORTEZ MASTO, A U.S. SENATOR FROM NEVADA

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

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

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

Drug companies must chip in for the cost of the Medicare drug program and pay penalties when they hike prices faster than inflation. Those penalties have benefits for families too by putting pressure on drug companies to lay off the price hikes we drive down costs for folks in commercial health plans.
In the process, we have saved money for the Medicare program, Medicaid in four states, and I am grateful that we will be able to look under the hood about issues with access to drugs in Indian Country. I also want to recognize, I am grateful that we also have drug manufacturing price transparency. And thank you for providing the MedPAC and MACPAC with access to certain drug payment information, including certain rebate information.

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

I have very serious concerns with the provision in the bill that opens the door to contracts that put state Medicaid programs on a mortgage plan for high cost drugs. And we have not even created a system, body, or mechanism that will determine whether the prices that drug companies charge consumers are appropriate. How do we
know when $2 million for a drug is fair?

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

The Chairman. Thank you Senator.

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

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

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

The Senator from Texas.
Senator Cornyn. Thank you, Mr. Chairman.

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

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

So I understand there is significant uncertainty whether this policy will lead to higher launch prices, or higher out-of-pocket spinning, or higher premiums. I
appreciate the Chairman putting Avik Roy on the phone, but I do know that there is enough money involved in this enterprise that there is all sorts of people with all sorts of points of view and all sorts of agendas. And so I just think that we need to be very careful.

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

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

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

So I hope the Chairman and the Ranking Member will commit to continue working with all of us before this package is ready for floor action.
The Chairman. I can commit that to you because I have already committed it to two or three other Members of the committee already before you even ask me. And I would also like to emphasize what he said about hopefully certain parts of stuff out of the Judiciary Committee can be mixed up with things that Senator Alexander has done. And you were leader on one of those bills that came out of committee.

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

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

Senator Cornyn. No.

The Chairman. I did not mean to.

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

Thank you.

The Chairman. Senator Portman?
OPENING STATEMENT OF HON. ROB PORTMAN, A U.S. SENATOR
FROM OHIO

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

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

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

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

It lowers out-of-pocket costs for seniors in Part D by having this out-of-pocket spending cap, 3,100 bucks.
I think that is important for the 2 million Ohioans who rely on Medicare for their health care coverage. This is going to provide more certainty and protect some of those patients with those complex medical conditions.

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

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

The policy that the Ranking Member has championed that deals with price spreading in Medicaid I think is really important. That has been a problem in Ohio, and I am sure in all of your States. PBMs sometimes keep a
portion of the amount paid to them by the health plans, prescription drugs instead of passing those along to the pharmacies. And I think that is going to be something positive out of this.

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

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

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

And again our work does not end here. But I look
forward to having the discussion today, and then helping
to move this back and forth.

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

Senator Whitehouse?
OPENING STATEMENT OF HON. SHELDON WHITEHOUSE, A U.S.
SENATOR FROM RHODE ISLAND

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

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

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

There should be a price index to protect U.S. patients from being the ones who were overcharged by companies who are charging for the same drug lower costs in other countries. So there are a lot of disappointments in where we are. I understand that bipartisanship creates its limitations. I am in the Cornyn squad here of being inclined to vote to move this
bill to the floor, but wanting a very clear understanding before we go to the floor that some of these issues that I just mentioned will be addressed because this is too important a problem for us to simply reach the goal of bipartisanship and then stop. We have to reach the goal of bipartisanship and then keep pushing until we see real change in these very difficult markets, which I think are corroded with monopoly misbehavior.

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

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

Senator Wyden. Mr. Chairman, if I could just respond to Senator Whitehouse who is very knowledgeable on this and is focused particularly on making sure that the consumer has more market power. That is really the driver that is behind all of the positions were taking.
And your work on the Judiciary Committee is particularly helpful as well.

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

So we will keep working with you on it.

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

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

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

The Chairman. I agree with you on importation, but
that is not within the jurisdiction of our committee
Senator Carper?
OPENING STATEMENT OF HON. THOMAS R. CARPER, A U.S. SENATOR FROM DELAWARE

Senator Carper. Thanks, Mr. Chairman.

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

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

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

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

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

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

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

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

The third and importantly, does it allow market forces to continue to work where they work? And where they are not working, does it provide reasonable
alternatives to help right a wrong?

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

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

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

Thank you.

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

Senators Thune, Scott, Young, Lankford, Burr, Stabenow, and Casey.
OPENING STATEMENT OF HON. JOHN THUNE, A U.S. SENATOR FROM TEXAS

Senator Thune. Thank you, Mr. Chairman.

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

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

There are notable improvements in transparency of a complicated and often opaque drug pricing process which I commend. The promotion of real-time benefit tools will aid in helping inform consumers of cheaper drug options. I have long supported efforts to tackle a critically important issue to pharmacists that this bill in part
addresses, and that is the DIR fees.

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

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

I think many of us have concerns and a lot of heartburn about what that does to the Part D program. And I believe inevitably it will lead to cost shifting.
We have seen that in so many other areas of health care where the government steps on the scale, providers cost shift to other payers. And I think we will see that here.

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

Thank you.

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

Senator Scott?
OPENING STATEMENT OF HON. TIM SCOTT, A U.S. SENATOR FROM SOUTH CAROLINA

Senator Scott. Thank you, Mr. Chairman.

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

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

Ultimately, it comes down to something quite simple. As we all seek to have a positive impact on the price of drugs, I think this legislation ultimately will do three things. One, which I think is quite positive, is it will cap the spending from the out-of-pocket perspective for seniors, which is very positive. Second, is I think it will ultimately stifle innovation. Third, it will
ultimately increase the list prices, which finally means that while we may celebrate in the short-term reduction in prices, I think in the long-term we will see the exact opposite.

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

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

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

Senator Cantwell and I have a transparency proposal that we have made. The committee has accepted that. We
have talked through several things on DIR fees. The committee has been very open to be able to accept those and include other ideas.

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

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

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

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

The question still comes back to the inflation caps. And I cannot get away from two issues. One is we have economist on both sides saying the inflation caps will
cause the list prices to go up, and inflation caps will not cause the list prices to go up. And we have battling economists on that, and we have got to figure out which way we are going to go.

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

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

The Chairman. Okay.

Now, Senator Stabenow.
OPENING STATEMENT OF HON. DEBBIE STABENOW, A U.S. SENATOR
FROM MICHIGAN

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

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

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

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

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

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

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

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

This legislation slows down price increases, which is good. But imagine the savings to taxpayers and patients if we actually cut prices. The good news is we have a chance to do that in a very simple way, uncomplicated way today. We can do what everyone says that they want to do. And that is why, along with the
majority of my Democratic colleagues we will be offering an amendment based on legislation of Senator Klobuchar’s to let Medicare negotiate lower drug prices just like every other plan does.

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

The Chairman. Senator Casey?
Senator Casey. Thank you, Mr. Chairman. I want to thank Chairman Grassley, Ranking Member Wyden for your work to produce a bipartisan package for today’s Markup.

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

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

This bill, of course, is not enough. The rising cost of prescription drugs is not happening in isolation. It is part of a larger challenge many Americans face every day trying to make ends meet. The simple way to say
it is flat wages and high costs.

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

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

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

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

Finally, Mr. Chairman, I want to say despite this
bipartisanship today that Senator Stabenow referred to, Republicans in Congress and the Administration are supporting a lawsuit that would destroy the Affordable Care Act with no replacement to ensure protections for pre-existing conditions, not to mention a guarantee of coverage for at least the 20 million Americans who got their coverage through the Affordable Care Act.

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

The Chairman. Without objection, it will be included. And with regard to -- Senator Casey. Thank you.

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

[The chart appears in the appendix.]


[Off mic.]

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

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

The Chairman. Okay.

Senator Cassidy?
OPENING STATEMENT OF HON. BILL CASSIDY, A U.S. SENATOR FROM LOUISIANA

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

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

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

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

What about drugs? This committee sets prices -- 340b, which has tremendous support, Medicaid best price. That is setting prices. Section 103 of this bill tells biosimilars you are either getting that price or this price. To pretend we do not set prices is a pretense.
Now, what about the inflation caps benefits? I would argue it does have benefits. Under the Medicare Part D protected categories, manufacturers have absolute power over pricing -- absolute power, because we the taxpayer must pay for whatever they offer. And just like absolute power corrupts the federal government, so absolute power corrupts that pricing.

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

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

I yield back.

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

Senator Brown. Mr. Chairman, could I make one more
comment really quickly over here?

The Chairman. Go ahead.

Senator Brown. Yeah, I thank you. And I always appreciate the comity of this committee -- comity with a “t.”

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

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

Senator Cornyn. Mr. Chairman?

The Chairman. Now we are turning to Senator Cornyn.

Senator Cornyn. This is such a transparent ruse. It is a lie that Republicans do not support coverage for pre-existing conditions. It is a lie. But you know the theory of the big lies, if you tell them often enough and loud enough, some people will believe it. And it is true that Democrats benefited in 2018 by perpetuating that lie.
But we have a responsibility to call it out for what it is. And I would just point out, you know, after being told if you like your policy, you can keep your policy. If you like your doctor, you can keep your doctor, and touting the great benefits of the Affordable Care Act, most of the Democratic Presidential candidates want to eliminate private insurance -- eliminate it for 180 million people who get it through their job. And they want to bankrupt Medicare, which is already on a path to insolvency.

So thank you for giving me a chance to say a word.

But this is really a --

[Simultaneous speech.]

The Chairman. Okay, I want to get --

Senator Casey. Mr. Chairman?

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

Senator Casey. Yes.

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

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

[Simultaneous speech.]

Senator Cornyn. We have a replacement, Senator.

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

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

The Chairman. Okay. Now we are ready.

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

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

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

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

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

Mr. Baker. Thank you, Mr. Chairman.

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

Mr. Baker. Certainly, sir. Thank you.

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

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

The next modification is to accept Cassidy 2. And then on page 12 of the Mark after Section 112 insert the
following: “Section 113, Study of Average Sales Price.” This provision would require GAO to study the difference between commercial and Medicare prices reported for ASP.

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

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

The next modification is to Section 123. On page 18 of the Mark before the last sentence in the first full paragraph under provision add the following sentence: “Data released under this provision may represent transactions that occurred two years prior to the plan year in which data is released.” This modification would
prohibit against inadvertent release of information that could potentially reveal negotiated drug prices.

The next modification is to Section 125. On page 21 of the Mark in the first sentence of the first full paragraph, following “electronic transmission of” but before “formulary and benefit information” insert “eligibility.” And further on page 21 in the second sentence of the first full paragraph following “formulary of such plan,” but before “pharmacy options” insert “information relating to cost sharing.”

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

The Chairman. Are you done sir?

Mr. Baker. I can be sir.

The Chairman. Yeah.

[Laughter.]

The Chairman. No proceed, please.

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

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

The next modification is to accept Cornyn-Cardin
Number 1. This would add a Section 130 to the Mark that would implement a recommendation from the Office of Inspector General to require all Medicare Part D plan sponsors to report suspected fraud, waste, and abuse information to CMS.

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

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

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

The next modification is in Subsection C, the Miscellaneous Provisions. It would modify Section 141 on page 27 of the Mark, substitute the fourth paragraph with “HHS would be prohibited from publicly posting any proprietary manufacturer information.”
The following modification is to remove Section 142 that appeared in the Mark and its entirety.

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

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

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

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

The following modification is to accept Hassan-
Whitehouse Number 4 as modified. This is a GAO study on increases in Medicare spending due to pharmaceutical manufacturer contributions to copay and patient assistance organizations.

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

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

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

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

Thank you, Senator Crapo.

So it is time for the questions now.

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

[No response.]

The Chairman. Well if there is not, I better not go then.
Okay. Let us go on to the amendments.
So we will recognize Senators to offer amendments.
I should allow a sufficient period of time for debate.
But I hope you can keep it as short as you can.
And Senator Toomey, if you do not feel insulted if I leave while you are offering the main amendment to our Mark, I am still going to go, but if —
Senator Toomey. Mr. Chairman, I assure you I am no longer easily offended.

[Laughter.]
Should I take that as being recognized?
Senator Crapo [presiding]. You are recognized.
Senator Toomey. Thank you very much, Mr. Chairman. And before you leave I do want to commend you and thank you for the very hard work that you and Senator Wyden have done on this -- very, very thoughtful and constructive, and I appreciate that.
I would like to ask unanimous consent to add Senator Lankford as a co-sponsor of this Toomey-Roberts Amendment Number 1.
Senator Crapo. Without objection.
Senator Toomey. Thank you very much. And I want to introduce this with just a little bit of context, Mr. Chairman, and I am referring to the really unique, among federal programs, the unique design of Medicare Part D.
And what I am referring to is the fact that it is based on competition.

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

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

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

Now, I think we have all acknowledged that the Part D benefit design has a problem, and the problem is there is a relatively small, but certainly not insignificant percentage of beneficiaries who experience catastrophic
unlimited out-of-pocket costs. And we all believe, I think, that something has to be done about that. And this bill does that.

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

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

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

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

We have a program in which costs are coming in below
projection, and now have declining prices in the form of premiums. Medicaid, itself, which has this mechanism has no competition mechanism. There are no formularies. There is no ability for plans to pit manufacturers against each other as Medicare Part D does and uses.

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

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

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

My colleague from Louisiana who is very, very knowledgeable, very passionate about this and I appreciate his inputs. He has observed that there are other circumstances in which Medicare sets prices. It is
true. It is also true that as a general matter we have been trying to get away from that, trying to get away from the fee-for-service model in which the government sets prices and move, for instance, in the direction of bundled payments, which dramatically reduces the government’s setting of prices. And we have tried to introduce competition where we can.

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

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

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

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

The Chairman. Yes, respond, and I am going to respond too.
Senator Wyden. Very good.

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

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

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

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

I would also just like to note for the record that as somebody who was supportive of Part D over the years, there has not been any break on the price accelerator. List prices for 100 brand name drugs that seniors take every day increased over 200 percent between 2006 and
2017. Inflation increased only 25 percent over the same period.

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

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

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

The Chairman. Yes, Senator Cornyn.

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

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

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

Mr. Swagel. Okay, very good.

So the inflation rebate, as we analyze it, will have
different effects. The main effect in reducing federal spending will come on the existing drugs for which there are not substantial rebates.

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

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

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

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

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

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

Senator Cornyn. Everything goes down, you are
saying?

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

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

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

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

The Chairman. Yeah.

There is a couple things that I want you to remember about Part D. I wrote it. So you ought to know that I want to protect it. I hope you also know that I have great respect for the Senator from Pennsylvania, and it happens that he and I agree on a subsidy limitation that I have been trying to get into farm bills for the last 10 years and been successful in the Senate, but not
successful in the House of Representatives, and that is the overall cap on subsidies that big farmers get from the farm program.

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

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

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

I call on Senator Stabenow.

Senator Stabenow. Thank you, Mr. Chairman.

I oppose the amendment as well. And before a brief statement about that, I want to just go back to the beginning and thank you and the Ranking Member for the work that is been done in committee. I do not in any way
underestimate the hearings that were done. That had not
been done a long time with pharma CEOs and PBMs, and I
think this has been a very important process. So I want
to thank you for that.

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

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

The Chairman. Shall we vote?

Senator Wyden. Please.

Senator Daines. Mr. Chairman, can I quickly?

The Chairman. Yes.

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

Mr. Swagel. It is exactly as you said before, the
protected classes remove the power of the insurer to
drive down prices.

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

Mr. Swagel. That is correct.

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

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

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

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

Senator Daines. And then I will say that I think my colleague and I, though, have common ground. If you wish to have a secondary amendment which would eliminate protected classes, I would support his bill. But the degree to which his bill feeds into protected classes, those sellers who have no competition and no ability for the purchaser, the taxpayer, or the patient to drive down the cost, therefore they can raise their cost 19 percent
per year compounded, that is not a free market. That is
exploiting the taxpayer.

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

The Chairman. The Clerk will call the roll.
The Clerk. Mr. Crapo?
Senator Crapo. Aye.
The Clerk. Mr. Roberts?
The Chairman. Aye by proxy.
The Clerk. Mr. Enzi?
Senator Enzi. Aye.
The Clerk. Mr. Cornyn?
The Chairman. Aye by proxy.
The Clerk. Mr. Thune?
Senator Thune. Aye.
The Clerk. Mr. Burr?
The Chairman. Aye by proxy.
The Clerk. Mr. Isakson?
The Chairman. Aye by proxy.
The Clerk. Mr. Portman.
The Chairman. Aye.
The Clerk. Mr. Toomey?
Senator Toomey. Aye.
The Clerk. Mr. Scott?
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?
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?

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Senator Casey. No.
The Clerk. Mr. Warner?
Senator Warner. No.
The Clerk. Mr. Whitehouse?
Senator Whitehouse. No.
The Clerk. Ms. Hassan?
Senator Hassan. No.
The Clerk. Ms. Cortez Masto?
Senator Cortez Masto. No.
The Clerk. Mr. Chairman?
The Chairman. No.
Can you announce the totals?
The Clerk. Mr. Chairman, the final tally is 14 ayes, 14 nays.
The Chairman. The amendment lost.
Next Amendment? And we are ready -- Senator Stabenow.
Senator Stabenow. Thank you very much, Mr. Chairman. And I want to thank colleagues who are co-sponsoring this amendment to let Medicare negotiate.
Let me take you back to the debate we had on the Republican tax cut. When the Republican majority on the committee wrote your tax bill, you did not think it was enough to just cap the rate of tax increases for Pharma or for wealthy individuals. You gave them a tax cut.
They wanted a tax cut. And the people of our country want a cut in the prices they are paying for prescription drugs.

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

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

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

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

We know that negotiation works. The VA negotiates
prices for our veterans, and saves 40 percent -- 40 percent compared to what is done with Medicare.

According to a recent AARP analysis, Medicare could have saved $14.4 billion on just 50 drugs if it paid the same price as the VA. And by the way, I want to thank the AARP for supporting our amendment today.

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

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

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

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

The Chairman. Senator Menendez --

Senator Stabenow. -- put people before profits --

The Chairman. I’m sorry.
Senator Stabenow. Mr. Chairman, that is all right. It is time to put people over profits.

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

Thank you, Mr. Chairman.

The Chairman. Senator Menendez.

Senator Menendez. Thank you, Mr. Chairman.

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

The Chairman. Yes, you may.

Senator Menendez. Yeah.

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

Mr. Swagel. I am.

Senator Menendez. Okay. And is it fair to say, to synthesize the letter, that what you say about negotiation is that it is only likely to be effective if it is accompanied by some source of pressure on drug manufacturers to secure price concessions. For example,
authority to establish a formulary. Is that a fair statement of what you said in the law?

Mr. Swagel. Yes, that is correct.

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

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

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

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

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

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

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

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

Senator Enzi. Mr. Chairman?

The Chairman. Senator Enzi?

Senator Enzi. Mr. Chairman, we have already tried that. The veterans have that kind of a program where there are negotiated prices, which means if there are
several drugs, one is the winner. Others are not available then to the veterans. So they were really relieved when we did Part D. And many veterans got on to Part D to get their medications because they could get what their doctor and they thought were most appropriate.

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

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

The Chairman. Senator Cardin?

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

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

We had two hearings on the PBMs, and we were all kind of glazed at how they operate. As a result, there
have been numerous amendments filed by my colleagues for
more transparency on how the pharmaceutical, the benefit
managers operate their plans.

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

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

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

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

    The Chairman. Okay, we will do that.

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

    Number one, the House of Representatives announced,
I think this week, that when they come out with a plan in
September, it is going to be the focal point of the House of Representatives. The President campaigned on exactly this issue. Now thank God the President has not advocated that lately, but who knows what he is going to do?

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

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

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

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

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

The Chairman. Senator Brown?

Senator Brown. Thanks, Mr. Chairman.

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

The Chairman. Can I interrupt you?

Senator Brown. Certainly, Mr. Chairman. You
always may.

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

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

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

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

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

My competitive licensing bill would prevent a formulary -- would prevent that kind of formulary. So this amendment -- it is what our constituents want. It will work. I ask for support of my colleagues.
The Chairman. Senator Hassan, and then Senator Wyden, and then we will vote.

Senator Hassan. Thank you, Mr. Chair.

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

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

So I am very grateful to all the work that you and the Ranking Member have done on this bipartisan package, which takes very important steps forward. But I do think without negotiating power for Medicare, this package is lacking the single most impactful thing we could do in terms of lowering prescription drug prices. That is why
I am supporting it but I would look forward to working with Members of both parties to see if we can talk about a negotiating system that also provides consumer and patient choice, and I think there are ways to do that. Thank you, Mr. Chair.

The Chairman. Senator Wyden?

Senator Wyden. Thank you, Mr. Chairman.

I want to speak in behalf of the Stabenow Amendment. She has brought so much energy and passion to this cause, and I so appreciate it and give my sense of where I think things are to my colleagues.

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

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

The Clerk.   Mr. Crapo?

Senator Crapo.   No.

The Clerk.   Mr. Roberts?

The Chairman.   No by proxy.

The Clerk.   Mr. Enzi?

Senator Enzi.   No.

The Clerk.   Mr. Cornyn?

The Chairman.   No by proxy.

The Clerk.   Mr. Thune?

Senator Thune.   No.

The Clerk.   Mr. Burr?

The Chairman.   No by proxy.

The Clerk.   Mr. Isakson?

The Chairman.   No by proxy.

The Clerk.   Mr. Portman?

The Chairman.   No.

The Clerk.   Mr. Toomey?

Senator Toomey.   No.

The Clerk.   Mr. Scott?

The Chairman.   No by proxy.

The Clerk.   Mr. Cassidy?

Senator Cassidy.   No.

The Clerk.   Mr. Lankford?

Senator Lankford.   No.
The Clerk.  Mr. Daines?

Senator Daines.  No.

The Clerk.  Mr. Young?

The Chairman.  No by proxy.

The Clerk.  Mr. Wyden?

Senator Wyden.  Aye.

The Clerk.  Ms. Stabenow?

Senator Stabenow.  Aye.

The Clerk.  Ms. Cantwell?

Senator Cantwell.  Aye.

The Clerk.  Mr. Menendez?

Senator Wyden.  No by proxy.

The Clerk.  Mr. Carper?

Senator Wyden.  Aye by proxy.

The Clerk.  Mr. Cardin?

Senator Cardin.  Aye.

The Clerk.  Mr. Brown.


The Clerk.  Mr. Bennet?

Senator Wyden.  Aye by proxy.

The Clerk.  Mr. Casey?

Senator Casey.  Aye.

The Clerk.  Mr. Warner?


The Clerk.  Mr. Whitehouse?
Senator Wyden. Aye by proxy.

The Clerk. Ms. Hassan?

Senator Hassan. Aye.

The Clerk. Ms. Cortez Masto?

Senator Cortez Masto. Aye.

The Clerk. Mr. Chairman?

The Chairman. No.

Announce the vote when you are ready.

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

The Chairman. Give it again, please.

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

The Chairman. The amendment lost.

Any other amendments?

[No response.]

The Chairman. Then we are ready for --

Okay, Senator Toomey.

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

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

Toomey Amendment Number 4 is a little different. It would prevent the Part D inflationary rebate from taking effect unless and until the Secretary of Health and Human
Services certifies that the implementation of that feature will neither increase launch prices for future drugs or result in higher beneficiary cost sharing due to those higher prices.

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

And I ask for a recorded vote.

Senator Wyden. Has my colleague finished his statement?

Senator Toomey. I have.

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

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

Ms. Bishop. No. The way that the inflation rebate is structured is separate from plan and PBM negotiations. It is a mechanism. You can think about it as a backstop to the negotiations that would be undertaken between the plans and the PBM.
A backstop is something that works sort of on the backend, obviously. So the plans and the PBMs have all of the authority that they have today to negotiate prices.

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

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

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

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

Senator Toomey. Mr. Chairman?

The Chairman. Yes.

Senator Toomey. I just want to briefly comment.

The reason -- everybody should know the reason it is out of order and not germane is because CBO believes that this amendment would cost money. It would diminish the savings. Why would it diminish the savings? Because CBO believes that the HHS Director will never be able to
certify that implementation of this inflation penalty will not result in higher launches of drug prices.

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

The Chairman. Senator Cardin.

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

Senator Wyden. We have to vote, Senator Cardin.

Senator Cardin. Oh, I am sorry.

The Chairman. He did not appeal the Chair.

Senator Wyden. It is ruled out of order.

The Chairman. Yeah. He did not --

Senator Cardin?

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

I am going to offer Cardin-Cornyn Amendment Number 2. Mr. Chairman, I will not be requesting a vote, and I will withdraw. But I have got to express my real disappointment that this was not included in the revised Mark. When I left last night, I thought it was included, quite frankly. And we have had a wonderful relationship with staff on these amendments. And I want to explain my disappointment.
And I first want to thank my Republican colleagues that support this. We have strong bipartisan support for this amendment on the committee.

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

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

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

The Chairman. Without objection, so ordered.

Senator Cardin. So this is a commonsense correction to a problem that we all have recognized. And I understand things sometimes do not get covered that should be covered in a Mark. I have confidence of our
leadership on this committee, but I just have to explain
I was disappointed that this was not included. And I
hope we will have an opportunity to correct that as this
process goes.

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

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

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

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

The Chairman. Senator Warner?

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

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

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

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

One of the things that we have in our circumstances right now is there is absolutely no limitation at all on launch prices for any drugs. And remarkably, we have no system at all, as well, to ever evaluate the efficacy of new drugs that come to market. So what Warner-Carper-Bennet Amendment Number 2 would do is it would put in place a procedure -- a procedure that is used in other industrial nations that would allow -- and other Members on the Republican side have talk with this. And again, I
hope we continue to work on this issue that would allow a
drug manufacturer to put out a launch price, but within
some period of time, six months, a year, there would then
be a review were an independent body would look at the
efficacy of that drug and put a price on it.

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

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

And then I would simply add one other comment, and
that is that the Cortez Masto-Warner-Hassan Number 8. It
looks well at this launch price issue, and it simply says
-- and I was disappointed this was not included in the
Chairman’s Mark because it said even if you do not want
to go as far as what I have suggested, and Senator
Bennet, and Senator Carper, it would say we ought to have
GAO study the launch price issue because I do think by
the good work that the inflation caps are putting in
place in this legislation, we are going to create a new impetus for drug companies to offer much higher launch prices. And would hope we would have at least had a GAO study on that.

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

The Chairman. Yes, we will.

Senator Lankford?

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

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

When new generics are put on branded tiers, that drives up the cost for people on Medicare Part D. To give you an example of this, in a recent study Part D plans had the generic drugs placed in the lowest cost-sharing tier, preferred generic only 14 percent of the
time in 2016 to 2019. There is an area where they are
continuing to place specialty generic medicines on one
formulary for specialty drugs, again driving up the cost
for seniors based on where they selected.

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

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

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

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

Senator Lankford. Yes, sir. We have.

The Chairman. Senator Roberts for 20 seconds, and
then Senator Young.
Senator Wyden. After Senator Roberts, if we could go to Senator Brown, and then Senator Young.

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

Senator Brown. It is all right.

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

Senator Roberts. Twenty seconds.

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

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

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

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

Thank you.

The Chairman. Thank you.

Senator Young, and then Senator Brown.

Senator Young. Well, Mr. Chairman, I too want to offer my sort of laudatory comments towards you and your
leadership on this whole endeavor. It is really important.

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

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

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

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

So I could not fully digest all this. Some of my colleagues are really quick studies and no doubt penetrated much of it, and they are building on a base of knowledge that maybe I do not enter this discussion with. Although I did spend four years -- I would note -- on the
Ways and Means Committee, and the process was different. And I would suggest that perhaps we could learn from that.

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

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

The Part D cost-sharing changes are an important first step as I see it to reducing costs for seniors. It is a small step. It helps a very small group of seniors, and that is not enough to get me to a yes. We need to be
helping millions more of our seniors in the Medicare Part D program who really need help with rising prescription drug costs. And that has been articulated by so many of my colleagues on both sides of the aisle here today.

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

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

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

So one pertains to the catastrophic phase of the benefit. I think we need to spread the rebate across the
entire benefit design so it does not disproportionately
fall on those who serve patients, seniors, and other
Americans with rare diseases. That is the first issue.
I like a commitment for the Chairman to address in coming
weeks as we look to improve this model that we are voting
on today.

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

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

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

The Chairman. I have talked to the Ranking Member
about that. You also have the advantage that the
Administration is working on exactly the same thing you are talking about. Now I do not know what the Administration wants to do interacting with us. But at least there is interest in the Administration on the point that you want to accomplish.

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

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

The Chairman. Senator Brown?

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

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

[Laughter.]

Senator Brown. Anyway --

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

Senator Brown. Perhaps.

Senator Young. Yeah, thank you.

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

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

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

Senator Brown. Thank you, Mr. Chairman.

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

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

We also have not done anything to require PBMs provide the negotiated price at the point-of-sale on this
committee Mark. This amendment would make these improvements. You addressed it, Mr. Chairman, as did Senator Wyden in your opening remarks. Fixing clawbacks is a huge priority for so many of us on this committee on both sides of the aisle.

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

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

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

Senator Brown. I withdraw Amendment 10.

The Chairman. Okay.

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

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

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

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

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

First of all, the effect of this model, the proposed International Price Index Model is to import the foreign price controls of countries that restrict access to drugs. And let us be clear who some of these countries are. More than half of the proposed reference countries
have GDPs that are less than 5 percent of America’s GDP. It includes countries like the Czech Republic, Portugal, Greece, Slovakia.

These countries simply do not have comparable health care systems. They certainly do not have anything like the innovative research and development and discovery in the life sciences and prescription drug space that we do. It is their goal to get their drug prices to converge as closely as possible to the marginal cost of production without any regard for all of the research and development, which is a necessary precondition for every new drug.

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

Look, I think we do need to address this. I think the way to address this problem is through trade
negotiations. This should be a very high priority of this Administration, and I hope it will be.

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

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

The Chairman. It is --

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

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

Let me first of all speak that Senator Toomey has correctly stated my concern about the policy that he wants to have in his amendment. I have stated that in regard to suggested rulemaking by the Administration, but I am going to still oppose his amendment at this point
because I just think that I do not want to get this issue wrapped up with all the other stuff we are trying to accomplish here.

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

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

Senator Cassidy. Mr. President?

The Chairman. Yeah, go ahead.

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

I also think that there is some other ideas that I think would be a little bit more effective at controlling that initial launch price. I am interested in working with my colleagues on that. So I will support it.
The Chairman. The Clerk will call the roll.

The Clerk. Mr. Crapo?

Senator Crapo. Aye.

The Clerk. Mr. Roberts?

The Chairman. Aye by proxy.

The Clerk. Mr. Enzi?

Senator Enzi. Aye.

The Clerk. Mr. Cornyn?

The Chairman. Aye by proxy.

The Clerk. Mr. Thune?

Senator Thune. Aye.

The Clerk. Mr. Burr?

The Chairman. No by proxy.

The Clerk. Mr. Isakson?

The Chairman. Aye by proxy.

The Clerk. Mr. Portman.

The Chairman. Aye by proxy.

The Clerk. Mr. Toomey?

Senator Toomey. Aye.

The Clerk. Mr. Scott?

The Chairman. Aye by proxy.

The Clerk. Mr. Cassidy?

Senator Cassidy. Aye.

The Clerk. Mr. Lankford?

Senator Lankford. Aye.
1 The Clerk. Mr. Daines?
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?
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?

LISA DENNIS COURT REPORTING
Senator Whitehouse. No.
The Clerk. Ms. Hassan?
Senator Hassan. No.
The Clerk. Ms. Cortez Masto?
Senator Cortez Masto. No.
The Clerk. Mr. Chairman?
The Chairman. No.
The Clerk. Mr. Chairman, the final tally is 14 ayes, 14 nays.
The Chairman. The amendment lost on a tie vote.
I think this is your -- Senator Hassan, Senator Cornyn -- do you have an amendment?
Senator Hassan. I just wanted to offer and amendments and speak briefly to two of them.
The Chairman. The way my staff has it lined up, I will call on Cornyn and then Hassan.
Senator Cornyn. I would defer to Senator Hassan.
Senator Hassan. Thank you, Senator Cornyn.
I just wanted to, first of all, thank you, Mr. Chair for including Hassan Number 4 in the Mark-up. I will offer and withdraw Hassan 1, 2, 3, 5, 6, 7, 8, 9, and 10.
I did want to speak to Hassan Number 7 which would be mandatory reporting of charitable contributions by opioid manufacturers. We have all read the stories of opioid manufacturers using deceptive and appalling
marketing tactics to increase opioid prescribing. And these tactics have fueled the epidemic that is devastating communities around our country.

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

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

Requiring these financial relationships to be disclosed is a commonsense step to help root out these conflicts. This amendment which Senator Whitehouse has joined me on would be an important addition to the comprehensive approach that this committee and this body has taken to combat the opioid crisis. I am hopeful it can be included in this package before it moves to the
And on Amendment 10, which I offered with Senators Cortez Masto and Brown, ensuring beneficiaries certainty in Part D during the benefit redesign, that is simply an amendment intended to make sure that as we transition under the terms of this bill that insurers do not abuse utilization management in a way that would impact beneficiaries who already have prescriptions that have been pre-authorized. We want those pre authorizations to stay in effect during benefit redesign to ensure stability and certainty for people who need these life-saving drugs.

Thank you very much, Mr. Chair.

The Chairman. Okay, thank you.

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

[Response of mic.]

The Chairman. Okay.

Senator Cornyn.

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

But I do want to point out that the Chairman’s Mark includes a redesign of Medicare Part D that would cap out-of-pocket costs for beneficiaries, but pour more
liability on the drug manufacturers during catastrophic coverage. This will benefit seniors, no doubt, but I have heard some concerns that the redesign may cause access issues for patients with severe mental illness.

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

So the Cornyn-Portman-Menendez Amendment would authorize the Secretary to modify a manufacturers’ liability in the catastrophic phase if the current manufacturers’ liability of 20 percent would threaten access to treatments for people with serious mental illness or other disabilities. This would preserve access to this vulnerable population and ensure that we are not negatively impacting innovation.
As I said, Mr. Chairman, I do not intend to offer the amendment, but I did want to lay that down as a marker and take you up on your offer to continue to have a conversation before this bill comes to the floor to address this concern.

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

Is there any objection to going to final passage?
[No response.]

The Chairman. The clerk will call the roll.

The Clerk. Mr. Crapo?
Senator Crapo. No.

The Clerk. Mr. Roberts?
The Chairman. No by proxy.

The Clerk. Mr. Enzi?
Senator Enzi. No.

The Clerk. Mr. Cornyn?
The Chairman. Aye by proxy.

The Clerk. Mr. Thune?
Senator Thune. No.
The Clerk. Mr. Burr?

The Chairman. No by proxy.

The Clerk. Mr. Isakson?

The Chairman. No by proxy.

The Clerk. Mr. Portman.

The Chairman. Aye by proxy.

The Clerk. Mr. Toomey?

Senator Toomey. No.

The Clerk. Mr. Scott?

The Chairman. No by proxy.

The Clerk. Mr. Cassidy?

Senator Cassidy. Aye.

The Clerk. Mr. Lankford?

Senator Lankford. No.

The Clerk. Mr. Daines?


The Clerk. Mr. Young?

Senator Young. Aye.

The Clerk. Mr. Wyden?

Senator Wyden. Aye.

The Clerk. Ms. Stabenow?

Senator Stabenow. Aye.

The Clerk. Ms. Cantwell?

Senator Cantwell. Aye.

The Clerk. Mr. Menendez?
Senator Menendez.    Aye.
The Clerk.   Mr. Carper?
The Clerk.   Mr. Cardin?
Senator Cardin.   Aye.
The Clerk.   Mr. Brown?
The Clerk.   Mr. Bennet?
Senator Bennet.   Aye.
The Clerk.   Mr. Casey?
Senator Casey.   Aye.
The Clerk.   Mr. Warner?
The Clerk.   Mr. Whitehouse?
The Clerk.   Ms. Hassan?
Senator Hassan.   Aye.
The Clerk.   Ms. Cortez Masto?
Senator Cortez Masto.   Aye.
The Clerk.   Mr. Chairman?
The Chairman.   Aye.
Senator Scott wants to vote as in person.
What is your vote?
Senator Scott.    Thank you, sir.    No, sir.
The Clerk.   Mr. Chairman, the final tally is 19
ayes and 9 nays.

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

Senator Portman?

Senator Portman. Thank you, Chairman.

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

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

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

I also want to thank you for including Portman 2 in the Mark. This comes out of work Senator Carper and I did with regard to Evzio, which is a miracle drug that reverses the effects of opioid addiction, opioid
overdoses. But the cost had gone up dramatically. It was because of these third-party reimbursement hubs, and we have now addressed that in this amendment, and I appreciate you including that.

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

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

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

So here is my recommendation. Instead of 100 percent, let us start with 20 percent. Let us do 20 percent in our legislation. When we get to the floor, we have a chance to talk about this more back to the
consumer. Let us get started on this. That would be a minimum threshold. It would also give the Administration the tools they need legislatively to be able to do this and not raise premiums. And I think there is an opportunity here if we are to adopt this amendment on the floor to make a huge difference in terms of lowering out-of-pocket costs, which is the big issue that I hear back home.

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

The Chairman. Thank you very much.

Now, Senator Burr.

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

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

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

Senator Carper. Yeah, I want to just comment very briefly on the comments from Senator Portman. I always enjoy working with Senator Portman and his team and
appreciate very much the work that we have done together on this point.

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

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

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

And I think it is in an idea -- I am told that you have some interest in, the Majority, as does the Minority led by Senator Wyden. But according to Secretary Azar, passing drug company rebates to patients at the pharmacy counter is one of the best ways we can bring down out-of-pocket costs for seniors.
And this change would also inject some badly needed transparency into our convoluted drug pricing system, and I would urge us to keep working at this idea between now and the time the bill comes to the floor, point-of-sale rebates to directly lower drug costs for seniors at the pharmacy counter. That is one.

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

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

This bipartisan bill rolls back over a decade of list price increases for insulin, decreasing prices for the most popular insulins by about 75 percent. And I would just say to our Chair and Ranking Member, I believe
you share the priority of lowering the price of insulin
and other drugs at the pharmacy counter for patients.

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

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

Senator Brown and then Cassidy.

Senator Brown. Thank you, Mr. Chairman.

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

While the Chairman’s Mark is a good bipartisan bill,
it is not a substitute for other measures like government
price negotiation, as we discussed, ending price spikes
for everyone, curbing drug corporations monopoly power,
as Senator Whitehouse talked about. Brown Amendment 2
takes the Chairman’s Mark a step further and creates a
penalty for companies that engage in price gouging, not
just in Medicare and Medicaid, but across the entire U.S. prescription drug market.

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

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

My Amendment would end this predatory practice.

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

The Chairman. Thank you.

Now, Senator Cassidy.

Senator Cassidy. Mr. Chairman, I speak to Cassidy Number 5. It is about value-based pricing. We are trying to find ways to make new drugs more affordable, and this amendment would allow for a cost-neutral demonstration from CMS allowing commercial value-based arrangements, exempting them from Medicaid best price requirements.
I understand that it is the other side of the aisle that does not want this amendment. So I enter for the record a statement from John Gruber, so-called architect of the Affordable Care Act. “We are about to enter an era of unprecedented treatment for rare disease and 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.”

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

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

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

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

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

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

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

With that, I withdraw.

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

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

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

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

The Chairman. Senator Casey?

Senator Casey. Thank you, Mr. Chairman.

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

I want to thank you first and foremost before I get to the amendment itself. I want to thank both Chairman Grassley, Ranking Member Wyden not only for the work on
this bill, but also for including two of my priorities in the Mark.

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

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

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

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

Extra Help is fraught with Administrative complexity, which I will not go into today. Even with the programs help, some of the participants face
coinsurance rates that prevent them from accessing needed medications.

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

Thank you both.

The Chairman. Thank you.

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

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

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

With that, this hearing is adjourned.

[Whereupon, at 12:33 p.m., the meeting was adjourned.]
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<td>THE HONORABLE BILL CASSIDY</td>
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<td>A United States Senator</td>
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<td>from the State of Louisiana</td>
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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, no 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.

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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