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MAKING PRESCRIPTION DRUGS MORE AFFORDABLE: LEGISLATION TO NEGOTIATE A BETTER DEAL FOR AMERICANS

WEDNESDAY, SEPTEMBER 25, 2019

House of Representatives

Subcommittee on Health

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 10:30 a.m., in Room 2322 Rayburn House Office Building, Hon. Anna G. Eshoo [chairwoman of the subcommittee] presiding.

Members present: Representatives Eshoo, Engel, Butterfield, Matsui, Castor, Sarbanes, Lujan, Schrader, Kennedy, Cardenas, Welch, Ruiz, Dingell, Kuster, Kelly, Barragan, Blunt Rochester, Rush, Pallone (ex officio),

Burgess, Upton, Shimkus, Guthrie, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Carter, Gianforte, and Walden (ex officio).

Also Present: Representatives Soto, Schakowsky, Walberg, McKinley, Johnson, Latta, and Rodgers.

Staff present: Jacquelyn Bolen, Professional Staff; Jeff Carroll, Staff Director; Waverly Gordon, Deputy Chief Counsel; Tiffany Guarascio, Deputy Staff Director; Josh Krantz, Policy Analyst; Una Lee, Senior Health Counsel; Aisling McDonough, Policy Coordinator; Joe Orlando, Staff Assistant; Alivia Roberts, Press Assistant; Samantha Satchell, Professional Staff Member; C.J. Young, Press Secretary; S.K. Bowen, Minority Press Assistant; Jordan Davis, Minority Senior Advisor; Margaret Tucker Fogarty, Minority Staff Assistant; Theresa Gambo, Minority Human Resources/Office Administrator; Caleb Graff, Minority Professional Staff Member, Health; Peter Kielty, Minority General Counsel; Ryan Long, Minority Deputy Staff Director; James Paluskiewicz, Minority Chief Counsel, Health; Kristin Seum, Minority Counsel, Health; Kristen Shatynski, Minority Professional Staff Member, Health; and Evan Viau, Minority Professional Staff, C&T.

Ms. Eshoo. Good morning, everyone. The Subcommittee on Health will now come to order.

The first thing I would like to begin with is all of us wishing our wonderful colleague, Congresswoman Matsui, a happy birthday.

Happy birthday, Doris. Happy birthday.

[Applause.]

Ms. Eshoo. Happy birthday. Happy birthday. That really is sound applause on both sides, Doris. You're in good shape. You're in good shape. But we all know that. Blessings on you, our friend.

I want to welcome everyone that's here in the audience. I see a lot of red shirts. I think that's all AARP. Thank you for being here and for your advocacy.

The chair now recognizes herself --

Mr. Walden. Madam Chair?

Ms. Eshoo. Yes.

Mr. Walden. If I could just point briefly.

Ms. Eshoo. Certainly.

Mr. Walden. We have a number of members on our side who want to waive onto the Sub.

Ms. Eshoo. Certainly.

Mr. Walden. How should we accommodate that?

Ms. Eshoo. Well, I don't think you need permission for that. They just need to -- I think what we need to know is the order in which they arrived, and after all the members -- the rules of the full committee provide for following the --

Mr. Walden. Right. Members on the Sub to go first.

Ms. Eshoo. All members of the Subcommittee go first and then the order in which they have arrived today I will recognize them.

Mr. Walden. And then in terms of seating, I know we have -- this is a very small room that was ~~which~~ chosen.

Ms. Eshoo. Well, let's see if we can get some more chairs. Let's see if we can get some more chairs. If they don't want to stay for the whole --

Mr. Walden. Should they --

Ms. Eshoo. If they don't want to stay for the whole hearing --

Mr. Walden. Right.

Ms. Eshoo. -- - they can come back. The staff -- committee staff --

Mr. Walden. Well, I think they want to participate.

Ms. Eshoo. Do you want to be here for the whole --

Mr. Walden. Well, some will. You know, we have the other hearing going on downstairs on vaping at the same time

--

Ms. Eshoo. Right. Right.

Mr. Walden. -- which is unfortunate. But --

Ms. Eshoo. No, we will be happy to recognize them and there are some reserved seats there it says for the press but they haven't taken them. So --

Mr. Walden. Well, that's -- okay. I know you --

Ms. Eshoo. Okay. We will get -- what was that again? Okay. So the staff will make room for them --

Mr. Walden. All right. Thank you.

Ms. Eshoo. -- and get name cards for them.

Mr. Walden. Yes, that would be excellent. Thank you.

Ms. Eshoo. Absolutely. Thank you.

I want to thank the members that are here today to waive on. I think it's an important rule of the committee, and I know that I have exercised it and it's an important rule of the committee. We want to accommodate you.

So with that, the chair now recognizes herself for five minutes for an opening statement.

Today, millions of Americans are fighting two battles -- one, their illness -- a condition that they may have -- and the cost of their prescription drugs to address it~~s~~.

One in four diabetes patients ration their insulin.

Twenty-three percent of American seniors report difficulty affording their drugs and 30 percent of Americans have skipped a dose due to cost.

As a nation, we are paying three to four times more for these needed drugs than other countries. Every member of this committee, every single one of us, has heard from our constituents about the high cost of prescription drugs and that is why we are beginning the journey today to address this issue in our country.

We have a law in our country that prohibits Medicare from negotiating directly with drug companies -- the only developed nation in the world with such a law.

So that is why we are considering four bills to finally allow Medicare to negotiate drug prices. Two of the bills -- H.R. 3 and H.R. 448 -- limit the negotiated price to be in line with what other wealthy countries pay for their drugs.

With these bills, Americans will no longer have to pay so much more for their prescription drugs than other countries. It is something that when people complain about the price, they always pose the question why is it that we pay so much more and the same drug is cheaper in other countries. It always attends that question.

I think our constituents deserve a much better deal.

Importantly, H.R. 3 prioritizes insulin as first on the list to be negotiated. Humalog, a common insulin, costs the average American $2,240 a year. If prices in the United States matched those in other countries, the same drug would cost Americans $347 a year, seven times less than it does now.

Under H.R. 3, every American -- this is a very important element of the legislation -- every American, whether they are enrolled in Medicare or have private insurance, will have access to the lower prices.

H.R. 3 also ensures seniors can afford their out-of-pocket drug costs, bringing those costs down to $2,000 a year from as much as $5,100 a year or more. This would be a godsend. This would be a godsend to people.

H.R. 3 also stops drug price hikes like the ones we saw from EpiPen and Martin Shkreli's price hike of Daraprim. The bill says that if a manufacturer raises the rate of inflation -- raises the price of any Part B or D drug, including generics, above the rate of inflation, the manufacturer must lower the price or pay the entire price above inflation back to the Treasury.

When H.R. 3 was introduced last week, I read some of the comments from my Republican colleagues and I want to address

them head on.

First, on bipartisanship -- I want H.R. 3 to be a bipartisan bill because I want this bill -- I want legislation to become law.

Secondly, H.R. 3 includes many provisions that President Trump and other Republicans have publicly supported. It delivers on candidate Trump's support for negotiating drug prices.

H.R. 3 also has a similar policy to President Trump's proposal to tie what Medicare Part B pays for prescription drugs to international prices.

H.R. 3 shares provisions with Senator Grassley's drug pricing bill, including capping out-of-pocket costs for seniors and lifting price hikes to inflation.

Second~~Second~~, Republicans say that this bill will stifle innovation and R&D. We all care about research and development and innovation because we want those miracle drugs to get to people.

But if they can't afford them, they simply don't have access.

Today, NIH spends more money on R&D than any single pharmaceutical company and most big drug manufacturers spend more today on marketing, sales, and overhead, than on R&D,

and this is a change. At one time, that wasn't the case.

Third, my colleagues call H.R. 3 socialism. That's the new buzz word. Did Republicans call candidate Trump a socialist when he said, quote, "When it comes to negotiating the cost of drugs we are going to negotiate like crazy."

Who here has not supported the VA's ability to directly negotiate drug prices? Congress unanimously voted -- this is extraordinary -- Congress unanimously voted to give the secretary of the VA authority to negotiate in 1992, resulting in the VA's prescription drugs costing about 40 percent less than Medicare's.

The cost of prescription drugs is an enormous burden for the American people and I think it's time for us to level the playing field for them.

I now have the pleasure of yielding the remainder of my time to Congresswoman Matsui.

Ms. Matsui. Thank you very much. So I get a little more time because it's my birthday, right?

Ms. Eshoo. Absolutely.

Ms. Matsui. Thank you, Madam Chair.

There are many reasons to undertake this important work, none more important than the everyday stories from patients across the country dealing with high drugs costs, including

seniors like Cynthia Stockton from Sacramento.

A few years ago, she developed seizures and discovered a brain tumor. She's on Medicare, and without prescription drugs her body would shut down and she would die.

The prescription she takes to treat her muscle spasms and seizures and boost her mental health cost a significant amount of money for someone on a fixed income.

Seniors like Cynthia deserve better. They deserve affordable medication and it underscores why we must get this right.

I look forward to working to make that a reality. Thank you, and I yield back.

Ms. Eshoo. The gentlewoman yields back.

I was going to yield time to Congresswoman Kuster but I don't have any more time. So -- I don't. I know that. I just looked up at the clock.

The chair now recognizes Dr. Burgess, the ranking member of the Subcommittee on Health, for five minutes for his opening statement.

Mr. Burgess. So my thanks to the chairwoman. We are convened here today to discuss the very important topic of drug pricing. Every one of us has heard passionate personal stories from our constituents about the ever-increasing costs

of prescription drugs.

So I am committed to addressing this issue and lowering out-of-pocket costs for patients. In fact, in December of 2017, as chairman of this subcommittee I asked our witness panel at a drug supply hearing not just to point out flaws, which they did, but to come to us -- come to the table with solutions.

Unfortunately, there wasn't a lot of coming forth with solutions. But still, we have pushed forward with discussions, most of the time bipartisan discussions, and legislation.

Throughout last Congress and this Congress we have held thoughtful hearings with robust witness panels to offer analyses on different drug pricing problems and possible legislation.

But this hearing seems to really come at us fairly quickly on a bill that was just released last week and it does seem to be a partisan exercise on this topic today, and that's unfortunate.

This committee has a history of working together to improve generic and biosimilar competition. For example, I worked with Chairwoman Eshoo on the Purple Book Continuity Act, which has passed the House, and I think we can both

agree that this is a better bill because we shared our ideas and we worked together.

Additionally, the House passed the CREATES bill. We worked on it last Congress, completed it in this Congress, and this will prohibit drug manufacturers from gaming the system by refusing to sell samples to generic manufacturers.

CREATES will directly address the thalidomide issues that Dr. Fowler mentions in his testimony and we need to build on that foundation to address other aspects of this market dynamic.

Going forward, we should be able to continue a bipartisan dialogue instead of being shut out of our conversations altogether.

I do support bipartisan solutions to lowering drug prices for American patients. I appreciate that in the past we have had bipartisan conversations about modernizing Medicare Part D in this Congress, including capping beneficiaries' out -- of -- pocket costs.

I would like to continue those conversations and welcome committee activity that enables productive discussions.

H.R. 3 is a proposal that was drafted behind closed doors by Speaker Pelosi and her staff and it is being forced through this committee by the chairman. This committee has a

long history of working together to address complex issues in the health care system including drug pricing.

Until last week, that was the case in this Congress as well. This committee has fought over the years to achieve bipartisan success in establishing pathways for new and innovative drugs and cures to come to market and get into the hands of patients more quickly.

Through FDA user fee reauthorizations and 21st Century CURES we have built a framework that spurs innovation to improve the health and well-being of the lives of patients and their loved ones.

Earlier this year, we saw on a "60 Minutes" program where Dr. Francis Collins of the National Institute of Health was on national television and used the word "cure" in referring to sickle cell disease.

I can't tell you how stunning that was for me. The release of such great human suffering is priceless. Yet, we do need a 21st century payment mechanism for our 21st century cures.

We need to ensure that such payment mechanisms do not impede innovation. While we should ensure that the government money is spent wisely, that should not come at the cost of limiting patients' access to care.

So, Doctor, I am uncomfortable with the idea of government action restricting patients' access to lifesaving medications.

You know, back in the early days of my medical practice back in the 1980s, as doctors we like to sit around and gripe about stuff, and we did.

So one of the things we griped about was the fact that there were treatments available in Europe that were not available in the United States.

Now, thanks to the establishment of user fees and other significant work done by this committee, the Committee on Energy and Commerce, to clear that regulatory bottleneck and speed the drug approval process over the past four decades, now the situation is reversed.

American doctors have more pharmaceutical tools ~~and~~ available to treat their patients and alleviate human suffering than do their European counterparts.

So we are going to hear a number of examples of that today. I certainly want to thank the committee for the work back in the '90s on the user fee agreements that led us to this point, and it is in that spirit of bipartisanship I hope we can go forward.

After we have this hearing today and get it out of our

system, we need to sit down and see if we can't do something that will be meaningful.

Thank you, Madam Chair, and I will not take the additional minute and a half.

Ms. Eshoo. I thank the gentleman.

Dr. Burgess, my door is always open. We will honor regular order here and I think that it's now time to recognize --

Mr. Burgess. Just a --

Ms. Eshoo. Certainly.

Mr. Burgess. -- parliamentary -- then can we anticipate a subcommittee markup before going to full committee markup?

Ms. Eshoo. I believe so, yes.

Mr. Burgess. All right. I'll take that as an assurance.

Ms. Eshoo. I just want to add that H.R. 3 doesn't limit access of any drugs. There's no formulary. It's just a fair price.

With that, I now would like to recognize the gentleman from New Jersey, the chairman of the full committee, Mr. Pallone, for his five minutes for an opening statement.

The Chairman. Thank you, Madam Chair.

Today, we are beginning the process of finally giving the federal government the ability to negotiate lower prescription drugs prices for the American people.

For years, Americans have been subsidizing prescription drugs for the rest of the world. Americans pay three, four, or 10 times the amount what people in other countries pay for the exact same drug and that's not fair.

And today we are beginning the process of leveling the playing field by discussing four bills, including bills introduced by Representatives Doggett, Welch, and Cummings, who have sought to tackle prescription drug negotiation over the years.

We will also discuss H.R. 3, the Lower Drug Costs Now Act, which I introduced last week with several other committee chairs. The legislation gives the secretary of Health and Human Services the authority and the tools to negotiate the price of prescription drugs for all Americans.

It ends the gauging of American consumers by establishing a maximum fair price on what we are willing to pay for prescription drugs based on what other countries are paying for the same drugs.

It incentivizes manufacturers to stop unfair price hikes on Medicare beneficiaries by requiring them to pay a rebate

back to Medicare if they increase prices faster than inflation and it caps out-of-pocket costs of the Medicare prescription drug benefit, giving American seniors the peace of mind of knowing that their prescription drug costs will not bankrupt them or empty their retirement accounts.

Now, I know Dr. Burgess said we are pushing this but, you know, Dr. Burgess, we are having a hearing today and if the Republicans want to work with us on this proposal, they can.

I mean, my concern -- I have to be honest -- is that when we passed Medicare Part D, and I was here, they insisted on putting this prohibition on the secretary negotiating prescription drugs.

That has to come out. There has to be a process of negotiating. Otherwise, I don't know how we are going to effectively bring prices down.

So if you want to work with us it's fine. But I think that this -- getting rid of this clause that says you can't negotiate and having that as a basis of the legislation I think is crucial.

And I remind them that the president recently indicated via Twitter that he welcomes what we put forth as Democrats.

So let's get this done because it's time that we

negotiate a better deal for the American people.

And now I'd like to yield 45 seconds each to three of our members. First, Mr. Welch, then Mr. Lujan, and then Ms. Schakowsky.

So I'll yield 45 minutes to Mr. Welch, who's one of the --

Mr. Welch. I'll take the minutes.

The Chairman. What? No, I mean, 45 seconds, because he's one of the sponsors of one of the bills.

Mr. Welch. Thank you very much.

This committee has to make a very simple decision -- will our government be an advocate on behalf of consumers and taxpayers?

Every other government in the world does it. Here, there is price setting. Opponents of this bill fear price setting. We have got price setting. It's by the pharmaceutical industry.

This bill does four good things. Number one, it sets a cap, 1.2 times. We are not going to be suckers, like the president -- President Trump said.

Number two, it spreads the benefits across the entire marketplace. So private employer-sponsored health care plans will benefit.

Third, it'll save hundreds of billions of dollars and it's about time.

Number four, the savings go back into the Medicare plan so that folks who are paying high co-pays and deductibles are going to get some overdue relief.

Let's pass this bill. Let's work together to make it happen. I yield back.

The Chairman. Thank you, and I yield 45 seconds to the gentleman from New Mexico.

Mr. Lujan. Thank you, Mr. Chairman. I want to echo the words of my colleague, Mr. Welch. It's about time that we come together to get this done. Democrats and Republicans have been talking about lowering prescription drug prices for some time.

During the last two years, you heard from everyone running for office that they were going to do something meaningful to require negotiation of prescription drugs to lower the costs, to make a difference for our constituents.

After Speaker Pelosi rolled out this particular piece of legislation, one of the bills that's before us today, even President Trump found time to tweet, "Good work, Nancy. Let's get this done."

Let's move this forward. There's a chance for us to

work together. Let's require negotiated drug prices and lower costs for the American people.

Plain and simple, let's get it to the president, get it signed into law, and make a difference for the people that entrusted us to get this done.

I yield back.

The Chairman. I've got 30 seconds left for Ms. Schakowsky.

Ms. Schakowsky. Thank you.

I am so proud of this committee for leading the charge to finally allow for negotiation of prescription drug prices, which we have been trying to do since 2005 when Big Pharma tucked into that Part D bill a prohibition.

Negotiation is the most effective way and as we move forward, though, I have three suggestions. I'll do it as fast as I can.

One, that we must ensure that this legislation addresses the issue of the typically skyrocketing prices of new drugs that are launched on the market.

Second, we must ensure that the limited number of drugs that are eligible for negotiations -- that we don't use that to be able to raise prices on other drugs.

And third, I believe that we have to include other

things like transparency in this legislation. I have a bill to do that so the drug companies have to explain their increases.

And let me just also thank you for not including arbitration in this legislation.

And I yield back.

Ms. Eshoo. The gentleman yields back.

And now it's a pleasure to recognize the ranking member of the full committee, Mr. Walden, for his five minutes for opening statement.

Mr. Walden. Good morning, Madam Chair.

Ms. Eshoo. Good morning.

Mr. Walden. There is no debate about the fact that Republicans and Democrats want to work together to lower drug costs for consumers.

We also believe in innovation and we believe in stopping bad actors.

Madam Chair, I have to strongly express my great frustration about the decision to sabotage both the traditions of this committee and the bipartisan work that you know was well underway to tackle high-cost drugs.

Our teams -- our teams were working well together to find solutions that become law. They were negotiating,

modernizing Medicare Part D, and then we went into radio silence.

Under Chairman Upton's leadership and mine, we wrote durable laws together to increase innovation, to find cures to diseases, to stop scams by some companies that kept competition out of the marketplace.

We all knew there was more work to do. We have worked in a bipartisan -- way, up until now, on those efforts. We did it on CREATES. We did it on pay-- for to -- delay. We did it on blocking, and we were doing it on these other issues.

I thought we were headed in good faith down that same path, until the Speaker's office dropped this partisan plan on our process. We were not privy to any of this and I am not sure you all were.

Congress needs to work together with President Trump. I've never seen a president lean forward more on an issue like this than him, and we can agree and disagree with different points.

But he wants to sign a bill that will work. Unfortunately, that's not what we are doing this morning. It's hard words for me to say because you are my friend. But this is partisan politics at its worst and it's an avoidable failure -- the failure to build on our bipartisan progress to

lower prescription drugs for consumers.

With a bipartisan inclusive process, Republicans have worked with Democrats to push for legislation that promotes competition, that lowers out-of-pocket costs for consumers, and establishes transparency and accountability in drug pricing.

We worked together to past the 21st Century CURES legislation, that's been referenced, and the FDA reauthorizations in 2017 that opened the door to more generics being approved in one year than in the history of the FDA, and we did that in a bipartisan way.

This committee we passed CREATES to stop bad behavior and then the Speaker's office shoved in a poison pill to make Republicans vote no on the floor, and did the same thing on the other legislation.

Our work last Congress resulted in the FDA, as I said, approving a record number of generics, including the first generic competitor to EpiPen.

My friend from Oregon, Mr. Schrader, helped lead that effort so if you got a medical device ~~that~~ where there's no competitor, we will put you in the front of the approval list.

If you look~~ed~~ over the past year and a half at the

legislation that has become law and passed the House, ourare bipartisan policies that have added up to $24 billion in savings to the federal government, and lowered prices for consumers. , Aand there's more we can do together if you'll come back to the table.

Many may not know this, but before Speaker Pelosi began to write her partisan plan behind closed doors, Republicans and Democrats on this committee had been working together, drafting policies in good faith thatand we believed, and the majority indicated, couldwe'd receive unanimous support in the committee.

These policies essentially mirror about 90 percent of the legislation our colleagues in the Senate have been working on and about 92 percent of what the Health Committee in the Senate was working on.

We were very close. Some of these policies included immense benefit to our nation's seniors in the form of modernizing Medicare Part D program, provide an out-of-pocket spending cap for seniors so you'd never -- you'd always know what the limit was.

But those bipartisan negotiations came to an abrupt halt. Why were you forced to walk away from the table? We wanted and still want to work with you in addressing this

issue for the American people.

But now we have before us a partisan plan that puts politics over progress. Are you even able to negotiate from here or is this is it, take it or leave it? Are you willing to make substantive changes so we can reach bipartisan agreement or is this the end? Check the box, score a point, move on?

We don't know because you haven't told us and, frankly, I am not sure you know yourselves. I think it's unfortunate you were forced to pursue the Speaker's strategy and not let our productive and bipartisan discussions continue. They stopped. They halted, and we all know it.

When it comes to setting prices, I was on the committee when we passed Medicare Part D. It was a huge fight, it's true. And there was a decision made to establish the program the way it is, and Democrats did want to set prices. In fact, they wanted to put in statute -- they wanted to put in statute the Part D premium and index it to inflation.

Thirty-five dollars in '06. Had they done that, it'd be $46 today. This week, Medicare announced the premium in 2020 will be $30 a month, not $35, and certainly not $46. About a third lower for seniors than if you'd followed the Democrats' plan to lock it in statute.

There's a way to make the free market work for consumers. There's a way to save for seniors. We remain committed to doing that once this process plays itself out.

I yield back.

Ms. Eshoo. I thank my friend for his five minutes and 27 seconds for his opening statement.

I think that we all need to take a deep breath and really roll our sleeves up and look for the opportunities to work together.

Mr. Walden. If the gentlelady will yield.

Ms. Eshoo. No, let me finish what I want to say. I understand people wanting to characterize things the way they view them. You have every right to do that. This is regular order. This is a hearing. We have witnesses. We can question them.

All ideas can be placed on the table. As I said in my opening statement, there are portions of H.R. 3 that include ideas from the White House, ideas from Senator Grassley, and we are going through regular order.

So my door is open. I think all the members know that. You know that, certainly, and there is a big difference between capping out-of-pocket costs and the actual price of prescription drugs.

Mr. Walden. I am very well aware of that and I agree with you.

Ms. Eshoo. And we need to work together on that. So --

Mr. Walden. Would the gentlelady yield?

Ms. Eshoo. Yeah, I guess -- I don't have -- I guess I can, right?

Mr. Walden. Yes. I am glad -- I know you, we have worked together on things. We have fought over things.

Ms. Eshoo. Right.

Mr. Walden. We have worked on things and we have done it in good faith always, and I take you at your word. We will come through your door.

Ms. Eshoo. Good. I welcome that.

Mr. Walden. Because we were on a path -- our teams were -- and this got dropped. We had no notice. I mean, the hearing got noticed. We were told it was going to be on Thursday. It got moved to Wednesday. It got noticed late in the day before a draft of the legislation was even available. I hope you appreciate our frustration.

Ms. Eshoo. You know what I don't want to do? I do --

Mr. Walden. I yield back.

Ms. Eshoo. -- but I don't want us to get lost in the weeds of the yin and the yang. When we were in the minority

we would complain about what time and who filed and what we didn't know and who didn't tell us.

Now the shoe is on the other foot. I am not saying that I prefer being in the minority. Trust me.

Mr. Walden. But --

Ms. Eshoo. But it is -- you know --

Mr. Walden. But I would -- I would just --

Ms. Eshoo. -- we do get into that but I think the main point --

Mr. Walden. I would just -- I know. Our teams were talking and meeting and working on language --

Ms. Eshoo. And we will. And we will.

Mr. Walden. And then it stopped.

Ms. Eshoo. And I don't think -- let me just say something about the Speaker's role in this.

The Speaker is second in line in the Constitution to the presidency, whomever that individual is. This is such a top priority for us that it came from there. It came from there.

Mr. Walden. My point.

Ms. Eshoo. Now, that this is not -- this is not to say that for the last two Congresses or three -- five, six, seven years -- that Democrats haven't had a caucus on this, working on all of the ideas and bringing them forward.

So parts of this bill are not brand new to us. It is a compilation, but I think that it's a serious undertaking for the people of our country. We want our economy to work. We want innovation to flourish. But we want people to be able to afford the drugs that they need. Some people can't live without them. So a price should not be a death sentence.

All right. Now we are going to get back to --

Mr. Bucshon. Madame Chairwoman?

Ms. Eshoo. Yes.

Mr. Bucshon. Can I ask a question?

Ms. Eshoo. Sure. Who is seeking to be recognized? Sure.

Mr. Bucshon. Since it appears that the chairwoman had extra time for her opening statement should the ranking member also get extra time --

Ms. Eshoo. If he --

Mr. Bucshon. -- to clarify their comments?

Ms. Eshoo. He did. He did. I recognized him.

Mr. Bucshon. Right. But then you just now went on about a five-minute talk without --

Ms. Eshoo. Well, let me ask you --

Mr. Bucshon. At the discretion of the chair, which you can do. But in fairness then the ranking member --

Ms. Eshoo. Well, why don't you stop talking and I'll ask the --

Mr. Bucshon. The ranking member should have time also.

Ms. Eshoo. Would you like to say something else, Greg?

Mr. Walden. I think I know how this plays out and I think it's time we heard from our witnesses and moved on.

Ms. Eshoo. Okay.

So now we will move to our witnesses and we want to thank each one of you for being here today. I'll introduce all three now.

Dr. Robert Fowler, thank you for being with us. He's professor emeritus at Baldwin Wallace University. Dr. Gerard Anderson, professor at Johns Hopkins Bloomberg School of Public Health -- thank you for being here. And Dr. Benedic Ippolito, research fellow in economic policy studies at the American Enterprise Institute.

Thank you to each of you for joining us today. We look forward to your testimony and at this time the chair will recognize each witness for your five minutes.

I think you know the system with the lights. Green, obviously -- we drive through green, right? Yellow, caution. Red, stop.

So with that, I'll recognize Dr. Fowler for your five

690 minutes of testimony, sir, and thank you again.

STATEMENTS OF ROBERT FOWLER, PH.D., PROFESSOR EMERITUS, BALDWIN WALLACE UNIVERSITY; BENEDIC IPPOLITO, PH.D., RESEARCH FELLOW IN ECONOMIC POLICY STUDIES, AMERICAN ENTERPRISE INSTITUTE; GERARD ANDERSON, PH.D., PROFESSOR, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

STATEMENT OF ROBERT FOWLER

Mr. Fowler. Chairwoman Eshoo, Ranking Member Burgess, and members of the committee, I am honored to be here today.

My name is Robert Fowler. I am here as an Ohioan, a religious studies professor, a husband and a father. Most importantly for today, I am here as a cancer patient.

In 2006, I was diagnosed with an incurable blood cancer called multiple myeloma. For the last decade, I have taken a chemo drug called Revlimid. The list price of that drug is almost $200,000 per year.

My experience being a cancer patient has taught me two important lessons. First, since myeloma treatments inevitably stop working for patients, causing them to relapse, we literally need new drugs to stay alive.

The importance of innovation is crucial to me.

The second is that drugs don't work if people can't afford them. As a new Medicare beneficiary, I will pay,

roughly, $12,500 a year out of pocket for my drug, Revlimid.

There is one big reason my drug costs me and the system so much. Under current law, Medicare is prohibited from negotiating directly with my drug manufacturer. As a result, Americans pay two to three times more than other nations for the same drugs.

Now, drug companies will tell you that they need high drug prices in order to fuel innovation. The brutal message implied in their ever-increasing drug prices is this. If you don't want to die, you must pay whatever we demand. That's simply not true.

Here is why. According to the Washington Post, nine out of 10 big drug companies spend more on marketing than research. Drug corporations' profit margins are almost three times the average of S&P 500 corporations, and we could go on.

There is plenty of money to lower drug prices and fuel the innovation I need to stay alive. Generic competitors were supposed to lower the price of my Revlimid by now. But Celgene, the manufacturer of the drug, has stopped at nothing to extend its monopoly, blocking generic competition and suffocating its product in a pile of patents.

And Revlimid could cost taxpayers an estimated $45

billion through 2028. I bring up this history to make the case that we, as taxpayers, must have a mechanism to push back.

Patients like me need immediate congressional action. As you work to fix our broken system, I urge you to take three concrete actions.

First, repeal the ban on Medicare negotiating directly with drug companies. According to the Kaiser Family Foundation, 86 percent of all Americans -- majorities of Democrats, Republicans, and independents -- support allowing Medicare to negotiate for lower prescription drug prices.

Second, ensure that Americans, regardless of insurance type, have access to lower priced drugs. Drug companies like Celgene should have to offer a better deal to people like me on a government health insurance plan as well as Americans who use private insurance.

Finally, cap seniors' out-of-pocket costs for prescription drugs. Paying over $12,000 per year out of pocket isn't sustainable for seniors.

It is not easy to live with an incurable disease. But I have no choice. The physical and mental toll of living with cancer is something I have to endure.

You do not have the power to take away my cancer nor do

you have the power to make my personal struggles with this disease any easier.

But you do have the power to make my prescriptions more affordable. I want to live many more years in spite of my blood cancer. To have a shot at that I need two things: lifesaving drugs and an affordable price.

Drug companies would have you believe that we must pick between innovation and affordability. I disagree. We can absolutely have both, and I am hopeful that after actions of this committee we will.

Thank you for your time.

[The prepared statement of Mr. Fowler follows:]

**********INSERT 1**********

Ms. Eshoo. Thank you, Dr. Fowler.

What you said you wish for we want to make your wishes come true. Thank you very much.

I now would like to call on Dr. Ippolito and thank you for being here as a witness. You have five minutes to make your presentation to us.

STATEMENT OF BENEDICT IPPOLITO

Mr. Ippolito. Well, Chairman Eshoo, Ranking Member Burgess, members of the subcommittee -- Chairman Pallone and Ranking Member Walden as well -- my name is Benedic Ippolito. I am an economist and research fellow at the American Enterprise Institute.

Prescription drugs can offer tremendous benefit to patients. But they can also represent a major financial burden. So I am glad that the committee is considering this issue so seriously.

Today, I am going to focus on two elements of recent proposals, namely, redesigning the Medicare prescription drug benefit, known as Medicare Part D, and allowing for direct drug negotiation.

First, the design of the Medicare Part D benefit has attracted criticism for justifiable reasons. Its current structure both raises program costs, mainly to taxpayers, and exposes beneficiaries to the kinds of financial risks that insurance is supposed to mitigate -- the kinds of financial risks that we literally just heard about.

Proposed redesigns to Part D would reduce open-ended federal spending, improve incentives to control overall

costs, and place a cap on the maximum out-of-pocket spending of enrollees.

I know there are some differences across the proposals we've seen in H.R. 3, what's come out of the Senate Finance Committee. But suffice it to say that there are enough similarities across them that I believe these are exactly the kind of policy changes that should be encouraged.

I am, however, less enthusiastic about proposals to allow the secretary of HHS to negotiate drug prices.

First, the penalties associated with walking away from negotiations are so severe, be it losing nearly all revenue or, literally, your intellectual property rights that they are -- excuse me, they are negotiations in name only.

Practically, the secretary of HHS is given power to dictate prices as they see fit. Regardless of what one thinks, this kind of centralized rate regulation is both challenging and highly consequential.

Indeed, the economics literature has repeatedly shown what likely seems obvious. Financial returns for successful drugs has a direct influence on the research and development decisions of firms.

Indeed, we've talked a lot about the introduction to Medicare Part D. There are, literally, studies that show the

very introduction of the senior prescription drug benefit altered the kinds of drugs that manufacturers decided to invest in. Namely, they steered more investments to that particular market.

I am particularly concerned because these kinds of pricing decisions are going to be made under intense political pressure.

So, for example, in cases where administrations emphasize, shall we say, four- or eight-year time horizons, there will be substantial pressure to sharply reduce current prices and enjoy the absolute benefit of lower drug spending while discounting the cost of reduced innovation that it's only realized beyond that kind of time horizon.

This is not optimal for society. Moreover, consider the incentives associated with H.R. 3's negotiation process or rate setting process.

Drugs that have no competitors would be subject to aggressive rate regulation. However, the same is not true of drugs that have at least one competitor.

Being second to market could prove substantially more profitable than creating a path-breaking therapy, particularly if we are thinking about rare diseases where it takes a relatively long time before we tend to see

competitors come into the market. The markets just aren't that big.

In addition, I worry about the unpredictability of such a system. Changes in the policy preferences of future administrations will likely manifest in highly variable rate regulation over time.

One might, for example, predict considerably different use of this broad pricing power under an administration led by Senator Bernie Sanders than, say, by the Bush administration.

This kind of uncertainty is very costly when we think about the kind of time horizons that somebody who's entering into either early stage investment or even at the Big Pharma stage of investment is thinking about.

You have to think about a decade-plus in advance. You're not going to know who's going to be president, who's going to be the head of HHS, what kind of policy priorities they're going to have, and so much more. That kind of uncertainty really is costly. That is a real cost that you have to think about.

Altogether, I worry that the system will lead to outcomes that stray far from what is best for Americans. However, none of this is to say that drug prices must remain

where they are. Indeed, they shouldn't.

I applaud reforms to the Part B benefit design and I encourage Congress to continue working to make our current regulatory environment work better.

Examples of policy options including reforming the protected classes in Part D, removing incentives to prescribe higher costs in Medicare Part B, addressing REMS abuse that we talked about, the CREATES Act, reducing patent thickets or other generic delaying tactics, improving access to lower cost biosimilars, and so much more.

Overall, this is a very important issue and I thank you for the opportunity be here today, and I look forward to your questions.

[The prepared statement of Mr. Ippolito follows:]

**********INSERT 2**********

Ms. Eshoo. Thank you very much, Dr. Ippolito.

Our next witness is Dr. Gerard Anderson, and when I introduced him, you'll recall, he's a professor at Johns Hopkins Bloomberg School of Public Health. Welcome to you. You have five minutes to enlighten us. And that's quite a necktie there.

Mr. Anderson. Well, this is my Johns Hopkins necktie.

Ms. Eshoo. Oh, I see. See, I didn't see the bottom of it.

Mr. Anderson. It's got a shape on it, too.

Ms. Eshoo. I couldn't figure it out but it's --

Mr. Anderson. So, you know, men don't have very much so we only have ties.

Ms. Eshoo. This is true. This is true. Yeah, this is true. Welcome.

STATEMENT OF GERARD ANDERSON

Mr. Anderson. Well, thank you for the opportunity to testify this morning and thank you to Ranking Member Burgess for the opportunity two years ago to testify on the drug supply chains hearing.

Rather than try to summarize my testimony today, I just want to focus on a couple of topics.

Beginning economics tells you that when there is competition the market attains a reasonable price, and for many drugs there is reasonable competition and the market appears to work.

However, for drugs, when there's no real competition, the prices are very high because the drug companies have all the power. In economics, we call this market failure.

We did a study of 79 drugs in the United States without any generic competitions. These drugs represent about half of all Medicare spending and they cost three to four times what other countries are paying.

There was also significant variation across these drugs. Some of these drugs only cost 30 percent more than what other countries were paying. Some of them cost 7,000 percent more than what other countries were paying.

We need to focus on where the market failure is greatest.

We also found that drug prices go up in the United States after the drug launch and they go down in other countries after the drug launch. So some control over prices is absolutely necessary.

Without a therapeutic alternative, drug plans in the Medicare program cannot bargain effectively. H.R. 3 focuses on these drugs without competition and where the spending is greatest.

I also understand why it's so difficult for us to rely on prices set in other countries. We don't do this for other goods and services.

However, it just doesn't make sense for us to pay three to four times what other countries are paying for the same drugs.

I know that many of you are concerned that if we use international reference prices that the prices are going to increase in other countries. I am not concerned about that for a number of reasons.

First, it assumes that the drug companies have the power to raise prices in other countries whenever they want. I doubt they have this power.

Second of all, it assumes that drug companies are not always -- already attempting to maximize their revenues in other countries. I just wouldn't want to be the French representatives for a drug company and say to my boss, oh, we could have gotten higher prices on France but we are getting so much money in the United States that I won't bother.

That just won't happen.

Third, many industrialized countries already use external reference prices, so that whole system is already baked into the system.

And finally, and probably the most important, these countries already have mechanisms in place to obtain lower drug prices. These mechanisms are not going to change if the United States pays lower prices.

I outline these things in the U.K., Japan, Germany in my testimony.

I know that many of you are concerned about H.R. 3 -- about innovation. I've spent 37 years as a professor at Johns Hopkins and I am totally in support of innovation.

My expectation is that drug companies will continue to support research because without research drug companies don't have anything to sell. They must invest in research in order to have a product.

Currently, the largest drug companies allocate more resources to marketing than they do to research. They spend less than 20 percent of their total revenues on research. This may need to change and they may have to reallocate some money.

Unfortunately, we may have to see fewer television commercials about drugs on television.

It's unlikely that U.S. researchers will suffer if lower prices are paid for drugs. While drug companies may reward certain companies that pay higher prices for a drug on the margin, drug innovation occurs where the best scientists are located. The U.S. has some of the best universities in the world and this is where the drug companies start.

Increasingly, drug research is done first in academic medical centers and then the drug companies purchase this research.

A recent example of this pattern is the first hepatitis C drug. The initial research was done in Emory, funded by the NIH, and then Gilead purchased it.

Most of the research that we see in the drug companies started at the NIH and at universities. The product -- the funding for Januvia, one of the big drugs, was $277 million by the NIH and they funded 93 different projects. Remicade,

another one, $218 million, and NIH funded 454 different projects.

If there are savings from H.R. 3, Congress will have an opportunity to improve the Medicare benefit. It's most important to limit the out-of-pocket liability of Medicare beneficiaries. Most private corporations have out-of-pocket limits. Medicare should.

[The prepared statement of Mr. Anderson follows:]

**********INSERT 3**********

Ms. Eshoo. Thank you very much, Dr. Anderson.

And now that our witnesses have all offered their testimony, the chair recognizes herself to -- for five minutes of questioning.

Let me start with you, Dr. Fowler. You were the first one up, and besides being a doctor you're a patient and you spoke quite eloquently about your status as a patient.

So remind us, what drug do you take?

Mr. Fowler. I take Revlimid made by the Celgene Corporation.

Ms. Eshoo. And does that drug have any competition?

Mr. Fowler. No.

Ms. Eshoo. No competition. I think it's important to note that H.R. 3 has 250 of the most expensive drugs in the United States that do not have any competition to be negotiated.

Now, that's a very, very important point.

So, Dr. Fowler, you can't go out and shop for what you need to stay alive any other place?

Mr. Fowler. That drug is keeping me alive. I've taken it for 10 years and it has worked wonderfully for me. I am reluctant to put that aside and go try something else when what I am taking is working so well. But the day will

probably come, statistics would say, where I will fall off the cliff. My disease -- I will relapse and I will need some other expensive treatment. So but for the time being, Revlimid is doing wonderfully well for me. It's just a pity that I have to pay the price that I do for it.

Ms. Eshoo. And how much did you say it was a year?

Mr. Fowler. Golly, I took it for 10 years, paid for by my university's medical coverage and now I am newly into the world of Medicare.

Very quickly, for the 10 years that I took it under the university's health plan, it started out that my insurance company was paying $70,000 a year to cover the prescription.

At the end -- at the end of July, this summer, when I retired my insurance company was paying $190,000 a year --

Ms. Eshoo. Wow.

Mr. Fowler. -- to pay the cost of the drug.

And, oh, by the way, that means over the 10-year period I calculate -- this is a rough calculation but I think it's fair -- I calculate that my insurance company paid, roughly, $1.4 million to pay for my Revlimid.

But that really --

Ms. Eshoo. And I think that what needs to be built into this is the appreciation of what those costs mean when

they're built in to other premiums for whomever is in that insurance pool. That is all part of it.

Mr. Fowler. Exactly.

Ms. Eshoo. Dr. Ippolito, what's your definition of a monopoly?

I mean, I've looked it up. It's the -- the definition is, the dictionary says, a commodity controlled by one party.

Mr. Ippolito. That sounds right to me.

Ms. Eshoo. Pardon me?

Mr. Ippolito. Sounds right to me.

Ms. Eshoo. It sounds right to you?

Mr. Ippolito. Yeah.

Ms. Eshoo. Do you see any likeness of monopoly in terms of what we are talking about when you have the most expensive drugs in the country and they have no competition?

Mr. Ippolito. They have no competition because that's been -- that's the policy. I mean, to be clear, one of the important things we want to -- we want to ask --

Ms. Eshoo. Well, we don't want that to be the policy, though. That's the point, isn't it? You don't want it to be the policy, do you?

Mr. Ippolito. Well, but what we are proposing is to keep them --

Ms. Eshoo. No, but you want competition, do you not?

Mr. Ippolito. I would eventually like competition.

Ms. Eshoo. Eventually?

Mr. Ippolito. There's a variety of ways -- yes, that's right.

Ms. Eshoo. When?

Mr. Ippolito. Well, so just to back up, briefly --

Ms. Eshoo. By when?

Mr. Ippolito. -- Dr. Anderson made the point that, you know, we are talking about a market failure here. To be clear, some of these are legislative monopolies. We give you a monopoly in order to incentivize you to make a product and then the hope is, eventually, we'll have generic entry to reduce the long run costs.

And so part of the question that's really important for this discussion and H.R. 3 is why are these monopolies. Is this just a drug that's in the stage where we literally set up a monopoly for them or is it that this a drug where, for example, they're using delaying tactics, patent thickets, and so on.

Ms. Eshoo. Well, we have done legislation to clear out the underbrush on that. But I think that you're evading a larger point and that is that when you have one drug on the

market it's one of the most expensive, one of the top 250 drugs that do not have any competition, that we want to do something about that because when you have a monopoly people don't have choices and Dr. Fowler is one of them.

And it's very costly not only to him, to his insurance plan -- his private insurance plan that he had through the university -- and now through Medicare, which is a public insurance program.

So we are talking about -- this is a program to bring down the cost of drugs for patients, and in doing so it is to save money across the board because the legislation moves across the board.

So I think we are both in sync on the issue of monopoly.

My time is expired and I will recognize Dr. Burgess for his five minutes of questioning.

Mr. Burgess. Thank you, Madam Chair. And again, just to reiterate, the CREATES bill that did -- we worked on last Congress and did pass this Congress still has not become law but it does address the issue of getting samples and the reason in the Revlimid instance, the reason the samples are difficult is because that medicine used to be known by another name, right? Revlimid was known by another name, and that name carried a connotation that people thought --

Mr. Fowler. Oh, you mean the predecessor?

Mr. Burgess. Yeah.

Mr. Fowler. Yes. It was preceded decades ago by thalidomide.

Mr. Burgess. Right. So there was a --

Mr. Fowler. It's a derivative of thalidomide.

Mr. Burgess. There was a barrier and that had to be overcome, and we are grateful that someone did figure that out and overcome it and you have it available.

And now I think samples have been made available so at some point we will see some relief on this. But CREATES was designed to help that and move that process along.

Dr. Ippolito, let me ask you a question. So America is known for innovation. We are all grateful for that. You know, we sat -- well, actually, it wasn't a hearing. It was a briefing during the time leading up to the passage of the Affordable Care Act.

And Doug Elmendorf came and sat in the big room downstairs. All the lights were off. There were no television cameras. There was no one transcribing the notes, and Dr. Elmendorf was asked how -- and he's the director of the Congressional Budget Office -- how much money are we going to get to spend now on other things that we are going

to be saving so much money with this negotiation that we are doing.

And I think his answer surprised some people. Since it wasn't on the record and no one could read about it, his answer was, it doesn't move the needle. And can you speak to that a bit? Is the situation different now where the needle is now just freely to move up or down with --

Mr. Ippolito. Yeah. I think it's important to -- based on, at least, the CBO numbers that I think you're referring to, it is the case that CBO generally has scored it that if you just let Medicare kind of negotiate and say go get them, then you basically get no budgetary savings and the reason is they don't really have any leverage to get anything unless you can actually exclude a drug, say, from a formulary, for example.

But it's important to keep in mind that that's -- that's a very different idea than what we are talking about in the kind of bills that we are considering today. I mean, the kind of bills we are considering today are if you don't agree to the HHS secretary's price, then either we confiscate your intellectual property or we fine you at 95 percent of your gross revenue, which is going to exceed 100 percent of your net revenue, basically, for all firms.

I mean, you know, we are talking about two ends of a spectrum. One is sort of a toothless negotiation. One is just price setting. Like, you know, I don't want to get into semantics but it's just the HHS secretary's price setting. And so, you know, the score you're talking about I would think of as being a totally end of the spectrum -- other end of the spectrum than what we are discussing today.

Mr. Burgess. And because this is more coercive, do you have an opinion as to how this could affect innovation?

Mr. Ippolito. Well, I mean, I think the question about what happens with returns and investment behavior isn't really one that's up for debate, certainly directionally.

We know -- we've seen -- when Medicare Part D was introduced we saw drug makers change the kind of drugs that they invested in because there was this new big market of seniors who were going to be consuming more drugs.

And so I don't think there's a lot of people that argue with that, right. We've seen -- if you think about malaria, malaria kills half a million people a year, and compare that to gout, which is an uncomfortable kind of arthritic condition that you have in your joints, right?

If we were thinking about just investing for pure social gains and for the good of the science, we've be investing

like crazy in malaria. But yet, between 2004 and 2016 we saw about nine publicly registered trials for malaria and 239 for gout.

And so this idea that there's no relationship between returns and what you invest in is kind of hard to believe. Rich people have gout. Rich people with insurance get gout. People who have malaria are poor and they don't have coverage.

So I think the direction is clear. The question and one of the big pieces of uncertainty is just how much is any given administration really going to put their foot down with this broad pricing power.

Mr. Burgess. Well, let me just ask you a question on the -- because one of the course of aspects of H.R. 3 is the excise tax and it's very complicated as you read through the language. I am still not sure that I understand it, how it's calculated.

But is that -- that excise tax does not get returned to the consumer, does it?

Mr. Ippolito. Well, I mean, again, it's sort of -- it's almost weird to think about this excise tax in the sense of a normal kind of a -- a normal magnitude tax because you're literally talking about a tax that in this would very quickly

escalate to about 95 percent of gross revenues. That's going to exceed 100 percent of the net revenues flowing to a firm for any given line of business.

And so whatever passed through looks like or doesn't look like is almost irrelevant because you're really talking about a firm that just isn't going to be viable in that kind of environment.

Mr. Burgess. Because of the confiscatory nature of the -- of the excise tax?

Mr. Ippolito. Yeah. It's just so large. Yeah.

Mr. Burgess. Thank you. And if the chair needs the time I will yield back.

Ms. Eshoo. The gentleman yields back.

Dr. Ippolito, just a factoid. NIH has invested zero in gout. NIH has invested $260 million for malaria.

Now, who is next to be recognized? The chairman of the full committee, Mr. Pallone, is recognized for his five minutes of questions.

The Chairman. Thank you, Madam Chair.

I wanted to ask Dr. Anderson -- oh, he's over here -- Dr. Anderson, single source brand name drugs that lack generic competition represent one of the largest categories of drug spending growth in the Medicare Part D program.

For example, in 2017, single source brand name drugs accounted for almost three-quarters of total Part D spending, and these drugs are not only highly expensive, they also lack competition that helps drive down costs.

Now, the Ways and Means Committee released a report earlier this week -- dare I mention the name of the other committee -- but they did release a report earlier this week that found that Humera, an anti-inflammatory therapy without a generic on the market and the best-selling prescription drug in the world, has doubled in price in the U.S. since 2012 and is currently priced at $2,436 per dose, or about 500 percent of the international average price.

So, Dr. Anderson, you have also done extensive work comparing these sole source brand name drug prices in the U.S. with the prices in other major economies.

On average, how much more do consumers in the U.S. pay for these sole source drugs than consumers in other large countries?

Mr. Anderson. So they pay about three to four times as much, on average. There are some drugs that only are 30 percent more. There are some drugs that are 7,000 percent more.

So it really depends on the drug and the market.

The Chairman. Now, can you give us an example of a brand name sole source drug that lacks any price constraints in the U.S. and what the same drugs cost in a country like Japan?

Mr. Anderson. So sure. So the number-one selling drug in 2017 was Harvoni, which is a drug that takes care of hepatitis C. It was $1,100 per dose in the United States. It was $438 in Japan.

The Chairman. You know, I was in Japan a couples times in the last two years to see my son, who was teaching there, and I tried to, you know, do a little survey once at one of the drug stores and I couldn't believe how much cheaper things were.

So what is the reason why it's cheaper in Japan?

Mr. Anderson. Well, Japan is very clever. What Japan does is there's a price and then it goes around and asks the pharmacies how much did you pay for the drug, which is always less than the price that's set by the government.

And so then they find that they bought it for 20 percent less or 10 percent less. And so then they say, oh, we are going to set the price next year at that much lower price.

So every year in Japan the price goes down after the launch and every year in the United States the price keeps

going up. As your example with Humera says, the price doubles. In the United States you can double the price. In Japan, you have to lower the price in order to sell your drug.

The Chairman. So, from your perspective, does using an average price across a certain subset of international countries, as proposed in my bill, does that provide an appropriate reference by which to compare U.S. prices?

Mr. Anderson. Absolutely. I mean, I don't see any reason why we in the United States, which are funding most of the research and development, should be paying three to four times what other countries are paying for exactly that same drug.

The Chairman. Well, H.R. 3 contemplates the use of, and I quote, "average international market price, or AIM price, to serve as a negotiation boundary for the secretary."

Is the use of the AIM price similar to the international pricing index proposed by President Trump for Part B drugs and is that an appropriate mechanism by which the secretary should negotiate?

Mr. Anderson. So President Trump did propose that. He uses it and he uses about 120 percent of the price. So it's effectively the same idea applied to Part D as he applied to

Part B, and almost every other industrialized country uses some form of external reference prices to set their prices. It might not be the only factor but it's one of the most important factors they use to set their prices.

The Chairman. All right. Let me ask you this. It may be the last thing I get a chance to ask you. But can you respond to Mr. Ippolito's claims in his testimony that it would be too complicated to determine transaction prices in foreign countries as compared with the U.S. prices for this purpose?

Mr. Anderson. Well, we were able to do it and publish them in the Journal of Health Affairs, so it's a peer-reviewed publication. We worked with the Ways and Means Committee to help them understand it. They were able to do it. Every single country that uses external reference prices is able to do it.

I really do hope the United States is as smart as these other countries and as smart as I am.

The Chairman. All right.

[Laughter.]

The Chairman. Of course -- of course, you mentioned Ways and Means, too. I hesitate to mention the committee but, you know, that's my problem, not yours.

Ms. Eshoo. Well, I think this is the sound of a very confident person --

The Chairman. Thank you. Thank you, Madam Chair.

Ms. Eshoo. -- to say that. Yeah. Thank you.

Now we'll recognize the ranking member of the full committee, Mr. Walden, for his five minutes of questioning.

Mr. Walden. Thank you, Madam Chair. I appreciate that.

Dr. Ippolito, as you know -- as we all know -- Medicare statute currently prohibits the secretary from using cost effectiveness thresholds to deny patients access to medical care.

Is it correct that several of the countries referenced in H.R. 3 used cost effectiveness standards in their government-run systems?

Mr. Ippolito. Sure. Yeah. Probably most famously the U.K.

Mr. Walden. And is it fair -- and is it also fair to say that fewer new medicines are available in those countries compared to the United States?

Mr. Ippolito. In general, the United States gets drugs faster than other countries and then there's a second way in which, you know, so the NHS or what is called NICE in England can decide whether or not to recommend covering a drug or not

indefinitely. So the answer is yes.

Mr. Walden. And what does this mean for patients in a country with hard-to-treat conditions for which new therapies are being developed every day?

Mr. Ippolito. It means what it sounds like. You get the drugs slower and sometimes you don't get the drug if it's up to a clinical effectiveness -- effectively, an agency to determine whether that they think the drug is worth covering for the National Health Service in England. I am just using U.K. as an example here.

Mr. Walden. Sure.

Mr. Ippolito. And if they recommend against covering the drug, which last I checked is, I don't know, 10, 15 percent of the time, then unless they lower the price that the drug is just not covered.

Mr. Walden. Just not covered. So, therefore, not available.

Mr. Ippolito. Yes. In general, yeah. Unless they lower the price.

Mr. Walden. Yeah. And in the U.K. do they ever deny parents the opportunity to take an ailing child out of the system to get treatment?

Mr. Ippolito. I've read things about this.

Mr. Walden. Have you read about Charlie Gard?

Mr. Ippolito. I don't know enough about it to speak confidently on the matter.

Mr. Walden. Yeah. All right. Well, it happened.

Walk me through on H.R. 3 the negotiation and how that works with ~~the 95 ---~~up to 95 percent confiscation of revenue if the company doesn't agree to what the government says the price is going to be.

Mr. Ippolito. Sure. So there's a -- there's a nominal negotiation, at least as I read it, where the HHS secretary can propose a price to cover the drug. He --

Mr. Walden. Any price?

Mr. Ippolito. As long as it is lower than a maximum amount allowed international.

Mr. Walden. Which is 120 percent of the IPI?

Mr. Ippolito. Yes. That's exactly right.

Mr. Walden. So the secretary -- if a drug was $100 under the -- under the International Pricing Index, could the secretary of HHS say, I am going to pay you $20?

Mr. Ippolito. I have not read anything that would preclude them from doing that.

Mr. Walden. And if you're the drug company and you say, well, that doesn't even cost my operations -- I don't know

that I can do that -- what happens then?

Mr. Ippolito. If you initially refuse the price then you get fined 65 percent of your gross revenues and that --

Mr. Walden. Gross revenues of the drug?

Mr. Ippolito. Gross revenues I believe of the drug, at least in my reading and that's -- yes.

Mr. Walden. And that's the first year, right?

Mr. Ippolito. And then escalates to 95 percent.

Mr. Walden. Ninety-five percent --

Mr. Ippolito. Yeah.

Mr. Walden. -- of the revenues. And you cannot sell that drug to anybody else at a price higher than what the government negotiates, correct?

Mr. Ippolito. It is my understanding that you at least have to offer the HHS secretary's price to everyone in the market.

Mr. Walden. All right. Do you do economics?

Mr. Ippolito. I do.

Mr. Walden. Can you imagine a buyer being offered that price saying, no, I think I will take a higher price?

Mr. Ippolito. Generally, we do not believe that people --

Mr. Walden. Generally?

Mr. Ippolito. -- leave that much money on the table.

Mr. Walden. Yeah, I don't either. All right. All right.

Look, we all want to get these prices down but none of us -- none of us wants to stifle innovation or access. For me, innovation and access is key, but so it price.

To Dr. Fowler's comment, the drug you can't afford is a drug that you might as well not even have. That's why we were working on the out-of-pocket cap in Part D and we were very close in our negotiations, and I think we can get there. I think we may still have the opportunity to get there.

And we were trying to stop the bad behavior -- the gaming of the systems, the REMS issue that, I think, all of you have mentioned at one time or another. We passed that out~~to~~ of here unanimously. There's so much we could do here.

I was on the committee when we passed Medicare Part D and we had virtually an all-night markup and it was a fight back and forth just over different philosophies.

And as I mentioned earlier, Democrats had an amendment that Mr. Strickland offered that they unanimously passed to lock in the premium rate -- $35 in statute plus -- in statute and inflationary increase, which would have put it at $46 a month. Now -- and now we know it's actually going to be

below $35, which is what was said in '06.

The other thing we had was CBO -- the Congressional Budget Office -- projected what they thought drug costs would be to the program, and I am told as of now it's about 33 percent lower than what CBO estimated. And so there are ways to get at this that would skin this cat -- that would allow us to prevent the kind of out-of-pocket extraordinary expenditures you're facing, Dr. Fowler, especially on Medicare.

There are ways to increase innovation and put market forces in the right direction, and I stand ready to work with my colleagues to get that done, given the opportunity.

And I yield back.

Ms. Eshoo. The gentleman yields back.

And now I would like to recognize the gentlewoman from California, our birthday person, Congresswoman Matsui.

[Laughter.]

Ms. Matsui. Okay. Thank you. Enough about that.

[Laughter.]

Ms. Matsui. I want to thank all you witnesses for being here today. This is very, very important regarding the pharmaceutical prices.

I want to ask a question about low-income Medicare

beneficiaries because I believe they deserve special attention as we consider legislation to make prescription drugs more affordable.

LIS enrollees -- low-income subsidy enrollees -- who take specialty tier drugs and receive Part D's low income subsidy do not face the same financial hurdles associated with cost sharing.

Nonetheless, many of these low-income seniors and persons with disabilities struggle to pay their health bills.

Further, LIS beneficiaries continue to account for the majority of beneficiaries who reach the catastrophic phase of the benefit and taxpayers bear much of the cost of treatment on premium and cost-sharing subsidies.

Dr. Anderson, I know you can be very succinct, too. But with the savings generated from drug-pricing legislation, what steps should Congress take to reinvest savings in ways that improve the LIS program and allow the subsidy to reach more people?

Mr. Anderson. Well, thank you, and happy birthday.

Ms. Matsui. Oh, thank you.

Mr. Anderson. So about a third of all Medicare beneficiaries right now qualify for LIS, and what that means is that they have, in many cases, not a very high burden to

pay when they use their prescription drugs.

But people who don't qualify for LIS are like Dr. Fowler and they do. And so if there is money and drugs are so important to people so they can have them, and if you have a $2,000 out-of-pocket bill, that's probably one month of your Social Security income.

Ms. Matsui. Mm-hmm. Right.

Mr. Anderson. And so you're making a lot of very difficult choices. So if there is the possibility to do something, increasing the number of people that are eligible for LIS is very important. At the same time, the prices have to come down so that the federal government can afford to do that.

Ms. Matsui. All right. Absolutely.

I know we talked a little bit about list prices before. But as a committee we've been examining the market dynamics of the drug supply chain and how each part the chain contributes to the end price the consumer pays.

While price concessions in a supply chain ultimately distort the net price paid for a drug, a stark fact of the matter remains. Out-of-pocket costs are often based on a drug's list price, leaving beneficiaries directly exposed to price increases.

Dr. Fowler, can you expand on why your out-of-pocket costs for Revlimid has increased dramatically now that you enrolled in Medicare? How does a Part D benefit differ from your employer plan when it comes to paying for high-cost specialty drugs?

Mr. Fowler. How long do I have?

[Laughter.]

Ms. Matsui. Just, you know --

Mr. Fowler. Ten years of experience on the private plan and almost two months under Medicare. So the differences that I am beginning to comprehend between the two systems are quite bewildering.

My insurance company was paying a huge amount back when I was employed at the university.

Ms. Matsui. Yeah.

Mr. Fowler. And I think I misstated earlier. They were paying $90,000 total when I started and $190,000 when I ended. What was my expense? My co-pay was almost negligible.

In the end, my co-pay each time the prescription was filled was $45. So I was paying out pennies and the insurance company but, really, my colleagues at the university who were picking up the premiums --

Ms. Matsui. Right.

Mr. Fowler. -- that's really who was paying the freight.

Ms. Matsui. Well, is it the --

Mr. Fowler. So I was paying almost nothing and the insurance company, or, in fact, my colleagues, were paying a monstrous amount.

But now I am in the world of Medicare. All of a sudden, my out-of-pocket expenses, $12,500 it looks like. I've had the prescription filled twice since I started the plan -- the Part D plan. So --

Ms. Matsui. Okay. So your out-of-pocket costs are greater is what you're saying, right now? That's the difference?

Mr. Fowler. Oh, considerably. I estimate it'll be $12,500 a year.

Ms. Matsui. Okay. Okay.

Dr. Anderson, drug companies have complete unilateral discretion to set their list price. Compared to the status quo, how will reassigning liability in Part D shift pricing incentives for manufacturers and impact overall cost to beneficiaries? I have about 25 seconds.

[Laughter.]

Mr. Anderson. Thank you. So Part B is one where, you know, you need to control the prices because the Medicare beneficiary pays some of that cost, and so right now there is -- the drug companies can set whatever price they want for it.

They're mostly biologics. They're mostly very expensive drugs. And so the Medicare beneficiaries are having to pay those costs. So setting some way to control the prices for those drugs is very important.

Ms. Matsui. Okay. Thank you, and I yield back.

Ms. Eshoo. The gentlewoman yields back.

It's a pleasure to recognize the former chairman of the full committee, Mr. Upton from Michigan, for five minutes of his questions.

Mr. Upton. Well, thank you, my friend, and I just -- I guess we could have made an opening statement written but I am going to just say a few things.

This is a really important issue. You know, drug prices impact every family. Everyone is concerned about it. We've seen all the stories. It has been for a while.

And with a divided government you have to get -- you have to work together to get things done, and this committee has had a long reputation, no matter who has been chair, to

getting things done.

And if you look back, when I was chairman one of the things that every one of us here worked on was 21st Century CURES, and I would say then that every member on both sides of the aisle, in fact, had a piece of that bill. They could take credit for it.

We all knew people in our districts, different associations that were involved in, and it really made a difference and will make -- continue to make a difference for a long, long time. And I think some of us know that Diana DeGette, who was my partner on this, we were working on a 2.0 bill. We are in the listening stage now to really look back and see where we can make it even work better for the different groups that are out there and, ultimately, do great things for our country.

But the point I want to make is it was bipartisan. In fact, I actually stopped a markup -- I think it was a full committee markup -- just so that we could spend a few -- another day to make sure that everybody was on board and of which they were when it passed 51 to nothing.

So this is a big issue. We want to get something to the president's desk. We need to take regular order to make sure that we do that with more than just one hearing but make sure

that we really do the process.

So one of the things that helped drive me to lead the charge was this awful disease which, frankly, I had never heard of before or at least didn't know any victims of this disease called SMA -- two beautiful little girls.

We now have a drug that is going to, I think, work, and that drug -- I saw a story -- I am going to put this in the record -- this is a story in the U.K. where this new drug for SMA in fact is being denied, which is really unfortunate.

And I would like to think that as time moves on it will be. They'll allow it and one of the concerns that we have perhaps with H.R. 30, if this was put in, is that you would have drugs -- you would restrict research and deny lifesaving drugs to whoever and really end up with something that none of us would want.

So I guess my first question would be are there considerations in this bill to ensure that HHS would evaluate patient need in determining the cost value of the treatment, and maybe, Dr. Ippolito, if you might answer that.

And then I have just another quick question before my time expires.

Mr. Ippolito. In terms of what the HHS secretary would evaluate it, based on my reading it was the cost of

developing the drug, cost of making the drug, and then I believe it was therapeutic value relative to the other option. I don't think I read anything to your specific concern.

Mr. Upton. Okay. One of the issues that both Dr. Fowler and Dr. Anderson raised was the amount of money being spent on advertising and marketing versus advertising -- versus research.

I've got some different numbers than that. Again, I will put this in the record but let me just share some of those numbers.

Pharma tells us that R&D -- their companies spend $90.5 billion on research and development and the amount of money spent on marketing and promotion is $28.1 billion. So, in essence, a three to one margin of which that $28.1 billion on ly $6 billion -- only, but that goes to advertising -- compared to the $90 billion, I will confess that.

And there was a study that was done -- again, I will put this -- ask to put this in the record -- with a good number of companies. I mean, they started with -- at the top with Bristol-Myers and Merck and Celgene and they go down the whole -- you know, we have Boeing and Raytheon, AT&T, and it is -- based on this table, the pharmaceutical industry spends

considerably more not only in -- well, at least in percentage of the revenue Celgene is 45 percent R&D versus Procter & Gamble just is 3 percent. And I just -- for your comments to say that they spend less than 20 percent of their revenues on research with more spent on advertising, where do you get those numbers?

Knowing that my time has expired, I will let you answer.

Mr. Anderson. So I can send you the information. I don't have it in front of me. But we took a look at their statements -- their financial statements for the drug companies and so we get just different numbers than they do.

I will show you the numbers that we got and how we got them.

Mr. Upton. Great. Yield back.

Mr. Burgess. Did the gentleman have a unanimous consent request?

Mr. Upton. I do, and I will --

Ms. Eshoo. Placed in the record. So ordered.

[The information follows:]

**********COMMITTEE INSERT**********

Mr. Upton. Thanks. Thank you.

Ms. Eshoo. Happy to.

For the record, in terms of the information that the secretary makes a determination on, it is a list. It's relative to the direct negotiations, research and development costs, prior NIH funding support for discovery and development of the drugs, market, manufacturing, and distribution costs, patent exclusivity data, domestic and international sales information, FDA approval information on alternative drugs on market, clinical effectiveness analysis and data on alternatives, and other advancements in treatments. So that fills out the record on the question that the ranking member of the full committee posed.

Now I would like to recognize the gentlewoman -- the gentleman from North Carolina, Mr. Butterfield, for his five minutes of questions.

Mr. Butterfield. Thank you very much, Madam Chair. Thank you to the three witnesses for your testimony today.

Dr. Fowler, thank you for your story. My staff has been talking with me about your story and just thank you so very much.

Over the past years that I've been here in Congress -- I believe it's about 15 years that I've been here and 12 years

on this committee -- I've heard so many people say that they cannot afford their prescription medication, both in Medicare and in private insurance, and that's just not acceptable.

I have a lot of industry in my district and I believe that innovation should absolutely be encouraged and rewarded. But, clearly, the American people need some relief.

It's time for Congress to act in order to ensure the American people have access to and can afford the treatments that they need.

And so, Dr. Fowler, I understand that in your testimony you say that under Medicare Part D you will spend over $12,000 a year on your medication. Is that correct, or is it $1,200? Twelve thousand dollars?

Mr. Fowler. That's correct. Twelve thousand five hundred.

Mr. Butterfield. Okay. Can you discuss how capping out-of-pocket expenses for prescription drugs will help individuals like you?

Mr. Fowler. It would help all of us to sleep easier at night knowing that our financial situation is going to be manageable. This brand new world of retirement and living off of Social Security, Medicare, retirement savings is -- I find it very precarious. I wish there were more -- less

anxiety and more confidence for the future.

Mr. Butterfield. Well, thank you for that. It's what I wanted to hear and thank you for putting that into the record.

The legislation that we are discussing today will help lower the price of prescription drugs for millions of Americans and help ensure that we are getting the best deal on prescription drugs for our seniors, and so I sincerely thank you very much.

Dr. Anderson, if I may please go to you. Thank you also for being here. It is unacceptable that Americans are paying on average three to four times more for their drugs than patients and our neighbors to the north, Canada, Germany, the U.K., and Japan, among others.

I wanted to ask you about a particular drug that is vital to the health of my constituents in North Carolina and across the country and that is insulin.

Ten percent of North Carolinians have diabetes. In some counties in my district almost 20 percent of adults have diabetes. The price of insulin has increased by 197 percent from 2002 to 2013.

According to a study by Kaiser, total Medicare Part D spending on insulin has increased 840 percent from between

'07 and '17. These figures are shocking.

Dr. Anderson, can you discuss why drugs such as insulin costs so much in our country? It's my understanding that six of the seven noninsulin medications used to treat type 2 diabetes are priced 600 to 1,100 percent higher in the U.S. than other nations. Help me get my hands around this.

Mr. Anderson. Certainly. So the first thing to recognize is that there are only three manufacturers in the country for insulin drugs. So there's not a lot of competition.

Second of all, the competition is in a very strange way. It's much like my iPhone. Essentially, I have an iPhone 10. We are about to be able to get an IPhone 11. It's going to add another $1,000 if I wanted to buy it.

What happens with insulin is they keep changing the product a little bit, either the way it gets distributed or it's a faster release or something like that, and then they can charge even more than they did yesterday.

And so what they are doing is slightly changing the product or the distribution in order to raise the price, and since there's only three of them selling it, that's the system that they're using.

Mr. Butterfield. Is it correct then to say that insulin

medications contribute significantly to Medicare spending on prescription drugs?

Mr. Anderson. Well, I mean, so many people have diabetes that, of course, it has a huge impact on the spending in the Medicare program, and the Medicare program is the one that's paying most of those bills.

Mr. Butterfield. Which contributes to the deficit which contributes to the debt.

Dr. Anderson, can you discuss why requiring the secretary to negotiate on a small number of drugs including insulin would help lower prescription drugs costs?

Mr. Anderson. Well, it would be simple because there's a number of drugs, somewhere less than a hundred, where the prices are three to four times what other countries are paying and the PBMs that are trying to negotiate these prices don't have any negotiating power. They have negotiating power when there's two drugs available and they can play one off against the other. When there's only one drug, there's no ability to play one off against the other.

Mr. Butterfield. Thank you very much.

Madam Chair, I yield back.

Ms. Eshoo. The gentleman yields back.

Pleasure to recognize the gentleman from Illinois, Mr.

Shimkus, for his five minutes of questioning.

Mr. Shimkus. Thank you, Madam Chair.

Ms. Eshoo. And we are really sorry about this announcement that you made.

Mr. Shimkus. All right. It's a long way off. You guys are stuck with me for months.

Ms. Eshoo. I don't know what -- I don't know what got into you but anyway --

Mr. Shimkus. Freedom. Freedom.

[Laughter.]

Mr. Shimkus. Thank you, Madam --

Ms. Eshoo. We are going to come to Illinois and have lunch with you.

Mr. Shimkus. Thank you, Madam Chair.

A couple things. Great hearing. This is a debate that I've been involved with now 23 years and I am sure we'll continue to have this debate for 23 more as we -- as everything evolves.

Dr. Ippolito, let me first go in response to another series of questions that you already received. What are your thoughts on the feasibility of HHS being able to correctly come up with a reference price for countries named in H.R. 3?

Mr. Ippolito. So yeah, I am considerably more

pessimistic than Dr. Anderson just because there's a few things to keep in mind. First off, yes, some other countries use reference prices but nobody matters nearly as much as the United States with the global market for pharmaceuticals.

According to IQVIA, we spend something on the order of the same amount as the rest of the top 10 spending countries in the world. That's not something to celebrate but that's something that you have to acknowledge, which means that when it comes to behavior of -- you know, of sovereign nations, as it were, that what we do really matters in a different way. And so what's going to happen is that drug makers are going to take all sorts of strategic actions. They're going to try to get into deals with countries to engage with these off invoice type pricing discounting behavior. We are going to see efforts to offer special package size, dose size, administration route combinations in certain reference countries and not offer them in the United States.

Mr. Shimkus. So you're telling me it's going to be difficult to do, from your perspective?

Mr. Ippolito. There's a reason that the speaker, wrote, we are going to use the net price of a country if practicable. It's because it's not easy.

Mr. Shimkus. Okay. Thank you.

Dr. Fowler, welcome. I think we all deal with cases like yours. Prior to Medicare Part D, what would our out-of-pocket costs be today?

Mr. Fowler. When I was back on the private --

Mr. Shimkus. No. No. No. Just, say, if you're in the same -- if you were in the same position you are today and we didn't have -- you know, there was a time we didn't have Medicare D. I don't know if you knew that. What would be your burden?

Mr. Fowler. I don't know.

Mr. Shimkus. Well, what's the -- what's the cost -- the basic cost of the drug?

Mr. Fowler. What's the market --

Mr. Shimkus. What's the market value of the drug without any negotiation?

Mr. Fowler. The retail price is about $200,000 a year.

Mr. Shimkus. So that would be your out-of-pocket cost?

Mr. Fowler. I suppose.

Mr. Shimkus. Yeah. So, I mean, it's good to have experience and be around here a little bit because prior to Medicare D there was no help for prescription drugs for seniors under Medicare. Nothing.

AARP is here. They were there. They were part of the

negotiations and, in the end, they supported the Medicare D proposal.

But pharmaceuticalogically or whatever, the world has changed, too. In those days, we had basic chemical formulations. Now we have biologics. Now we have this -- these massive costs.

So in that language, when you get outside of the protected area it's 5 percent of the cost of the drug, and I think if anyone's talking to their constituents -- I remember going to Olney, Illinois, which is the home of the white squirrels, and before a dinner -- it's in the beautiful 15th Congressional District. We have white squirrels there. And I met with a constituent who was outside paying similar costs to you, Dr. Fowler, on a lifesaving drug. And I think part of our debate and concern is that we want to have those drugs available. So we've got to fix this. And so I think there's places where we can go on, you know, capping out-of-pocket costs in the extension to this new world of biologics. So I think there's a -- I just think there's a lot of things to do. We are -- we -- I think I can talk for Republicans, basically -- are really concerned about government creating a formulary in prices. I remember small drug companies coming in. Raised $10 million to find a cure. Going back to their

investors and say, we are almost there -- we need $10 million more. Under this new H.R. 3 proposal, Dr. Ippolito, would you see any venture capitalists or anybody really doing that anymore?

Mr. Ippolito. So this is actually one of the biggest misconceptions about how R&D works in the pharmaceutical space.

I think there's this idea that this is the purview of Big Pharma. You make a drug. You go back to the chemist and you say, okay, mix something up again. That's really not how this works. What you really have is early stage investment is, largely, funded by venture capital firms and is done by small biotechs, and those venture capital firms don't have any allegiance to the drug market. They're just as happy to invest in a new scooter, you know, rental app or whatever.

So, you know, we do have to keep in mind --

Ms. Eshoo. Well, I think my VCs are going to have a problem with what you just said, but go ahead.

[Laughter.]

Mr. Ippolito. No, there's too many scooter rental companies already. But the point is that the capital is very mobile and that is the thing to keep in mind.

Mr. Shimkus. My time has expired. So with that, I will

yield back. Thank you, Madam Chairman.

Ms. Eshoo. The gentleman yields back. It's important to note that there are no formularies in H.R. 3 and the issue of whether patients will have access to the medications that they need in Medicare, Medicare is going to continue to cover all of the drugs that it does today. The bill does not stop Medicare from covering prescription drugs or limit patient choices and I think that that is -- that's front and center for seniors. So that's why I am adding it to the record.

I now would like to recognize the gentlewoman from Florida, Congresswoman Castor, for five minutes of questioning.

Ms. Castor. Thank you, Chairwoman Eshoo, for holding this very important hearing on how we make prescription drugs more affordable.

There is a celebrity here in the audience, probably the most famous, the top consumer advocate from the state of Florida, Jack McCray, who works for the AARP, is in the audience. Jack, thank you very much for being here. He's worked on these issues for years and years, and I am grateful that this committee is -- finally, we have in our sights some terrific legislation to finally take on Big Pharma and to do everything we can to lower prescription drug prices.

Dr. Fowler, your written remarks where you say what the drug companies really think is pay us or you will die. Well, hopefully, we pass these bills out and those days will be over.

And I also want to compliment my colleague and friend, Peter Welch, who has worked for many, many years on negotiating drug prices through Medicare. I have been allied with Representative Welch for many years and, Peter, I appreciate your leadership on this.

Let's get into the details a little bit on this. Under current law, the secretary of HHS is prohibited from interfering with the negotiations between drug manufacturers and pharmacies and prescription drug plan sponsors. That's kind of un-American, isn't it? We just say you can't negotiate.

This clause is often referred to as the noninterference clause of the Medicare Part D statute. It was enacted in 2003 at the time that Medicare Part D was approved.

Since the implementation of the Medicare Part D program, Medicare spending for Part D has increased form $46 billion in 2007 to about $80 billion in 2017 for an average annual growth of 5.6 percent.

Additionally, the Congressional Budget Office has

determined that for Part D beneficiaries our neighbors, who take brand name specialty drugs, the average annual net spending on such drugs tripled from 2010 to 2015.

All of the four bills before us here would address this in different ways.

Dr. Anderson, can you explain what this noninterference clause is? Is that a fair name anyway and what implications do this provision in law currently have on the secretary?

Mr. Anderson. So the noninterference clause means that you can't interfere between the negotiations between the PDP and the drug company. So that's the negotiation that can take place between the PDP and the drug company, but Medicare can't do it.

You mentioned all those increases. Where the increases are occurring is in high-cost specialty drugs and that's where the Medicare program, which is paying right now 80 percent of the cost, has no ability to negotiate, no seat at the table to do anything about those prices.

So where we are seeing most of the increases is where Medicare cannot negotiate.

Ms. Castor. Why was that even included back then?

Mr. Anderson. Well, in the past they thought that the drug companies and the pharmacy benefit managers would be

able to negotiate prices, and they were.

And as I said in my testimony, for many drugs they are able to negotiate prices. But what's happened over the last 16 years since the legislation has passed is we've seen a growth in the number of these very expensive high-cost drugs.

Ms. Castor. And that's not helping beneficiaries, is it?

Mr. Anderson. Well, some of the drugs are very beneficial. They cure diseases. They treat diseases. They are, in fact, very important. But if you can't afford them, then you can't take them. And what's interesting about Dr. Fowler's example is if he's insured privately he's probably got very good insurance.

Unfortunately, if he has Medicare, he doesn't have an out-of-pocket cap and, as he says, he's going to pay $12,000, whereas when he had -- was insured by his university he paid virtually nothing.

Ms. Castor. So are you saying that we shouldn't tie the hands of the federal government to negotiate prices. If we really want to put beneficiaries and our neighbors front and center, you would address this noninterference clause and allow negotiation?

Mr. Anderson. You would need to do it because this is

where it's for a small subset of drugs where there's no competition and Medicare right now is paying 80 percent of the cost. That's where the growth is occurring.

Ms. Castor. And would you agree that negotiation is a market-based tool?

Mr. Anderson. You can make it a market-based tool. Correct.

Ms. Castor. Okay. I agree, and what impact do you think this would have on the average Medicare beneficiary's pocketbook?

Mr. Anderson. So --

Ms. Castor. Oh, excuse me. My time has expired. I am very passionate about this and I thank you for your testimony.

Ms. Eshoo. We appreciate your passion and members are going to have the opportunity to submit questions to the witnesses and we ask that you respond to those questions forthwith so that -- because it's very hard to get everything in in five minutes, as you can tell.

It's now my pleasure to recognize the gentleman from Virginia, Mr. Griffith, for his five minutes of questions.

Mr. Griffith. Thank you very much, Madam Chair, for this hearing and, as you know, we need to continue to work

through this as this issue is complicated and needs further analysis and additional input, and I am going to have some questions later that I think will raise some issues that show that we are going to have to do some additional work.

But am I correct that you're willing to commit to regular order after this hearing with a subcommittee hearing and a full markup hearing, Madam Chair?

Ms. Eshoo. Can you repeat the question, please?

Mr. Griffith. Yes, ma'am.

Ms. Eshoo. I am guilty of looking at my phone.

Mr. Griffith. I understand. And the question was is that, you know, as we work through some of these questions, they're complicated and so forth, and I am just confirming that you are committed to regular order --

Ms. Eshoo. Yes, and it was another one of our colleagues asked me that.

Mr. Griffith. Okay.

Ms. Eshoo. This is regular order. We are having this hearing. We'll have a markup in the full committee. I believe we will have a markup on the subcommittee.

Mr. Griffith. All right. I appreciate that very much --

Ms. Eshoo. Sure.

Mr. Griffith. -- because I do think it's important.

Ms. Eshoo. It is.

Mr. Griffith. That brings me -- and that brings me to my first question, which is to you, Dr. Ippolito. I hope I said that close to right. I was not here earlier because we had two hearings going on and I was downstairs asking questions.

The idea of intellectual property is so important to our country that it is enshrined in the Constitution, Article 1 Section 8 Clause 8 -- grants to Congress the powers to promote, quote, "the progress of science and useful arts," end quote, by providing inventors the limited but exclusive right to their discoveries and authors -- they're included as well.

This applies to copyrights, patents, and trademarks similarly protected by Congress under the commerce clause, Article 1 Section 8 Clause 3. Together, they are all protected under the umbrella of intellectual property.

Can you speak to the bills before us today and how they would undermine this important constitutional right either through excessive taxation or seizure?

Mr. Ippolito. Right. So I think the key here is to understand what the kind of penalties are if you do not

accept the HHS secretary's price and we are talking about either, effectively, all of your net revenue or, literally, the seizure of your intellectual property.

And in terms of -- you know, I really do want to emphasize we are talking about early stage investment and the uncertainty. It's long-term investments, and so on.

The fact that if you do not agree to some price that is very hard to predict -- 10 years from now it's going to be a function of who's the president, who's the HHS secretary, what kind of political dynamics are, and so on, plus you know that they can also just take your intellectual property if you don't like the answer. Well, that's one heck of a disincentive to get into that business.

And so in terms of -- you know, if you want to lower prices, fine. Just come out and say what the price is going to be for something. But don't tell me that the answer is, oh, we'll come up with a price 12 years from now and see if you like it and, you know, we'll go from there and if you don't like it we'll take your intellectual property.

Come up and say what the price is you want to pay; otherwise, this kind of thing is so much uncertainty it's going to be hugely detrimental to the firms that want to get into this kind of business.

Mr. Griffith. Well, and you say it's detrimental to the firms getting in. Wouldn't it be natural for one of those companies perhaps to look for a different venue in which to place their company and maybe offshore it to someplace in Asia or some other location where they wouldn't have these restrictions?

Mr. Ippolito. I mean, I think the -- I think the first order that you would expect is, and I will use a different example than the scooter sharing. But, you know, venture capital firms don't need to invest in pharmaceuticals. They can invest in anything they want to invest in and that capital is mobile.

And so my first order expectation would be that if you make it too unattractive to get into this business, well, then fine, we'll invest in something else. We are not beholden to this market.

Mr. Griffith. One of my other concerns that I hope will get worked out in subcommittee is that -- as we go forward with the markup is that I am not sure we aren't violating on parts of this bill where they do a look back prior to the passage of the bill and start charging people -- I am not sure we are not violating both the civil aspects of ex post facto and possibly even bills of attainder. What say you?

Mr. Ippolito. I mean, it is true that if you're talking about the inflation caps I think we would be retroactively taking back -- price increases back to I think as far as 2016. I am not -- I don't know enough about the legal environment to know but --

Mr. Griffith. But it looks punitive to me. I will have to do some more study on it before we get to subcommittee. This is our first hearing on this particular bill. So I look forward to that.

I will say in the short time I have remaining that the whole system is complicated. We need more transparency.

Dr. Anderson has said the drug companies are raising the prices and the PBMs can negotiate if there's more than one. He's right about that. On the other side of that coin, we heard drug manufacturers in a hearing last year or the year before say that when there is more than one the PBMs hold them hostage and ask them to raise their list price so they can then give a bigger discount. The problem is when Dr. Fowler goes to pay his co-pay he's paying it on the list price and not on the discount price that the PBMs have gotten after they ask the drug company to raise it. It's outrageous. There's a lot more work we could do together. Working together in a bipartisan fashion I think we can.

This committee has always had a history of doing that, and I yield.

Mr. Ippolito. And I want to -- I want to emphasize one thing just on that point. The Part D benefit redesign does that. Part of what's encouraging that is the terrible incentive structure in Part D. This idea of high list to net spreads is what it's called. It's because you can use this benefit design to offload all these costs onto the federal government and then just stick it with the patient out of their pocket. It's a bad benefit design. So, you know, I know negotiations will be part of this but don't lose sight of the fact that there is a really good idea on the Part D benefit redesign here and incentive finance, too.

Ms. Eshoo. The gentleman yields back and I thank him for his questions.

I now recognize the gentleman from Maryland, Mr. Sarbanes, for his five minutes of questions.

Mr. Sarbanes. Yeah, thank you, Madam Chair.

There's a statistic which I always find incredible that there are three Big Pharma lobbyists for every member of Congress, and so, you know, we are constantly having to fend them off.

But I want to remind us that there are 750,000 Americans

for every member of Congress. So if you do some math there, you have to give those pharma lobbyists credit, and I know a lot of them are watching so I want to salute them for this. That means each pharma lobbyist is holding back 250,000 Americans. That's what's been happening over the last however many decades it is, because all those Americans want to see these prices lower and somehow the lobbyists have managed to keep that from happening. So that's pretty impressive. But it's changing. It's changing.

And I think what happened is that the demand -- the desire, the thirst for something real that could help families across the country is beginning to overwhelm the inside game that's been played for so many years, and maybe those lobbyists are going to step to the side a little bit so they don't get trampled by Americans who want to see a change.

So I think that's why we are at this point, finally, because so many families out there are affected and they've just had enough and they want to see a change. We got a lot of good proposals here that really do something real to address drug pricing in America.

So let me -- let me ask you, Dr. Anderson. I am very interested in this cap that is contained within H.R. 3 with

respect to the out-of-pocket costs that seniors would face with respect to prescription drugs under Medicare Part D, and it's a $2,000 cap.

So talk to me about that in a number of different ways. First of all, in addition to that I gather the manufacturers will now also be partly on the hook with respect to weighing in and alleviating some of the impact of the drug costs. So that, obviously, creates some interesting incentives in terms of the price that they set on the front end.

But also with respect to that $2,000 number, that wasn't, I assume, just kind of pulled out of thin air. There must be some rationale behind it. Why is that the number that makes sense? What does it represent in terms of significant benefit for patients? How will it help affect behavior on the part of the industry in ways that make a positive difference for families out there who are facing these high drug prices?

Mr. Anderson. So everybody seems to agree that we need to have an out-of-pocket cap in the Medicare program, much like most private insurance companies. Most self-insured companies have an out-of-pocket cap.

So there's agreement that it should be -- there should be an out-of-pocket cap. It's just where it should be set.

So the Trump administration originally said almost $5,000. The Senate Finance Committee said $3,100, and H.R. 3 says $2,000.

And so what we took a look at is who's affected at $5,000, $3,000, and $2,000, and less than 1 percent of Medicare beneficiaries were affected by the $3,000 or $5,000 cap. About 4.5 percent of Medicare beneficiaries are affected by the $2,000 cap.

However, it really doesn't cost very much to help so many more seniors by lowering the cap from $3,000 to $2,000 and especially if you changed the way it's financed through having the corporations pay more, the drug companies pay more, and the PDPs pay more instead of right now Medicare paying 80 percent of that cost.

Mr. Sarbanes. Thanks very much.

And as my time closes here, I just want to emphasize, Madam Chair, that the design elements of the proposal that is contained in H.R. 3 for sure, and I know there's been careful attention to designing the other proposals as well, but I really want to emphasize that these have been carefully put together, they are -- the various provisions are complementary in terms of the positive impact that it can have with respect to drug prices. So it's a very good

product -- legislative product that will make a difference.

And with that, I will yield back my time.

Ms. Eshoo. The gentleman yields back.

Pleasure to recognize the gentleman from Missouri, Mr. Long, for his five minutes of questions.

Mr. Long. Thank you, Madam Chairwoman.

And, Dr. Fowler, on the medication that you take it is a chemotherapy regimen. Is that correct?

Mr. Fowler. Yes, chemotherapy.

Mr. Long. And how often are you required to undergo chemotherapy?

Mr. Fowler. Excuse me?

Mr. Long. How often are you required to undergo chemotherapy for this?

Mr. Fowler. Well, it comes in capsule form.

Mr. Long. Oh, okay. Okay.

Mr. Fowler. Little capsules. I take 21 days of capsules and then seven days off. I don't understand the medical science behind it but that's --

Mr. Long. Okay. So you don't have to go somewhere and take chemo in a traditional chemo --

Mr. Fowler. No. It's a simple.

Mr. Long. Okay. Okay. We had a very dear friend that

succumbed to that disease. She had to travel to Little Rock to take her treatment and did that for years and years and years, and like I said --

Mr. Fowler. Right.

Mr. Long. -- so God bless you and --

Mr. Fowler. Thankfully, I don't have to do that.

Mr. Long. -- keep up the fight. You bet. Yeah.

Dr. Ippolito, in your testimony regarding price setting, you question the ability of regulators to know all relevant information distilled via markets where they can be subject to pressures.

Can you talk about the more -- talk about that more and why the Pelosi plan takes numbers from these referenced countries on their face and why that is not well thought out?

Mr. Ippolito. Well, so there's two points. The first is that you have to remember that other countries are solving a different problem than we are. Other countries are relatively small. So Canada is a very small part of the pharmaceutical market. They can make what economists would call a partial equilibrium decision. That is, they can basically assume that we are going to set a price and it's not going to matter that much for how anybody else behaves. The United States, that's just different, for better or for

worse. We spend so much that we are the straw that stirs the drink. We are -- we are what matters in the pharmaceutical market. So what was right for one other country may not be right for us, not to mention we may have different preferences and different willingness to pay and all that kind of thing.

So there's a lot going on here that's different between the countries.

The second point, the more broad point is, look, whether you love rate setting or hate it, it's not easy. Like, we've seen this. Almost, you know, about half of states plus did some version of hospital rate setting back in the day. We had five states that had long-lived rate setting regimes and they all succumbed to various different forms of political pressure, misuse of the system, must literal complexity, and all sorts of other reasons.

So it's not like we haven't seen this type of thing tried before. Even if you like it, it's very hard. These are complicated markets.

Mr. Long. And you're surely not old enough to remember when Reggie Jackson said, "I am the straw that stirs the drink."

Mr. Ippolito. No. Somebody told me to say that. I

have to --

[Laughter.]

Mr. Long. Busted.

Can you explain where the Pelosi plan fails in understanding the tradeoffs between spending and future drug development, and why the effort under H.R. 3 to treat tradeoffs other countries face is identical to the U.S. is incorrect?

Mr. Ippolito. So I worry a lot about that. I think that what we have is a system where the HHS secretary gets to set a price. There's no real negotiation happening and there's going to be tremendous pressure to value the near-term gains that come from a real benefit, which is paying less for drugs. That's great. I want to pay less for everything that I have. But I also care about another kind of access, not just access today but I care about access to some, you know, treatment for ALS or Alzheimer's or whatever it might be.

And so the question is not, you know, how do we -- how do we hammer the cost down as much as humanly possible. The question is how do we solve this joint problem of maintaining access today and making sure we have some long-term vision and I worry that the way this is set up is we are really

going to give short shrift to that long-term vision.

Mr. Long. Okay. And can you talk about the lack of certainty that will be created under H.R. 3 as different administrations may maximize the federal rate setting allowed under H.R. 3?

Mr. Ippolito. I mean, you know, this is one of these things where you have to sort of guess how this would evolve. I think it's -- you know, what we know is that there's some maximum price and it's this reference price.

But you can go anywhere below that you want. And so the question is what is any given administration going to do with that power and, you know, frankly, if you just listen to the rhetoric, for example, I use Senator Sanders is obviously running for president right now. Based on my observations and listening to the rhetoric that I hear come out of his campaign, I would expect quite different things than if I were to imagine, you know, Tom Price for HHS secretary or whatever. And I don't even -- I don't even want to assign a value judgment to which is better. But the point is, literally, that regardless of what you think is better, the sheer existence of uncertainty is costly. So, you know, firms are not what we call risk loving. They are risk averse. They do not like uncertainty and what we have is

uncertainty over decades-long projections for investments.

And so that's really what I worry about, even independent of whether you think the price is going to be too high on average or too low on average or whatever.

Mr. Long. Okay. And Madam Chairwoman, just to correct the record I would like to state that Marionville, Missouri is the home of the white squirrel, not 10 miles from Anywhere, Illinois that Shimkus tried to claim it was.

I yield back.

[Laughter.]

Ms. Eshoo. Well, thank God you made that distinction. We are really grateful to you, Mr. Long.

The gentleman yields back.

Pleasure to recognize the gentleman from Massachusetts, Mr. Kennedy, for his five minutes of questioning.

Mr. Kennedy. Thank you, Madam Chair. Thank you for holding this extremely important hearing. Thank you for your witnesses for being here and your testimony.

Dr. Fowler, thank you for your moving words, sir. This committee has heard you loud and clear, has heard an awful lot of additional witnesses in very similar circumstances.

As members of Congress every day we hear stories about patients and families who are draining savings accounts and

falling into deep debt just to afford medication that can keep them alive.

We listen as terrified exhausted patients tell us about drugs that could treat their treatable disease if they could afford it. We watch parents, including some back in my home state, who marched into headquarters -- in front of headquarters of a pharmaceutical company carrying the ashes of their children because the treatment that could have saved their lives was too expensive.

And I understand that this is a big hard problem. I understand the complexity around it. Dr. Ippolito, I appreciate your testimony and your candor on this and the challenges that exist and the choices that have to be made in a piece of legislation.

I would say there's choices being made in the status quo at the moment that is an absolute abject failure to an awful lot of people that need care and that care exists.

And so I don't -- I don't dismiss any of the concerns that you raise. I also think that we also have to recognize there's a cost of not doing anything. We have had so many hearings here over the course of even my tenure where we've had executives from a number of pharmaceutical companies, PBMs, et cetera, up at that dais right where you are that

literally just did this, over and over and over again.

And so at a certain point, what else are we supposed to do than make a choice? What else are we supposed to do other than force an issue? What else are we supposed to do than say, you know what? Fine, here it is. And you want to push back, you want to debate it, fine. But you can't keep waiting for somebody else to solve this problem. I literally asked a question of an executive at that table what else we should do, and the response was, call a hearing in Congress, invite us to testify, and solicit advice. At that dais in front of Congress at a hearing to solicit advice. That was the response I got.

So at a certain point, what else are we supposed to do when every other witness keeps doing this, from pharmaceutical industries and from the industry writ large?

And so my patience, and I think an awful lot of us, are wearing thin. Again, understanding the complexity, but to point out a couple of obvious shortfalls in the system, Dr. Fowler, you indicated that you are on a medication made by Celgene. You indicated that the -- I believe the market price for that was over $200,000 per year. Is that right?

Mr. Fowler. Yes, that's my understanding.

Mr. Kennedy. And do you know what your out-of-pocket

expenses were, roughly, in 2017 or 2018?

Mr. Fowler. Well, back when I was still employed, my out-of-pocket expenses for the year were about $600.

Mr. Kennedy. And do you know how much the drug costs annually to produce?

Mr. Fowler. Excuse me?

Mr. Kennedy. How much it costs to produce that drug?

Mr. Fowler. To produce? My understanding is that it costs Celgene about $240 a year to produce the drug.

Mr. Kennedy. That's my understanding. Do you have any idea how much Celgene spent on stock buybacks those two years?

Mr. Fowler. I don't possess that information.

Mr. Kennedy. I will help you out. It's about -- it's $5.7 billion.

Mr. Fowler. Yes.

Mr. Kennedy. Do you know if Celgene during that period of time increased or decreased the price of your drug during that period?

Mr. Fowler. Excuse me? The --

Mr. Kennedy. Do you know if Celgene increased or decreased the price of your drug?

Mr. Fowler. Oh, it went up and up and up year by -- I

took it under my university's plan from 2009 to 2019, for 10 years, and it went up and up and up. It more than doubled over the course of 10 years, constantly inching its way up.

Mr. Kennedy. So we've got a company that takes $5.7 billion in a stock buyback for a drug that costs -- in profits, right? In profits. The drug in your circumstances $240 to manufacture. And did you get any benefit about of the stock buyback?

Mr. Fowler. I am sorry. I am not hearing that clearly.

Mr. Kennedy. I am sorry. A company that took $5.7 billion stock buybacks --

Mr. Fowler. Ahh.

Mr. Kennedy. -- in profits, right?

Mr. Fowler. Okay.

Mr. Kennedy. For -- across their portfolio. Did you get any benefit from a stock buyback that they --

[Laughter.]

Mr. Fowler. Not that I am aware.

Mr. Kennedy. Not that I am aware of either.

At a certain point -- at a certain point, I understand the challenges and complexities here. At a certain point, I do think we have to say enough is enough and we will force this issue. If this is what it takes in order to get some of

our companies at the table to help us solve this problem, then this is what it's going to take, because I think a lot of us have been sitting around these tables for long enough getting the run around without anybody actually wanting to solve this problem.

And I yield back.

Ms. Eshoo. The gentleman yields back.

And I now recognize the gentleman, and that he is, Mr. Bucshon from Indiana, for his five minutes of questioning.

Mr. Bucshon. Thank you, Madam Chairwoman.

I was happy to hear right at the beginning of this hearing a commitment to a subcommittee markup and regular order, and in that vein, I think you mentioned recently we may have additional questions for the record and that may be critical for the witnesses to respond quickly, and I agree with that. These answers could prove critical to helping us understand all the issues and I would like to know if you can commit to receiving the answers to the written questions before we proceed to a subcommittee markup.

Ms. Eshoo. Well, I think it makes sense that we organize this so that the witnesses can respond in time and that you can make use of what they respond for what come next.

Mr. Bucshon. Thank you.

Ms. Eshoo. So we'll do our best to coordinate it.

Mr. Bucshon. I appreciate that commitment because it is important. A lot of times in five minutes, as you pointed out, we can't get all our questions in and sometimes there's more to that story.

And also I would just like to say that the comparison of private insurance and Medicare Part D is totally legit and that's why I think in a bipartisan way we need to proceed with Medicare Part D reforms that does limit out-of-pocket costs and make other changes that make it more effective and efficient for the patients and I think we can do that in a bipartisan way. I think that is important.

I want to talk about access. I was a heart surgeon before I was in Congress and, for me, the key is patient access to affordable health care. I want to talk about what a recent report from the U.K., and this is -- and I will read this -- about a father who was 38 and he -- it says who can't get cancer drug on NHS -- the National Health Service. He was heartbroken as his son, age seven, asked him, when are you going to get better, and it turns out he was diagnosed with blood cancer -- I think the same condition that you have, Dr. Fowler -- at age 38. And but he knew he couldn't -

- he knew a drug that could prolong his life and that was Revlimid, which is, I think, what you're on. That's a coincidence. That wasn't -- I didn't plan that. Didn't know that you were on that. But he didn't qualify for the treatment under the NHS because at the National Health Service you have to have -- it says here you have to have a failure of therapy three times -- you have to have a recurrence before you qualify for this new innovative drug.

And so I just wanted to point that out that one of the risks of doing the wrong thing in the U.S. on drug pricing can, in my view, severely limit potential access to medication that we would otherwise have available.

And I agree, we need to get the out-of-pocket costs down but there are other ways to do that. So with that, Dr. Ippolito, quickly, in my last two minutes, several of the countries referenced in H.R. 3 governments frequently denied patient access to drugs using standards that determined the value of a person's life.

This is a situation we are in here. Under the standards the value of some people's lives, such as a disabled person or an elderly person gets a lower score than the value of a younger healthier person.

For example, a child with a neuromuscular disorder may

be worth half as much as a healthy child. That's not my words. That's what's been reported that countries do. This can result in fewer vulnerable individuals having access to treatments that they need.

Do you feel it's ethical to place a value on a life of a human being?

Mr. Ippolito. I don't know if I am best suited to answer the ethical element and maybe it's a bioethicist or something. But it's certainly -- I mean, the general point I think you're making is it speaks to the fact that if you want to do cost effectiveness-based coverage decisions and pricing decisions, you do need to make some fairly explicit decisions.

Mr. Bucshon. Correct.

Mr. Ippolito. What are you willing to pay for as a country, how much is that worth, and this does vary by a variety of characteristics.

Mr. Bucshon. Right. So my point as a provider would be is that the U.S. federal government, potentially, in the negotiations could make policy decisions that are essentially medical decisions on who gets access and who doesn't based on cost.

Mr. Ippolito. There is some question, in my view, about

how exactly the HHS secretary would consider how good a drug is relative to previous therapies and a few of those other considerations.

But that is at least nominally part of the calculus they're supposed to consider.

Mr. Bucshon. Yeah. So, I mean, again, as a provider I don't -- I think it's up to the medical professionals and the families and the patients to work through these situations. It is up to us to figure out how to improve Medicare Part D -- no doubt about that.

But one of my big concerns is if the federal government gets more into this space, which is being proposed in H.R. 3, is that you will indeed have financial decisions being made by different administrations that may very well limit access based on the government's perceived value of your individual life and the lives of the American people as a whole.

I yield back.

Ms. Eshoo. Doctor yields back, and now I would like to recognize Mr. Schrader from the state of Oregon for five minutes for his questions.

Mr. Schrader. Thank you, Madam -- thank you very much, Madam Chair.

Dr. Fowler, you talked eloquently about your situation

and Medicare -- going from private care to Medicare. It gives me pause when I hear all this call for Medicare for all and I see Medicare does not provide quite the same benefit that your private care did, which is -- which is something we should all consider.

But more to the point, you also talked about some of the other problems we have in the prescription drug space. You have talked about the CREATES Act and the issue that it tries to address.

This committee worked on a very bipartisan basis to push out a number of bills -- my BLOCKING Act. We talked about the patent reform the chair and others worked on.

Do you feel those types of bills would be of much benefit to beneficiaries in Medicare or just the population writ large?

Mr. Fowler. So you're asking in particular about the CREATES?

Mr. Schrader. Yeah. Use that. That's the one you're familiar with.

Mr. Fowler. What I know of that -- when I first learned that that was being discussed it really intrigued me because it seemed to make a great deal of sense for my situation with Celgene, who, apparently, has written the textbook on how to

avoid the production of a generic. They've been stupendously successfully in avoiding a generic, and so I would be delighted to see action finally taken on something like that.

Mr. Schrader. Well, I wouldn't pick on any one company personally, but there's a lot of, you know, unfortunate loopholes I would call them in the current legal construct that allow companies to game the system a little bit to their advantage. That's the nature of business, to some degree.

But we passed a bunch of bills along those lines that I would hope we have a chance to get passed out of the House of Representatives as a bloc of bills that would have wide bipartisan support because we worked really, really hard on those.

Taking a little different tack, Dr. Anderson, you know, the bill before us is a good solid attempt to lower costs, frankly, for every American, not just those that are seniors.

We have some negotiation that goes on already in the VA and DOD. Why not adopt that? Why not adopt a VA price, for goodness sakes? I know they've got a formulary.

But I think you could get past the formulary issue with Medicare by just supplying the Medicare reduction from commercial rates to the class of drugs that a drug that's not on the formulary would be in and get some huge savings.

We'd save a lot more money. Wouldn't have to create a second bureaucracy. If it's good enough for the VA should be good enough for seniors, for goodness sakes. Seems like a smart common sense way to go that we can implement pretty rapidly.

Mr. Anderson. So the VA pays and so does DOD about 30 to 40 percent less than what Medicare does. So yes, you could -- you could adopt that.

The problem, of course, is, you know, can you do that for all Americans or can you do that just for the VA and, you know, that's the uncertainty of this thing.

But I think you should definitely be taking a look at the VA approach to setting rates because they do negotiation and they've been doing it for many years and you, the Congress, authorized them to do it very successfully.

Mr. Bucshon. Yeah, bipartisan would keep us from getting -- it would help -- some of my folks on the far left are very concerned we are not including enough drugs and on the far right, you know, we are taking some other countries' standards for our own. We've been doing this for a long time. It's bipartisan and I think there's a way to actually get that -- get it done.

Dr. Ippolito, you're concerned about the secretary being

kind of the judge of all things, being -- having total discretion. I share some of that concern.

In Oregon, where I am from, we have a list of prioritized services that a medical -- that medical experts, not politicians like me, get to talk about what's the most cost effective, what's the best value, how we should go about things.

We have MedPAC here that we use, another group of medical experts, not politicians and not appointees to decide, you know, what could be best practices that, you know, they provide us information.

What do you think of the Senate bill's approach where they actually have this advisory P&T committee that would be a more technical, a more science-based group of folks than just one person deciding how these drugs negotiations go on?

Mr. Ippolito. It's probably a step in the right direction. I think you're going to run into some of the same challenges. Scaling up a real -- if you really want to get into something like a cost-effectiveness style recommendation, that's a fairly advanced undertaking.

The man to my left probably would be a good choice to lead that, though, if you wanted to do it. But I think adding some expertise would help. I don't know outside of

giving some formal guidance that it would solve one of the big concerns I have, which is the uncertainty element. That's one element I would keep in mind.

Mr. Bucshon. Fair enough.

With that, I yield back. Thank you, Madam Chair.

Ms. Eshoo. The gentleman yields back.

Pleasure to recognize the gentleman from Georgia, the only pharmacist in the United States House of Representatives.

Mr. Carter?

Mr. Carter. Thank you, Madam Chair. And in the Senate as well, so thank you. In Congress, we'll say.

Madam Chair, seriously, I want to -- I want to just take just a second and thank you because I will tell you the truth, we just finished a five-week break during August and in my district I went around the whole district telling them that I serve on the oldest, most diverse, most bipartisan committee in Congress and that is the Energy and Commerce Committee, and I truly believe that.

And what we've been working on here and what we -- and I told them about what we working in -- robocalls, surprise billing -- that we've worked on in a bipartisan fashion.

We've also worked on prescription drug pricing in a

bipartisan fashion. We passed at least nine bills out of here in a bipartisan fashion, three of which I was the co-sponsor on that I am very proud of. I have to tell you that I was extremely disappointed whenever I saw the Speaker's plan here.

And we knew it was coming, we never saw it -- but when we saw it. But I want to thank you for your commitment that we will have a markup in subcommittee on this because it is extremely important for us to engage in regular order and that's very important.

Why is this issue so personal to me and it is so personal to me? Because listen, I was the one on the other side of the counter for so many years.

I was the one who had to tell the patient how much this medication was. I was the one who witnessed the mother crying because she couldn't afford the medication for her daughter.

I was the one who watched the senior citizens try to make a decision on whether they were going to buy medicine or whether they were going to buy groceries.

That's why it's so personal to me and that's why I want to do something about it and I am going to do something about it, and we are doing something about it.

Let's not sell ourselves short. We've passed some good legislation in this committee that we need to continue to work on.

I am concerned because I will be quite honest with you, my years of practice in pharmacy I've seen nothing short of miracles as a result of research and development and I applaud the pharmaceutical manufacturers for that.

However, it does you no good whatsoever if you can't afford it. I understand that and I get that. But I am extremely concerned, and I want to ask you, Dr, Ippolito, about the impact on research and development, about this proposal specifically about what I consider to be the price controls, because the price controls, I feel like, are going to -- are going to inhibit research and development and I cannot -- I cannot adhere to that. I cannot go along with that.

Mr. Ippolito. Yeah. I mean, I think I share some of your core concern, which is, you know, it would be great if we could, you know, get every drug under the sun. But if nobody can afford it, well, then it doesn't do anybody any good, right.

So I don't want to spend the entire country's GDP on pharmaceuticals. But the question is how do we make sure

that we keep making progress while actually having folks get access to these drugs.

And when I look at -- I mean, when I look at the Part D -- I know you want to talk about the pricing but the Part D redesign I think is a good example of that.

Mr. Carter. And if I could mention, we have actually in this committee -- we have actually sought input. What you see here are 83 -- 83 different comments that we've had about how we can revamp our Part D system. We can make it better.

Mr. Ippolito. Yeah. And so I think -- I do want to keep emphasizing that. I really do think there's a lot to like there and it does get at, I think, this balance that you're trying to strike.

With the price setting, you know, like I've said, we know the direction of the effect. If you reduce the prices a lot you're going to see some reduced innovation. The question is exactly how much and that's hard for anybody to predict.

Mr. Carter. It is hard to predict but -- and listen, as abrasive as we find it to be, you're absolutely right. Venture capitalist are -- this is going to make them look elsewhere.

I mean, I would like to think that yes, they're in it

for the good of man and I am sure some of them are, but they're also in it to make money. And I am not opposed to anybody making money but at the same time we have to be realistic here.

And I've looked and I see what we've done. I am co-chair, along with my good friend, Representative Mark DeSaulnier from California, of the Cancer Survivor Caucus here in Congress. What we've seen -- we've seen a 22 percent decrease in cancer and deaths due to cancer since 1991. And HIV and AIDS -- we've seen a 85 percent decrease since 1995 as a result of research and development. This is phenomenal.

And when I hear this I think about the dreaded disease Alzheimer's, what kind of impact. By 2050, it's estimated that 14 million people will have this disease and it will cost this country $1.1 trillion. If we don't have research and development into this, we are going to lose. We are going to lose that battle. That's why we've got to make sure that that incentive remains there.

Mr. Ippolito. Yeah, and I think that's exactly the kind of thing that I think about. There are access today -- there's concerns about access today. But we've got to keep in mind access tomorrow, and access tomorrow means access to something that we don't actually know what it's going to be

and that's kind of the hard part of it. But when you put it in terms of things like Alzheimer's, I think it's a good way of understanding just the kind of -- just the kind of rewards that are out there if we do this right.

Mr. Carter. I realize I am out of time. But I will say there are plenty of things that we can do outside of drug price controls.

Thank you, and I yield back.

Ms. Eshoo. The gentleman yields back. I think any company would be interested in the market -- very interested in a market of 14 million people.

I now would like to recognize the gentleman from Vermont, who has spent a considerable amount of his legislative time in the Congress working on the very issue that we've called the hearing on today, Mr. Welch, for five minutes of his questioning.

Mr. Welch. Thank you very much and thank you for the hearing.

First, I would like to put in the record three letters. Mr. Carter and I have been working on DIR fees and I would like to introduce a letter from the National Community Pharmacists Association and also one from the American Pharmacists Association, and third, a statement from our good

colleague, Elijah Cummings, chair of our Oversight and Government Reform -- Oversight Committee who's been a champion on trying to bring down drug prices.

Ms. Eshoo. So ordered.

[The information follows:]

**********COMMITTEE INSERT**********

Mr. Welch. A couple of things. We have done a lot together in this committee. But we are now facing a very clear question and it's -- let's be candid. We have a disagreement, and the question is do we need to have our government play a role to protect consumers or maintain the status quo where we don't. That's it, and there's an honest difference of opinion on that. There are arguments that I am hearing from some of my colleagues who oppose this that they're worried about innovation. Totally valid concern. We have to have innovation. There are concerns that this is, quote, "price setting" because it's unusual for government to be involved negotiating.

Now, my view, the price setting is being done by the pharma industry because here is what's happened. We are here, in my view, because of egregious overreach by the pharmaceutical industry.

You know, we went with an industry that started out with scientists and pharmacists trying to come up with cures and that was a good day's work for them when they came up with something, to these pharma companies essentially being Wall Street entities.

And, bottom line, many of the patents that they have are not a result of them inventing the drug. They bought the

drug. NIH -- taxpayers paid for it and then smart Wall Street folks bought it, and with the benefit of the patent they used that pricing power to overreach.

And secondly, they're in a situation where they've got a market because people like Dr. Fowler have to have it. Your family wants you to have it. Your employer wanted to have it.

Think about how much it costs your employer to provide that insurance. But our employers around this country want to help their workers so they buy employer-sponsored health care and that includes pharma coverage, in many cases.

So that's a guaranteed market for the drug companies. And then, of course, you have legislators passing the Medicare program, the Part D program, and the Medicaid program. Drugs are included and that's a market. So you have got pharma that benefits from taxpayer research, buys the product -- doesn't invent it in many cases -- spends more on advertising than it does on research, spends more on price -- stock buybacks than it does on research, and then they're called to account for some of these other maneuvers like selling their drug to an Indian nation as a way of trying to extend their patent -- or evergreening -- their constant defense is if you do that it'll stifle innovation. You know,

I've had it. It's not true. It's bogus. And this is the hard question for us because this is a bipartisan committee. But we really do have a disagreement on this question of whether the government should be involved. There's a lot of folks that think if government gets involved it's automatically bad. Sometimes that's true, but this is a case I believe where if government isn't involved the status quo continues. It's going to crush everyone.

I just want to ask you, Dr. Anderson, on this question of innovation -- when I was in a meeting with Secretary Azar, he expressed with clarity, and he's got significant experience as a leading executive in one of our best pharmaceutical companies, that it is not true.

Your view on that? How can we avoid stifling innovation if we have some type of price negotiation?

Mr. Anderson. So, essentially, what you got to recognize is where innovation is really starting and it's starting at the NIH and going to academic medical centers. That's where all the basic science and the first drug development typically occurs.

It's not occurring in the big drug companies. And so the key question is are you going to continue to fund NIH, and I assume you will. And so we will continue to get drug

development.

Mr. Welch. Okay. Dr. Ippolito, I mean, I share your concern. I mean, certainty -- there is certainty right now whatever price you want to charge we'll pay. That's the certainty we have.

On the proposed bill, money that is saved some of it will go back into scientific research at NIH. Is that a good thing, in your view?

Mr. Ippolito. Yeah. The NIH does a lot of really good basic research.

Mr. Welch. Appreciate that. Thank you.

I yield back.

Ms. Eshoo. The gentleman yields back, and we are all grateful to you for the work that you have -- that you have done for -- over a long period of time.

Pleasure to recognize the gentlewoman from Indiana, Mrs. Brooks, for five minutes.

Mrs. Brooks. Thank you, Madam Chairwoman, and I apologize. We've been going between a couple different hearings this morning. But thank you all so very much for being here today.

I think there's no question that Americans pay too much for health care including the cost of prescription drugs. In

this committee we've held many hearings to try to work through solutions and we actually even came to some bipartisan agreements in the process, which I think demonstrated, I think, contrary to what my dear friend and colleague across the aisle just said, we aren't trying to protect the status quo. We actually had been doing some pretty important things in this committee and we were making progress.

However, I think there are some very serious concerns with H.R. 3. The bill does require companies to, quote, "negotiate" prices with the federal government for up to 250 drugs that don't have the generic or biosimilar competition. We were working on that in some bills also. We were working on access to generics before H.R. 3 was dropped, and if companies would refuse they'd face a huge penalty tax on gross sales of each drug. And for Medicare drug programs, if a drug price rises faster than inflation going back to 2016 the manufacturer would face another huge tax on those revenues above inflation.

And I do think we really do need to think about the dramatic chilling effect of innovation and breakthrough medicines coming to market. I've learned through all of this that some of our peer nations -- Germany, United Kingdom,

Australia, Canada, France, and Japan -- often have access to many -- to fewer of the new drugs than we are able to get here in the United States, meaning that despite the cost, patients can't get their hands on new lifesaving drugs in many of these countries. And if we share that same drug pricing model of our peer nations I worry this could become a reality in our country.

So I want to share a story of one patient, Krystal Hekau. Krystal lives in New Zealand. She has aggressive breast cancer. While she inched her way up the waiting list required for radiation treatment -- the waiting list for radiation treatment -- she learned the cancer had spread to her spine. Now her doctor tells her that a new medication could prolong her life. But the government's drug-buying entity, PHARMAC, has not approved it. She has two children at home. The oldest is five. And so while -- and so she may not get this drug -- will probably not get this live-saving drug.

Lower drug prices are a goal this entire committee shares. But I think if we push forward this particular piece of legislation it will reduce access to drugs and lower prices aren't going to matter because many people aren't going to get access to drugs that they need.

Dr. Ippolito, is it possible that the economic incentives under H.R. 3 would lead to manufacturers denying their lifesaving products to patients in our country or in other countries?

Mr. Ippolito. It is unlikely, in my view, that at least as it's currently written that a drug manufacturer would decide not to offer a drug that currently exists or that they've already made in the United States.

In part, the reason is that simply they'd be fined more than they would even make if they sold the drug in the first place, regardless of what the price they got was.

So that I have less concern about. I think I have more concern about -- well, depending on how this evolves, which is hard to predict, but depending on how low the prices are, the question is who's going to want to enter and to discover new drugs and who's going to want to market new drugs. That's the bigger question to me.

Mrs. Brooks. And so let me ask you about that, because my home state of Indiana is a top life sciences hub. A lot of medical innovation, public-private partnerships happening between industry and academia all the time. It's really created tremendous growth and innovation to patients and to the companies in Indiana, not just -- but, more importantly,

to the benefit of the patients from this innovation.

How would -- what is your concern about how this -- the drug pricing plan will impact U.S. jobs and workers, and the companies that are bringing these drugs to market?

Mr. Ippolito. You know, I think the biggest concern would be on not on the basic science side where it's more the academic medical centers and NIH-funded work. You would be more concerned about the people who are currently being funded by venture capital firms or who are currently recouping lots of money when a large pharmaceutical company buys their compound or whatever it may be. It's hard for me to put any sort of firm number on that kind of thing. But yeah, sure, I think directionally we know which direction that would go.

Mrs. Brooks. And that would go in a negative direction when it comes to innovation. Is that correct?

Mr. Ippolito. Yes, I think that's correct.

Mrs. Brooks. Okay. I yield back. Thank you.

Ms. Eshoo. The gentlewoman yields back.

Who is next? Recognize Dr. Ruiz from California for his five minutes of questioning.

Mr. Ruiz. Thank you, Madam Chair. Seeing firsthand the devastating effects of skyrocketing drug prices in my

practice in the emergency department and speaking with a lot of patients, and I have treated patients who never got their prescription filled because they couldn't afford it or patients who rationed their medication to make it last longer.

And I know I've told this story in this committee before but it's an important example for folks in the room who haven't heard it.

I had just finished a community forum prior to even thinking about running for Congress on health care access, and as I was leaving the church where we held the forum I noticed an elderly woman who was digging in the trash -- a big trash bin.

I went over there and I asked her, you know, what are you doing. She said, well, I am digging for aluminum cans to get some extra money so I can pay for my insulin. I said, really, you're having -- you know, you're having to do this.

She said, yes. Then she said, but don't worry, Doctor. Don't worry. I am only taking half of my dose so that I can make it last longer.

And as you know, it's almost like not taking anything at all, and a lot of patients are doing that. In fact, according to a Kaiser Family Foundation poll, close to 30

percent of adults have either not filled their prescription, rationed their medication, or skipped medication in 2019. Thirty percent of adults, one out of -- nearly one out of three.

So, in other words, the sick are not getting the care or the treatment that they need and that same poll showed that one in 10 adults reported a decline in health. So it's not just that they're not getting the medication; their health is getting worse because they couldn't afford to take their medications prescribed by their doctor.

So I just want to remind everybody here that this isn't about a cost savings to the government or some pay-fors for other things. This isn't a cost savings to drug makers or to health insurance companies. This isn't even about saving costs to hospitals.

The primary goal here is to save patients out-of-pocket costs. That should be the number-one metric in which we evaluate any policy that comes out of this committee and this House of Representatives to make sure that patients don't pay more out of their own pocket.

So when we talk about the importance of reducing the cost of medications, we need to talk about the out-of-pocket costs to the patient and how we ensure that the policies that

we are considering here result in savings to the patient.

So H.R. 3, the Lower Prescription Drug Costs Now Act, does just that by capping out-of-pocket costs for our seniors. Additionally, it is imperative that we require HHS to negotiate drug prices and that those negotiated prices will apply to Medicare and commercial plans.

So, Dr. Fowler, I was very intrigued by your story and your experience, and stories like yours are not uncommon, which is why we are here discussing these important issues today.

So can you amplify your history and what -- on a personal level how has the cost of your medication impacted your life?

Mr. Fowler. Thank you. I guess I would return to what I said earlier about the double anxiety over my medical condition -- I have to do lab work every three months to check on my numbers and I will do that as long as I live because I have an incurable disease.

So there's that constant thought in the back of my mind that I am living with such a disease. But I keep my wristband on from the International Myeloma Foundation so I am constantly remembering that I have that to deal with, even though the day is going well.

But then there's the financial -- the financial uncertainty that we may run out of money, God knows what expenses might pop up on down the road.

Mr. Ruiz. And we know the importance of mental health and stressors have on ultimate outcome of illness and treatment. So the additional stress of having to -- figuring out if you're going to be able to afford the medication, in your case for multiple myeloma -- is that correct?

Mr. Fowler. Yes.

Mr. Ruiz. Is adding to the burden of disease for you. Was there anything that you had to postpone or decisions you made that you couldn't do for yourself or your family because of the cost or the worry for the cost of medication?

Mr. Fowler. No, thankfully. I had excellent coverage through my employment and that worked wonderfully well, and I am very, very grateful for that.

Mr. Ruiz. And what kind of doctor are you?

Mr. Fowler. I am a Ph.D.

Mr. Ruiz. Ph.D. kind of doctor. Great.

Mr. Fowler. A religion scholar.

Mr. Ruiz. Wonderful. I love that. Thank you so much for your service.

Ms. Eshoo. The gentleman yields back.

I now have the pleasure of recognizing Mr. Hudson from North Carolina for his five minutes of questioning.

Mr. Hudson. Thank you, Chairwoman Eshoo, for holding this important hearing.

I know we all agree that drug prices are too high and that Congress must take action to help our constituents. Since I first came to Congress, I've followed two guiding principles. Any legislation I work on should benefit the people of North Carolina's 8th District, and second, I will work with anyone, Republican or Democrat, to get a good policy across the finish line.

The legislation we are considering today is extremely partisan, though, and it holds no chance of becoming law. It threatens the golden age of innovation and the access to new breakthrough therapies we've seen in the last 20 years.

Our constituents don't care which party had which idea. They just want relief at the pharmacy counter. When there are serious bipartisan options on the table that would save our constituents money and preserve the overwhelming greater access we enjoy in our health care system, why are we considering legislation that threatens to undo the very real positive in our health care system?

My main focus in this debate is to save constituents

money, to protect access to lifesaving cures, and to promote innovation in the rare disease space.

So, Dr. Ippolito, I have a few questions for you, if you don't mind. I recently read reports in the Mirror and Black Pool Gazette about the U.K. denying coverage of a drug for Batten disease, a rare childhood illness.

According to the reports, two children with the disease died waiting for treatment while the drug was undergoing a quote, unquote, "cost effectiveness review" by the government.

Is the U.K. one of the countries that would be referenced under H.R. 3?

Mr. Ippolito. Yes, it is directly referenced and then it's also -- secondarily it's referenced by a bunch of the other countries in the basket as well.

Mr. Hudson. I appreciate that. In Medicare Part D, most beneficiaries with trouble affording their medications are on complex drugs with big price tags. Would you agree it would be less disruptive to our unmatched access in the U.S. to institute out-of-pocket caps, which many Medicaid Advantage plans use to save beneficiaries money?

Mr. Ippolito. Yes. I mean, I think that's one of the things that there's been a lot of agreement on, especially

when you think about the whole point of insurance.

I mean, the whole point is that you're supposed to avoid these catastrophic financial hits. And so when you look at the Medicare Part D benefit design right now, aside from -- there's all sorts of incentive problems the Part D benefit redesign that's in this bill helps to improve but there's this other just completely unforgivable element, which is it's not really insurance if there's no -- if there's no cap on what you can spend.

And so I think it makes total sense as a future as a redesign of the program.

Mr. Hudson. Thank you. Do you believe H.R. 3 will push manufacturers to address diseases with unmet needs or, rather, towards lower cost follow-on products?

Mr. Ippolito. See, this is one of the interesting questions, I think -- what kind of compensation of drugs would we get under this system.

And so the way I think about it anyway is, well, what drugs would be liable or which ones would be eligible for negotiation and which wouldn't, and the answer is single-source drugs.

And so, in general, that's kind of an interesting decision because we have a policy that literally makes drugs

single source by, you know, legislation. And so it's a little bit odd to sort of focus on those.

But it's particularly concerning if you're a -- you treat a smaller population because you are going to face fewer competitors in the near to mid-term. And so what that means is you're going to be eligible for rate regulation for a long time. And so it's entirely possible that a second to market drug could be more profitable than a first to market drug. It's something to really, really consider and you also got to consider things like, you know, the kind of gamesmanship that you may get with you launch a drug but then you also launch an authorized generic so that you're not the only sole source.

So it's a long way of saying that the answer is yeah, I worry about that space but I worry about a lot of this.

Mr. Hudson. Thank you for that.

Some view the biopharmaceutical industry as just taking and marketing innovations developed by NIH. However, the NIH has noted it is the private sector that makes the investments to translate basic science discoveries into potential new drugs.

Clinical trials were the most expensive aspect of the research and development pipeline and just over one in 10

drugs actually make it from clinical trials to patients.

The private sector spent an estimated $97 billion in R&D, three times the total NIH budget. Can we afford to lose or cut that investment as is likely under this legislation?

Mr. Ippolito. I would prefer not. But it's also important to me -- you bring up the NIH. The NIH does good work. I mean, they fund real science that matters.

But it's important to understand what problem they're solving, which is they're solving a public goods problem in sort of economic parlance, which is there's a bunch of facts about, like, the human body that you cannot patent. You can't have intellectual property protection over those.

And so we worry that if we just left it up to the market we'd get too little innovation in the basic science and so that's what the NIH is really good at. It's filling in that basic science first level about things that we need to know about the human body and then it's private sector that comes in and some academics and things where they come in and say, okay, well, what can we use that information to actually do now, and that's the key.

Mr. Hudson. Thank you, Madam Chair. My time has expired. I yield back.

Ms. Eshoo. The gentleman yields back.

It is a pleasure to recognize the gentlewoman from Delaware, Ms. Blunt Rochester, for her five minutes of questions.

Ms. Blunt Rochester. Thank you, Madam Chairwoman and Ranking Member Burgess, for the recognition and for the hearing, and also to the witnesses for joining us today.

Whether it's shopping in the grocery store or taking a tour of a small business in Delaware or even a constituent who approached me, like you, Dr. Fowler, who was in need of lifesaving cancer drugs but she can't afford them, this is the number-one issue that I hear about in my state.

It is just the number-one, whether it is the cost of health care in addition or more specifically the cost of prescription drugs.

And so today, we really have an opportunity to take critical steps towards lowering drug costs in a way that patients will feel directly. I mean, they will feel it in their pocketbooks.

And I would like to start by focusing on a concerning trend that's impacting low to middle income seniors who don't qualify for federal subsidies that help with drug costs.

According to USC's Schaeffer Center for Health Policy and Economics, from 2007 to 2015 the share of beneficiaries

with high drug spending who do not qualify for low-income subsidy, or LIS assistance, and reach the catastrophic phase of their prescription coverage increased from 18 to 28 percent.

Dr. Anderson, what beneficiaries typically have reached catastrophic -- the catastrophic phase of their drug coverage and are faced with continued costs?

Mr. Anderson. So when the legislation passed back in 2003, it was people that had multiple chronic conditions who were taking a lot of drugs. What's changed over the last 10 or 15 years is it's now one drug that costs $30,000, $50,000, $500,000. That puts you immediately into the catastrophic cap.

So we have a new set of drugs that we didn't have when the legislation was passed.

Ms. Blunt Rochester. You anticipated my next question, which is why do you think that number has increased from 18 percent to 28 percent, and I don't know if there's more that you want to share about the why.

Mr. Anderson. No. I mean, it is essentially that we now have new drugs that we didn't have before, which is a very good thing.

But when Medicare pays 80 percent of the cost and they

can't negotiate, then it doesn't matter how much of the cost that you can charge. Three hundred thousand, $400,000, $500,000 and Medicare is going to pay for it.

Ms. Blunt Rochester. And according to the Kaiser Family Foundation, in 2017, 1 million Medicare Part D enrollees had out-of-pocket spending above the catastrophic threshold with average annual out-of-pocket costs exceeding $3,200, over six times the average for all non-LIS enrollees.

Furthermore, Part D enrollees with a high out-of-pocket costs but now LIS assistance would have saved a collective $1.4 billion if Medicare Part D had a hard cap on out-of-pocket spending.

Dr. Anderson, there are disagreements about where to place the out-of-pocket cap. Do you think a $2,000 cap would be a significant help to many beneficiaries, and why?

Mr. Anderson. So if I am on -- just on Social Security I am going to get about $20,000, maybe $22,000. So $3,000 versus $2,000, that's really money to me. That's one month of Social Security. I care that I get an extra $1,000 and have it to spend on other things that I want to do.

So I think going from $3,000 to $2,000 is very important.

Ms. Blunt Rochester. Thank you.

And USC also found that the average total per person spending has grown more rapidly for non-LIS beneficiaries who reach catastrophic coverage compared to beneficiaries who received LIS subsidies.

This spending growth was primarily because of the difference in the price and utilization of cancer and mental health drugs.

Dr. Anderson, how can this multi-pronged approach taken in H.R. 3 address the cost of prescription drugs in a way that just capping out-of-pocket costs can't do alone?

Mr. Anderson. So the first thing you got to recognize is that many of these drugs are more expensive because they keep raising the price.

So putting something into the legislation that says you're going to cap the price increase at inflation or something like that is absolutely important because many of these very expensive drugs were not very expensive five or 10 years ago and they've become expensive because of increasing prices.

So that is a very critical thing that we haven't talked about very much today.

Ms. Blunt Rochester. Thank you. My time is about to expire. But I did, again, want to thank you so much for your

testimony. I, too, come from a state that believes in innovation and know that innovation is important.

But I also know that we can't price these drugs like we do a car. This is about people's lives. And so I thank you so much for your testimony. I thank you for this important hearing, Madam Chairwoman.

Ms. Eshoo. The gentlewoman completes her questioning.

We are going to recess now. We have, what, two votes? Two votes on the floor and we will return on the heels of our voting on those two votes and continue with the members that haven't questioned yet as well as those that are waiving onto the committee and would like to ask questions.

So we'll stand in recess.

[Recess.]

Ms. Eshoo. The committee is now back in session and we will now recognize the gentleman from Montana, Mr. Gianforte, for five minutes of his questions. Thank you for your patience, too.

Mr. Gianforte. Thank you, Madam Chair. Thank you to the panel for being here today.

The costs of prescription drugs are too high and Montanans are struggling to pay for the medications that they need. Republicans and Democrats on this committee have been

working together across party lines to bring down the cost of prescription drugs with increased transparency, better access to generics, increased permitting of biosimilars.

We've worked on and passed these bills that will save billions of dollars in drugs for patients. We've voted to remove barriers to generic drugs and stop pharmaceutical companies from gaming the system and preventing competition.

Unfortunately, our bipartisan work on drug prices is too often hijacked and politicized by House leadership. The Pelosi drug plan is no different. It was written behind closed doors. It's an end run around our bipartisan work.

Speaker Pelosi continues to put politics above bipartisan progress to bring down prescription drug prices. Her plan would have devastating consequences for patients. It would lead to rationing of lifesaving medication, big government price fixing, and government bureaucrats between you and your medication.

Speaker Pelosi could have joined our bipartisan efforts to bring down prices for patients and create more transparency in the system. Instead, she bypassed this committee, ignored our bipartisan work, and chose to put out a socialist plan that won't even get a vote in the Senate.

This is not a pragmatic approach and the American people

deserve better than this.

Dr. Ippolito, Montana is a graying state. In fact, a quarter of our state's population will be older than 65 by 2030. This is far faster than the national average. It's also estimated that in Montana rates of Alzheimer's will increase by 35 percent by 2030, and nationwide the disease will cost more than $1 trillion by 2050 if we don't get a new treatment.

We have all known or loved someone with this devastating disease and seen its impacts firsthand. Cures for Alzheimer's and other diseases will be critical for our seniors and for health of my state's economy.

The Pelosi plan establishes an exorbitant excise tax or, rather, price control of up to 95 percent of the gross sales of a drug if a manufacturer does not negotiate or fails to reach an agreement on price.

Could you explain what is the economic signal that this bill sends about the seriousness of our nation in dealing with these devastating costs that are going to be coming as our population ages?

Mr. Ippolito. Sure. So, I mean, the decision that any drug investment -- somebody making a drug investment is going to have to make is a simple one. You're going to have to

make a prediction of what are my expected profits, right.

As much as I would like to think that everyone's doing things just for the good of other people, we have to be a little bit more realistic. And so you have to make some prediction about how much am I going to be able to sell this drug for and what are my costs going to be.

And as I look at this particular plan, I see a very challenging -- a very challenging calculus, in particular, because when you make that prediction you're going to know that, well, we certainly know the maximum the price can be, at least in concept. But we need to then say, well, geez, how much lower is that is it really going to be. And as I've tried to emphasize with my written testimony and oral, there's a lot of uncertainty that goes into that and I feel there's going to be a tremendous amount of political pressure to really emphasize short-term -- short-term gains, which are good. You know, everyone likes paying less. But they do come at the expense of long-term benefits as well -- long-term costs, I should say. You know, you can almost make an analogy to we often have trouble with the national debt because there's an emphasis everybody wants to spend now and nobody ever wants to be the person really putting a cap on spending.

Mr. Gianforte. It has been said that capital is a coward and it tends to flee risk. I think that's part of the problem with this approach to price controls.

The Pelosi plan would also mirror a socialized foreign health care system with price controls for the U.S. Despite research that shows that price controls suppress innovation and impede patient access to new medicines, are you worried like I am that only one in 10 drugs ever get approved by the FDA and that we've seen more and more companies getting out of the Alzheimer's space after high-profile costly clinical trial failures? Shouldn't we be concerned that we are going to tax this industry about of existence?

Mr. Ippolito. Yes. I mean, I think this is -- this is the number-one long-term question that we have to think through. How much are we willing to incentivize. I think, you know, I don't want to spend the entire GDP on drugs and I doubt anybody else does. I like schools and roads and things of that nature, too.

But as you note, there's tremendous value to some of these cures and that's part of what I worry when I look at this bill is we are identifying drugs that are really successful.

You can be successful for a lot of reasons. It could be

that you're totally taking advantage of loopholes in the system, and I -- you know, I think I am with anybody there where I say, yes, let's close those down. Let's get rid of this delaying tactics, you know, when we should be having generics and so on.

But, boy, do we really want to signal these really valuable drugs and make them the most exposed -- that is, these brand name drugs that are really successful? You know, I worry a little bit and the Alzheimer's example is exactly the kind of example that I would worry about.

Mr. Gianforte. Okay. Well, I just -- Madam Chair, I would just submit to you that we agree on the objective. We need lower drug prices. I would like to see American ingenuity continue to be plied against these diseases that are going to be so costly and so detrimental to families.

And with that, I yield back.

Ms. Eshoo. The gentleman yields back.

Now I am pleased to recognize the gentleman from California, Mr. Cardenas, for five minutes of his questions.

Mr. Cardenas. Thank you very much. It's unfortunate that we are discussing such an important topic and I think I just heard the Fox News description of the legislation we are contemplating today the Pelosi plan, just like what happened

with the Affordable Care Act. All of a sudden, it became Obamacare.

And even though many Americans have benefited tremendously from it, they actually polled people and said, are you for Obamacare and they said no. Then they said are you for the Affordable Care Act -- same person, different question -- are you for the Affordable Care Act and they said yes, once they started receiving that care.

So, hopefully, we can get through this legislation with the least amount of politics and focus on the issue at hand. The issue at hand is that I don't think there's a person who has run for Congress, successful or not -- I think the people up here have been successful, I assume -- who hasn't told their American constituents, would you like me to lower drug pricing -- would you like to see that happen, and everybody probably cheers them on and says yes and then, ultimately, we get voted for and here we are with the opportunity to actually discuss and, hopefully, pass legislation that hits the mark and does it well.

Thank you, Doctor, Doctor, Doctor for being here and giving us your expertise and your perspectives on what we are trying to do here.

First, I would like to ask a question of Dr. Fowler.

You transitioned from private insurance to Medicare, correct?

Mr. Fowler. Yes.

Mr. Cardenas. Can you give me either something you choose, positive or negative, that you have experienced in that transition that you either continue to benefit from slightly or maybe in a more positive way and maybe something that perhaps you haven't when it comes to prescription drug pricing?

Mr. Fowler. Oh, my. Just very briefly, being under the insurance policy of my university was so simple and easy, transparent. When my wife and I realized we needed to take the plunge into Medicare it was -- the complications of the whole system were just so incredibly baffling.

We have a wonderful person who walked us through everything. In Ohio, we call it the OSHIIP program, the state -- housed in Columbus, and this wonderful person walked us through all the Medicare options in two three-hour sessions and we finally made our decisions.

And, of course, everything was complicated because I had this super drug at a super cost. So there's that. But and then the shift in the cost. Once upon a time, I paid almost nothing for co-pays for this super drug and now it looks like it's going to cost me $12,500 a year for my Revlimid. So --

Mr. Cardenas. But the drug itself did it cost Medicare and/or your private insurer a similar amount, I mean, on the same day.

Mr. Fowler. I am not sure I understand the question.

Mr. Cardenas. What I am getting at is we are talking about prescription drug pricing and they only give me so many minutes and I just wanted to know if, when it comes to the price of the drug that somebody was paying for that price, whether it was the insurance and then passing a portion of that onto you or not. You had the benefit of that drug coming to your ability to use it. At the end of the day, Medicare is still providing you that opportunity to take that drug.

Mr. Fowler. Yes. Yes.

Mr. Cardenas. Okay. In the interests of time, I would like to reiterate what the chairwoman pointed out earlier.

Mr. Ippolito, you mentioned something about gout, which is an interesting example, and then the chairwoman pulled out what seems to be a fact -- I don't doubt her -- that NIH has not provided funding for research for gout. Yet, when you mentioned malaria, Mr. Ippolito, she mentioned that NIH is in fact -- has, in fact -- provided funding for research on malaria, thank God, which I think was an excellent example of

should we as the -- an incredible nation should we be in the business of trying to be assistive with solutions to make lives better, healthier, and provide opportunities for innovation.

And I think that one of the things that's interesting that actually has been criticized already in this committee is that some of the money actually goes to NIH instead of going back into the ecosystem, perhaps back into the insurers' pockets for having paid that original price for those prescription drugs and/or perhaps a portion of that going back to the consumer. I think that I have tremendous confidence that by the time this is done, this legislation, hopefully, will have shaped it in a way that people have the confidence that they should have that we do need to reduce prescription drug pricing in America and we do need to pay attention to the fact that sometimes the United States can learn from other countries and actually do something a little bit better than we have.

I am sorry I am out of time. I yield back.

Ms. Eshoo. The gentleman yields back.

A pleasure to recognize the gentleman from Florida, Mr. Bilirakis, for his five minutes of questioning.

Mr. Bilirakis. Thank you, Madam Chair, and thank you

for holding this hearing. I really thank the witnesses for being here and their patience.

But, Madam Chair, what I want to do, first of all, I am the co-chair of the Rare Disease Caucus, and lowering prescription drug prices and increasing patient choice without impeding research and development of breakthrough cures and treatments is very important to me. Obviously, it's important to everyone. We all agree on that.

Mr. Ippolito, I have some prepared questions. But let me ask you this. What is your position -- I know what your position is on H.R. 3 but how can we lower prescription drug prices? Is it through competition? If you can give me a statement on that I would appreciate it. How would you do it if you were in our position?

Mr. Ippolito. Well, I think I would focus primarily on the incentives that people making the drugs have, namely, what kind of pricing incentives do they have and then what kind of research and development incentives do they have.

And so when I look at exactly what you guys are talking about in terms of reforming the Part D benefit design, I see a very good combination, at least in concept -- there's details to be hashed out -- in concept there's a really good reform there where we say we are no longer going to engage in

this behavior where we have this terrible benefit design where these really high list price that Gerry was talking about in large part or at least in part can be -- can be traced back to this incentive that's in this benefit, which is jack up your list price as high as you possibly can so that you can offload all this cost onto the federal government, and patients are stuck there paying these massive out-of-pocket costs.

And so when I look at that benefit redesign, I see a really nice shift towards a much more sustainable program. I see much better incentives facing insurers who have to care a lot more about the costs of the drugs that they're providing, and we are now knocking down this idea that we are just going to get away with high prices not because we have some great value that we are proposing but because it's a way to take advantage of a benefit design.

So I think I would look at the incentives that are facing the market actors here and I think the Part D redesign is a really good example of that.

Mr. Bilirakis. Very good. Thank you.

Okay. Now to H.R. 3, and I know that the -- I am just following up on what the members -- some of the members have asked and I will give you some more time.

Do the economic incentives in H.R. 3 signal to manufacturers to invest in rare diseases or lower cost follow-on products?

Mr. Ippolito. Yes. So this is a very -- this is a good question. The composition of drugs -- we don't just care about how many drugs or how much money was spent on research. We care about what we get out of it.

So we care about the composition of drugs and what kind of treatments are we getting. And so one of the things that you do need to think about is how are different drugs going to be affected differently under this proposal.

And so one of the things that I would certainly emphasize is that this price setting arrangement would only apply to single-source drugs -- only apply to drugs that do not have competition.

Drugs that are less likely to have competition tend to be drugs with smaller market share -- excuse me, market sizes. And so if you are particularly concerned about rare diseases, that is something that I would emphasize that it's -- if you expect it's going to be a longer time before you get that second entrant, well, then you're going to be eligible for this rate restriction for a very long time. So it may actually depress the incentives there particularly.

Mr. Bilirakis. Thank you for your input.

Again, the Commerce Department found that the price controls in foreign countries already suppress worldwide private research and development investment by 11 to 16 percent annually, leading to fewer new medicines launched each year.

Under this price control plan -- H.R. 3 -- would the U.S. remain the leader in biomedical R&D? If not, which countries would take the lead in biopharmaceutical research, in your opinion?

Mr. Ippolito. So there's two things. There's where is this kind of research and investment taking place and then there is which market is it aimed at.

So right now, there is a good and bad thing, which is that we are the biggest market for pharmaceuticals in the world, period. I believe IQVIA puts us at spending about the same amount as the rest of the top 10 spending countries in total.

So we are likely going to still be a large spender in terms of pharmaceuticals. But it is entirely possible, as we have other large countries like China and India becoming wealthier and so on, that they become more of the target markets for these kinds of things or perhaps the EU as their

policies evolve.

Mr. Bilirakis. Thank you very much.

And Madam Chair, under your leadership -- your capable leadership -- you know, we've already proven it this year, early this year, we can come up with a good bill and we can all agree on it and, of course, it must pass the Senate. Otherwise, it's not going to do any good.

So, you know, I hope that we make some progress and get something out by the end of the year. So I really appreciate your holding this hearing and I yield back.

Ms. Eshoo. The gentleman yields back. I share your wish and we'll work hard. This is -- this needs to be resolved for the American people. Every single member here knows that.

And now it's a pleasure to recognize the gentleman from Kentucky, Mr. Guthrie, his five minutes.

Mr. Guthrie. Thank you very much. It is great to be here and thanks to the chair for holding this hearing.

Getting on this subcommittee has been one of the blessings of my time in Washington, D.C. It's amazing. I had a person in my office about three days ago or last week who was talking about that they're on the verge of curing sickle cell anemia -- that they can actually reprogram a gene

to go in and replace through -- not a transfusion but a bone marrow transplant in sickle cell anemia, and just an artificial pancreas we can cure hepatitis C with a pill now. It used to be a liver transplant. I mean, all the things that's coming out of the United States, and it's both NIH and it's private research.

And I know one of my friends here was talking earlier about NIH and our support for NIH. That's one thing people ask me in town halls or things -- well, can you all agree on anything in D.C. I say, well, yeah, the stuff you don't see on television. There's a CURES bill with NIH. It's been bipartisan. I think we can all look -- not that we did it but hopefully we created a platform that very smart people focusing on very strong diseases can move forward.

And at the beginning of this Congress I met with -- I met with the ranking member of the O&I of this subcommittee so Oversight and Investigations of this stuff within our jurisdiction and we wanted to make drug pricing our number-one issue. And we talked about it and we said, well, you got really kind of three buckets. One is the EpiPen situation, which Judiciary Committee needs to handle. It is -- I mean, all of us agree that that's bad competition and it should be handled that way.

The second one that we focused on was insulin. It's not a blockbuster drug. It's been around for a hundred years at most but it's gone up from $100 to $300. We've had hearings. We've tried to move forward on legislation with that. That stalled and it's kind of gone to this direction.

And the third thing I said, but as we focus on that what we don't want to do is get in the way of the precision medicine that's coming forward.

Because when you look at -- and it's simple for me and it's simple for a lot of people -- when you talk about drug price and we think of we are going to figure out what -- make a tablet and we'll make a million tablets and sell them. And so we want to figure out what that price should be, and we can -- that's what we need to focus on.

But that's not exactly what's going on today in the research world. It's making that pharmaceutical for that person based on that genome.

And so, Dr. Ippolito, I am really concerned that if we pull the private research out of that, and even though we give it to the National Institutes of Health, do you think the National Institutes of Health alone is going to be a good substitute for what's happening in our -- in our world today?

Mr. Ippolito. So I can only speak to sort of the

current iteration of NIH. I don't know what you might have in mind -- if you gave them a ton more money.

But, in general, it's worth thinking about kind of the role that the NIH fills in this research and development process, which is quite long.

The NIH really helps us overcome what is called the public goods problem, namely, there are a bunch of things that are really, really important for drug development and all sorts of other --

Mr. Guthrie. Like mapping the genome.

Mr. Ippolito. Right, like mapping the genome --

Mr. Guthrie. The brain research that --

Mr. Ippolito. -- which you can't -- you don't get intellectual property protection. That's a fact about the human body, you know.

And so what we worry about is if we just left that up to the private market, well, any given firm is going to be just disincentivized to learn about these things because they can't hold onto it. As soon as they learn it, anybody can try and steal it from them and use it make their own drug.

So what we do is we give the NIH money to try and help us overcome that public goods problem, namely, let's learn some things about the human body, for example, and then let's

let a bunch of firms use that.

So it's the reason why hepatitis C we have a cure and within a couple years the price came down from $90,000 to $20,000 to cure hepatitis C. It's not because it went generic. It's because we learned something about hepatitis C and a bunch of firms went after and tackled the same problem.

And so the NIH is an important part of the current R&D investment infrastructure. It really helps us do something that is hard to do without government intervention.

But it's not really equipped to do the whole process. So unless you have something really drastic in mind for changing what the NIH does, then it seems like there's still half of this puzzle that we still need to have a market for.

Mr. Guthrie. So and I understand some of the things I described are more procedures than pharmaceuticals. But chemotherapy was a procedure. Now it's become a pharmaceutical.

So and it leads to -- matter of fact, I am on a bill trying to figure out how do we treat the oral tablet like a -- like the procedure because of the way the co-pays and things work for people that are going through chemotherapy. And so I don't think we can sell too much short. As we look at this, as we look at price controls in health care and we

are all here trying to get the prices down and try to make them more marketable, and one of the problems is we are the research arm for the world. We pay for the research the world gets and I know I've got a statement here. There's a lady from England, Louise Moorhouse, who has PKU. That has been part of a study but now the National Health Service isn't going to cover her. She went through a study. She changed her life. Now she can't get the study in England because of the limits of price controls in their system.

So that's why, hopefully, a longer legislative process and we need to do it -- can't delay it. We got to do it -- I mean, we can't go on forever. But we need to try to solve the problems. But if we don't do this right we are going to have some unintended consequences and hopefully not lose the miracle research, a lot of it coming out of my good friend's district -- matter of fact, a lot of it coming right out of there and it's just fantastic. And you see it every day what's happening and I appreciate it.

And I yield back.

Ms. Eshoo. The gentleman yields back.

It's a pleasure to recognize Mr. Flores from Texas for his five minutes of questions, and thank you for your patience.

Mr. Flores. Yes, ma'am. Thank you, Chairman, and thank the panel for putting up with us. I mean, you have been here for an incredibly long session. I would like to continue the discussion that Mr. Gianforte and Mr. Bilirakis started about what happens with our ability to continue being the most innovative pharmaceutical market in the world.

Because under the Pelosi plan -- it is the Pelosi plan. It's not this committee's plan. It's the Pelosi plan. Under that, there is a provision to negotiate prices. I think some of us maybe could find a way to get comfortable with negotiating prices. But it's got to be done in a way that's fair. Not the way the VA does where veterans don't have access to 48 percent of the pharmaceuticals that the rest of the country has. Not in an environment where you have a 65 percent to 95 percent excise tax.

So, Dr. Ippolito, what would a 65 -- I think you have already answered the question -- a 65 to 95 percent excise tax would drive innovation to other markets? Is that still your position?

Mr. Ippolito. Yes. I think there's no question. If the penalty is 65 to 95 percent of your gross revenue, which is going to be more than in the -- once you get to 95 percent it's going to be more than all of your net revenue.

Mr. Flores. Right. So if you're -- whether you're a large pharmaceutical company or you're a couple of folks in a garage that found a new way to treat a serious disease, and you have gone to -- you go either to your investment committee and the big pharmaceutical company or you go to your venture capital or private equity community as the small folks who are funding, they're going to say, yeah, fine -- we'll do it but don't develop the IP in the United States. Develop it somewhere else.

And I think that if you look at the countries that really made a focused effort to try to develop IP when it comes to pharmaceuticals it's China and India. And so that raises a whole new issue.

I mean, would you support that thesis that the IP is going to be developed somewhere else?

Mr. Ippolito. So I guess I don't know as much about literally the legal ramifications of where exactly it's developed. But there's no question that, you know, you emphasized the small biotechs. That's really where this kind of uncertainty over pricing --

Mr. Flores. Exactly.

Mr. Ippolito. -- and what is going to happen is going to really be felt.

Mr. Flores. Because their funding source is going to demand that they go somewhere else.

Mr. Ippolito. Their funding sources are quite mobile.

Mr. Flores. And as a person who used to be funded by private equity, I know that they always go to the place that's going to provide the least risk and the highest return.

And so since we are talking about the fact that it could wind up in China or India, let's talk about China and drug safety there for a minute.

Eighty percent of the ingredients in U.S. branded pharmaceuticals come from China today because they've made an overt effort to invest in this space and to drive U.S. manufacturers out of business.

And so I've got several examples, two of which affect me personally. The first example is Heparin, which doesn't affect me personally, but we know that we had 81 deaths from that in 2007-2008.

Then a couple that affected me personally and for hypertension, Losartan, it was recalled because it had NMBA in it, which is a carcinogen. And I think that one of the things that that's used in is rocket fuel.

Then so the replacement drug was Valsartan, and then it

got recalled later because it was contaminated with NBMA. And so if you think about the impact that we could -- that bad policy on pricing could have in terms of the safety of health care for Americans it's pretty profound.

So with that, Madam Chair, I would ask unanimous consent to enter a few articles into the record.

The first is from the South China Morning Post dated July 18th of 2018. It says, "Chinese blood pressure pills sold in the U.S. recalled over cancer-linked ingredient." The next one is August 14th, 2018 from NBC News, says "FDA Recalls: A Reminder that China Controls Much of the World's Drug Supply."

And one of the lines in here about this says because they are toxic to the DNA you have to control them.

The next one is from WebMD dated November 19th, 2018, and it talks about the challenges American drug companies have because their sources -- their drugs are coming from overseas.

Another one dated January 14th, 2019, from USA Today, "Blood Pressure Drug Recall: FDA Investigates Foreign Plants that Made Drugs with Cancer-Causing Impurities."

Then the next one is from Bloomberg dated January 30th, 2019, said "How a Tainted Heart Drug Made in China Slipped

Past the FDA."

The last one -- excuse me, the next one is from NBC News dated September 30th -- excuse me, September 23rd, just a few days ago -- "FDA Explains Blood Pressure Drug Recall Again."

And the last one is also dated the same day, September 23rd, 2019, from CBS News, "More Blood Pressure Pills Recalled Over Cancer-Causing Chemical."

Everybody on this committee needs to know that we can't do anything that drives innovation to another country like China that could cause us to have a tainted drug supply or that, as one of these articles talks about, pharmaceuticals from China could be used as the next weapon against us if it's all produced there.

Thank you. I yield back.

Ms. Eshoo. The gentleman yields back, and so ordered. All of those articles will be made part of the record of our hearing.

[The information follows:]

**********COMMITTEE INSERT**********

Ms. Eshoo. And two, just very briefly to the gentleman's comments, I think that as we are examining this issue today as large as it is, as impactful, as important, as critical as it is, I really think that our Health Subcommittee needs to do a lot more work relative to America's drug supply.

We have shortages. We have tainted products. We have to bring the FDA in. I think you all saw -- I sent to you the op-ed that Congressman Schiff and I did that the Washington Post had published, and I think it's a national security issue as well.

So we are going to have a joint hearing on that. But our subcommittee has a lot of work to do and I am very pleased that you brought those articles to place them in the record.

We appreciate it, Mr. Flores.

Mr. Flores. Madam Chair, if I may --

Ms. Eshoo. Yes. Sure.

Mr. Flores. -- with your forbearance, thank you. I look forward to that and thank you for letting me waive on today. I hope to waive on when we get into that particular issue.

Ms. Eshoo. Wonderful.

Mr. Flores. Thank you.

Ms. Eshoo. You're always welcome here.

Now, to recognize not the last -- what do they say, the first shall be last? Last but not least.

The gentleman from New York, Mr. Engel, for five minutes of questioning.

Mr. Engel. Thank you, Madam Chair. I have a statement I am going to make and I hope we can get to the questions at the end. If not --

Ms. Eshoo. Why don't you -- do you want to put your statement in the record and ask your questions?

Mr. Engel. Well, I will --

Ms. Eshoo. So that you have time? Because you have waited all day.

Mr. Engel. Let me -- yes. Let me -- let me --

Ms. Eshoo. Whatever you wish.

Mr. Engel. Thank you. Thank you, Madam Chair, for holding today's important hearing on proposals to -- would allow the federal government to negotiate drug prices and bring relief to our constituents.

I am always shocked and I was here at the beginning -- and disappointed to know that other countries pay far less for the same medications than we do.

A recent study of 10 other high-income countries found that, on average, they spend only 56 percent of what we pay for the exact same drugs, and unlike our broken drug-pricing system, these countries negotiate their drug prices.

So I am pleased to see that we are considering the Medicare prescription drug price negotiation act from Congressman Welch, which would repeal the noninterference clause enacted by the 2003 Prescription Drug Improvement and Modernization Act.

This horrendous 2003 law which I voted against prevents Medicare from using its purchasing power to lower the cost of life-saving drugs such as insulin, and Congressman Welch's bill would go a long way in righting this wrong.

I want to also thank Speaker Pelosi and Chairman Pallone for their leadership in crafting the Lower Prescription Drug Costs Now Act, which I am pleased to co-sponsor.

This comprehensive legislation delivers on our promise to the American people to lower prescription drug prices by allowing the federal government to negotiate, eliminating price gouging and capping out-of-pocket costs.

I look forward to helping move this legislation to the House floor, and while we work on these bills we should also continue our work on legislation that addresses the other

factors of rising drug prices.

This past August, I introduced the REFUND Act, which would protect Medicare beneficiaries from wasteful spending on excessively large single-use drug vials. This common sense legislation would enable seniors and the Medicare program to recoup money wasted on these oversized vials.

Earlier this month, Congressman Guthrie and I led 90 of our House colleagues on a bipartisan letter to the FDA on drug shortages, which can increase the cost of vital drugs in some cases.

And last week, Congressman Larry Bucshon and I introduced the bipartisan bicameral Advancing Education in Biosimilars Act. This legislation would create federal programs to promote the use of biosimilar drugs, which are generic versions of high-prices biologics.

Our constituents are demanding action on high drug prices and I am honored to serve on this committee where our chairwoman, Anna Eshoo, does such a great job which is leading the effort so far to fix the epidemic of price gouging.

So let me ask Mr. Anderson this. The 2003 Prescription Drug Improvement Modernization Act created Medicare Part D. Again, I voted against it, and it provides inadequate drug

coverage for seniors.

Currently, 60,000 of my constituents are enrolled in Part D plans and my constituents, especially those with chronic conditions such as diabetes, frequently tell me that Part D coverage is too expensive.

In 2019, seniors in my district will have to spend upwards of $5,100 before they receive some relief from a so-called catastrophic phase of the Part D benefit.

As we all know, many seniors have fixed incomes with the majority of seniors living with incomes below $26,200.

But, Dr. Anderson, you note in your written testimony that Medicare Part D was designed on budget constraints instead of sound insurance principles.

It's my understanding that H.R. 3 would reform this benefit. So how would the Lower Drug Costs Now Act address rising out-of-pocket costs for seniors with Medicare Part D coverage in a district like mine?

Mr. Anderson. Well, in yours and probably everyone else's basically, Mr. Fowler -- Dr. Fowler has talked of how the fact that his drug benefit was quite good when he was employed by the university and not very good when he was employed and he's under Medicare.

And the reason is he didn't have to pay very much when

he was under the university. He has to pay a significant amount. He says $12,000. You say $5,000 in your district, on average.

That's a huge amount of money for somebody who's on Social Security and that's all their income. Five thousand dollars is probably two months out of 12 of their total income.

They don't have that amount of money. So limiting it to $2,000 is still a lot of money. It's probably one month of their Social Security income. But it's way better than two, two and a half months of their Social Security income.

So I think this is a very important change.

Mr. Engel. Thank you.

Dr. Fowler, I know you have talked about the financial hardships. Can you describe the financial hardships and emotional toll that Revlimid's price increases have placed on you and your family?

This drug costs four times more in the U.S. than the United Kingdom. It's outrageous.

Mr. Fowler. So you're asking me about the -- what the trauma of dealing --

Mr. Engel. What an average family goes through with this.

Mr. Fowler. Excuse me?

Mr. Engel. What an average family that gets these costs goes through.

Mr. Fowler. I am not sure I am understanding the question. What would an average family -- how would they have to face this? What kind of challenges they would deal with?

I am not sure I am an average family so --

Mr. Engel. Okay.

Mr. Fowler. -- I am fortunate to have had good coverage as an employed person and I think we are going to be okay on Medicare. But I am very nervous about it because the out-of-pocket price under Medicare is so significant and that, on top of the medical issues of facing my disease, altogether the package is very daunting.

Mr. Engel. Thank you. Thank you, Madam Chair.

Ms. Eshoo. I thank the gentleman.

And he -- let's see, is Mr. -- yes, Mr. Walberg of Michigan is welcome to the subcommittee and recognized for five minutes of questions.

Mr. Walberg. Thank you, Madam Chair. I appreciate that and appreciate the panel for being here. It's an important subject that we ought to be dealing with and spending a lot

of time on dealing with it.

Mr. Ippolito, thank you for being here. You have made it clear that the risk associated with bringing a drug to market is rather large and if you don't have a chance of getting your investment back it's really going to discourage some of that.

Can you explain along that line that to lower costs in the current prescription drug market we need more of what works -- competition and market innovation -- and less of what doesn't, meaning more bureaucracy and Washington interference?

Mr. Ippolito. Well, I think there's a number of ways to lower drug prices and, indeed, there are a number of ways where we can harness competition.

I think one of the things that I know this committee has worked on but some others have is we have a regulatory framework for drugs. We have -- we give exclusivity and then we have this exclusivity period end. Then we have competition come in and we drive prices down.

And one of the things that I think a lot of folks have mentioned in this discussion is that that might not be working quite as well as it's designed to work.

And so one of the things that Congress can do is work to

make it so that patent thickets or so-called REMS abuse, which is in the CREATES Act, and other sort of ever greening style tactics aren't as successful at delaying the competition that we are supposed to be getting after these exclusivity periods.

So I do think there are ways. Even if we just look at our current framework, we can just focus on making it better as a step one and then kind of go from there.

Mr. Walberg. Okay. Takes some of the impingements out of the way.

It's my understanding as well that the industry provides a source of funding for research at universities and academic medical centers like those in my state, University of Michigan, and other places, and that these collaborative efforts are often focused on the nation's most scientific and technological health challenges.

Mr. Ippolito, what would be the impact of this plan on universities and academic research centers?

Mr. Ippolito. Yes, there is no question. I mean, the industry -- the industry does -- it's sort of funny. I think a lot of folks think of there being this very hard wall between the pharmaceutical industry and academic research and so on.

But there really isn't. They do fund and they do engage in a lot of collaborative efforts. You know, a number of my -- the colleagues that I work with when they were -- when they were grad students or post-docs were funded by industry resources.

So there's no question that there's some benefit from that. It's not the only source of the way that they fund research and it's not the only way that universities are funded.

But there's no question that there is positive benefit.

Mr. Walberg. But making it more difficult would make it more difficult as well to fund programs that in fact helped your colleagues?

Mr. Ippolito. Sure. Yeah. No, I like them having jobs so on a personal level --

[Laughter.]

Mr. Walberg. And the impact -- and the impact that they had, going forward, for the drugs as well.

Brand name drugs pay numerous discounts and rebates across many channels. Is it fair to contrast the pricing of drugs in a single federal program to that in a whole nation or basket of nations.

And secondarily, would it not be more appropriate to

consider the aggregate cost to net price for a drug?

Mr. Ippolito?

Mr. Ippolito. Yes. So this gets at -- this is kind of in the weeds but, I mean, this is actually a really big deal when you talk about drugs -- what is the price.

That's a surprisingly hard question to answer, and yeah, so drugs, when they leave the factory they have a price and it's basically the list price and it's like the MSRP on an item of clothing or a car.

The only problem is it doesn't actually represent the transaction price of almost anywhere in the supply chain except for sometimes a patient's out-of-pocket costs are based on that number.

And so what you get is this extremely complicated pricing environment. So in my written testimony I included just to show in 2019, for example, branded drugs, the amount that the manufacturer actually gets paid ranges anywhere from 5 percent to 95 percent of the list price of the drug.

And so when you think about trying to do this on an international scale and understand what exactly they pay, I think that's actually going to be extremely difficult -- just empirical challenge whether or not you think it's a great idea.

So I do urge some caution when you go down that route.

Mr. Walberg. Okay. And finally, wouldn't an inflation penalty as envisioned in H.R. 3 merely incentivize manufacturers to charge high introductory prices?

Mr. Ippolito. Certainly if there's no restriction on the launch price there is no question that you would try to. Manufacturers launch at a low price, try and get a lot of market share, and then they increase their price over time.

To the extent that you are not allowed to increase your price over time, of course, there's going to be attention to try and retilt the pricing schedule -- that is, increase your launch price. Exactly how much they're going to do that is up for debate. But I don't think the direction there is any debate.

Mr. Walberg. Thank you. I yield back.

Ms. Eshoo. The gentleman yields back. It's called whack-a-mole.

[Laughter.]

Ms. Eshoo. I remember that word.

Now, I am pleased to recognize the gentleman from Ohio, and he really is a gentleman, Mr. Latta, for his five minutes.

Mr. Latta. Well, thank you very much, Madam Chairman,

and I want to thank you very much for allowing me to waive on to today's very important subcommittee's hearing. I really appreciate it.

And I also want to thank our witnesses for being with us today.

This is an issue all about the patient. It's about my constituent, who is seeking a lifesaving medication or picking up a blood pressure prescription at the local pharmacy.

I want to see prescription drug prices go down just as much as the rest of America, and I've repeatedly voted for measures that aim to do just that.

However, H.R. 3 isn't that answer. Under the Pelosi plan, you know, this went against the bipartisan nature of this committee, which has a history of working together and delivering solutions.

I encourage the same partnership to help our constituents by focusing on bipartisan legislation that will reduce drug costs in patients and ensure patient access to current and future medical treatments.

If I could star with you, Mr. Ippolito. In 2018, the FDA approved an advanced medicine for treating migraines, saying it gave patients a novel option for reducing the

number of days with migraine for this painful and also debilitating condition.

Yet, more than a year later this treatment still is not available in three of the countries that are referenced in H.R. 3 being Australia, France, and Japan.

And could you explain why this might be the case? And, you know, just talking about migraines, when I was a kid I had migraines. And so I understand what people go through. Back when I was a kid you just -- you didn't have anything -- you know, you just hoped -- take an aspirin, that was it.

However, I met someone -- it hasn't been too long ago, that has a persistent migraine 24 hours a day. So I am not sure how the person functions, because I know what a migraine is.

But could you explain why, when you look at Australia, France and Japan, why this might be the case that these would not be available in those three countries?

Mr. Ippolito. Sure. I don't know the exact reason for the specific drug that you're talking about but there are a couple candidates.

So the first is that at least some of the referenced countries that we are talking about use various forms of negotiations, cost effectiveness analysis or what have you.

That takes time. That is, they need to make a decision about whether a drug is worth covering or not. That doesn't happen instantaneously. And so it is often the case that the United States tends to be on the leading edge of getting access to medicine relative to some of our international peers.

The second is that even after they go through that process they still have to make a decision about whether or not they're going to offer that drug to be covered under the health plan.

And so the answer could be it's in delay or the answer could be that they concluded their analysis and decided that it's just not worth covering.

Mr. Latta. Let me just follow up with that because, again, I think that's an important point.

If they're not going to cover that drug, what is person's option then? You know, let's just say it's a live saving -- not just maybe a migraine type medication but maybe a lifesaving cancer treatment drug. What's a person's, you know, in one of those countries that will not be covered, what's their option?

Mr. Ippolito. Well, so I suspect it would depend a little bit on the country. But often the way this works is

you would get denied initially or not recommended for coverage, and then you could go back effectively to the negotiating table and they say, we'll accept it if you lower the price, and go through some prolonged negotiation.

You know, these are the kind of -- these are the kind of, even -- I don't want to assign sort of a normative value to any of this -- these are the hard decisions.

If you're going to centralize these decisions, somebody has got to care about costs. EDF to Incentivize low cost or somebody has to draw a line somewhere, and these are the kind of hard decisions that you do have to make if you have it so that it's centralized where, you know, say, it's the National Health Service in the U.K., making a decision about what is and what isn't covered.

Now, the question and what's a little bit different about H.R. 3 on this point is that it's -- in theory we are saying that everything is going to be covered but we are going to come with this, you know, negotiation that, you know, we'll either take your intellectual property or not in H.R. 3 we'll take all our revenue if you don't accept it.

It seems to me that that wouldn't be as much of an issue in H.R. 3. In H.R. 3, I would worry more about not the stuff that already exists. I would worry about that next wave of

stuff that doesn't exist yet. That would be the real concern for me.

Mr. Latta. In my last half minute, let me ask another real quick question, if I may.

Isn't it true that beneficiaries still pay co-insurance on Part B drugs based on the ASP plus 6 percent, so an inflation cap does nothing to reduce beneficiary costs?

Mr. Ippolito. That's a good question. I do need to -- so the way this interacts with Part B I do need to go back and revisit because basically the ASP calculation is a calculation of the average sales price to a whole bunch of payors. And then you have a Plus 6.

And so it depends whether or not that is really going to include this new mandated price from HHS or not and how that gets folded in.

And so I have to plea a little bit of ignorance on the exact answer.

Mr. Latta. Madam Chair, I see my time has expired and thank you again for letting me waive on.

Ms. Eshoo. The gentleman waives back. You're always welcome here at our subcommittee.

And, yes, I would like to ask for unanimous consent to place the following in the record -- the documents for the

record: the statement of support from AARP, statement of support from the AFL-CIO, a statement of support from AFSCME, statement of support from the American Hospital Association, statement of support from America's Health Insurance Plans, sometimes known as AHIP, a statement of support from Families USA, statement of support from Patients for Affordable Drugs Now, statement of support from the Pacific Business Group on Health, statement of support from the Alliance for Retired Americans, a statement of support from the California Medical Association, letter of support from the American Medical Association, a letter of support from the United Auto Workers, a letter from 340B Health, statement from the National Association of Chain Drug Stores. We'll have to tell our colleague, Mr. Carter, that.

A letter from the National Association of Specialty Pharmacy, a letter from the American Society of Health System Pharmacists, a letter from the National Grange, a statement from the Americans for Tax Reform, a statement from the Partnership to Improve Patient Care, a statement from Retire Safe, a statement from Academy of Physicians and Clinical Research, a statement from the Council for Affordable Health Coverage, and a letter from Chairman Elijah Cummings.

So these -- hearing no dissent, those will be placed in

the record. And how do you want me to do this, Doctor? Do want me to take it?

So ordered.

[The information follows:]

**********COMMITTEE INSERT**********

Ms. Eshoo. The gentleman is recognized.

Mr. Walden. Thank you. Thank you, Madam Chair, and thank you, Dr. Burgess, and I appreciate the courtesy.

I just wanted to follow up on earlier comments and thank the chairwoman for her, and I know she's genuine in this because we've worked together on a lot of things, her openness to working with us, and we will set up that appointment ASAP to see where we can find common ground.

And your comments at the beginning of the hearing about regular order and the importance of it, including the markup in subcommittee, which I hope will be fulfilled because I think that's -- I am telling you, we are all in agreement. This is a huge issue we need to address.

We have some differences of opinion on how to get there. We have them at the witness table. We've been blessed with three really bright capable people. They don't even agree.

And so -- and so we want to get it right, Madam Chair. So thanks for agreeing to the subcommittee markup. Thanks for also agreeing to make sure we get the answers to the questions that we pose back before we have to begin voting, and I do hope we can go through a real regular order on this and get to a positive conclusion for consumers out there. And I hope as we are getting this bill evaluated as well,

Madam Chair, that we would get more than just the number for savings to the taxpayers from CBO but also I think we are all committed -- what's it mean for the patient? What's it mean for the mom that's going up the counter? What's it mean to the dad who's going up to the drug counter? Are they going to see savings out of pocket? Because I think that's also our ultimate goal as we reform the modernized Medicare Part D.

So, with that, Madam Chair, thanks for you indulgence and look forward to working with you again, and I will yield back.

Ms. Eshoo. I thank the gentleman, my friend.

And I will do my utmost so that we have a process here that is a solid one, the way it should be done. That doesn't mean that everyone is going to agree with everyone. We may just end up having some differences, and we need to respect that with one another.

But in coming out of the gate, I have -- I am more than comfortable making these commitments because I think that regular order is exactly what it is. There should be a regularity to it and that we move in a way where we are respectful of one another.

H.R. 3 is written for patients. It's written for

patients. And I think it was Mr. Sarbanes said, you know, when you count the number of members of the committee each one of us representing 750,000 people, they all care about this.

So we have our work cut out for us. I can -- I see where the different fissures are and but that doesn't mean that we can't stretch ourselves to see if we can come together on -- because we all care about it.

So with that, I don't anything else to add to the record. You have already inserted your records, and all of our thanks to the three of you. You have been here for a long time. 10:30, let's see, that's a long time. Three, four, four and a half hours.

But know that your testimony has mattered to members. I think there have really been probing excellent questions from all of my colleagues on the subcommittee.

And I think that you have helped us to understand things in a broader deeper way today.

So Dr. Fowler, our thanks to you. Stay healthy. We want to bring down your co-pay. $12,500 is too much.

Dr. Ippolito, you don't look old enough to come and testify here. But thank you for it, and while I don't agree with some of the takes of your testimony I think you have

presented yourself in a very nonmenacing way and I think that's very pleasant. I am going to remember you for that.

Dr. Anderson, thank you for your forthright and your wonderful necktie. To everyone that stayed in the hearing room, thank you.

This subcommittee meeting is adjourned.

[Whereupon, at 2:56 p.m., the committee was adjourned.]