UNSUSTAINABLE DRUG PRICES: TESTIMONY FROM THE CEOs (PART I)

HEARING

BEFORE THE

COMMITTEE ON OVERSIGHT AND REFORM HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTEENTH CONGRESS

SECOND SESSION

SEPTEMBER 30, 2020

Serial No. 116–122

Printed for the use of the Committee on Oversight and Reform

Available on: *govinfo.gov, oversight.house.gov* or *docs.house.gov*

U.S. GOVERNMENT PUBLISHING OFFICE

41–982 PDF WASHINGTON : 2020

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UNSUSTAINABLE DRUG PRICES: TESTIMONY FROM THE CEOs (PART I)

Wednesday, September 30, 2020

HOUSE OF REPRESENTATIVES,
COMMITTEE ON OVERSIGHT AND REFORM,
Washington, D.C.

The committee met, pursuant to notice, at 10:07 a.m., in room 2154, Rayburn House Office Building, Hon. Carolyn B. Maloney [chairwoman of the committee] presiding.

Present: Representatives Maloney, Norton, Cooper, Connolly, Krishnamoorthi, Raskin, Mfume, Wasserman Schultz, Sarbanes, Welch, Speier, Kelly, DeSaulnier, Lawrence, Gomez, Ocasio-Cortez, Pressley, Tlaib, Porter, Comer, Jordan, Foxx, Massie, Hice, Grothman, Palmer, Cloud, Higgins, Norman, Roy, Miller, Armstrong, Keller, and Steube.

Chairwoman MALONEY. The committee will come to order.

Without objection, the chair is authorized to declare a recess of the committee at any time.

I now recognize myself for an opening statement.

Good morning, and thank all of you for being here today.

A year and half ago, on January 29, 2019, our former chairman, Elijah Cummings, held this committee's first hearing of the new Congress. The topic of that hearing was the same issue we are examining this week, the astronomical price increases of prescription drugs.

Chairman Cummings cared deeply about this issue. As the very first witness to come before our committee, we invited Ms. Antroinette Worsham. You may remember her. She testified about the devastation of losing her daughter, who had to ration insulin because she simply could not afford it.

Since Chairman Cummings is not with us today, I would like to ask the committee's indulgence to play a short clip of his opening statement from that hearing.

[Begin video clip.]

Chairman CUMMINGS. I have been waiting a very long time to hold this hearing. For the past decade, I have been trying to investigate the actions of drug companies for all sorts of drugs, old and new, generic and brand name.

We have seen time after time that drug companies make money hand over fist by raising the prices of their drugs, often without justification and sometimes overnight, while patients are left holding the bill. The pharmaceutical industry is one of the most profit-

able in the world and one of the most powerful. Fourteen drug companies each made more than $1 billion in profits just in the third quarter of 2018, and they have the best lobbyists money can buy.

Let me be clear. There are powerful interests here that do not want us to interfere with those massive profits. But there is a strong bipartisan consensus that we must do something, something meaningful to rein in the out-of-control price increases. Even President Trump has said that drug companies are "getting away with murder."

But tweaks are not enough. We need real action and meaningful reform. We all recognize that research and development efforts on groundbreaking medications have made immeasurable contributions to the health of Americans, including new treatments and cures for diseases that have affected people for centuries. But the bottom line is that the ongoing escalation of prices by drug companies is simply unsustainable. This is a matter literally of life and death, and we have a duty to act now.

Our constituents are demanding it, and I am grateful that we are finally starting down the road with this hearing.

[End of video clip.]

Chairwoman MALONEY. I remember Chairman Cummings at that hearing so very well, sitting right here in this very chair, listening intently to Ms. Worsham's testimony, his fierce determination, his empathy. I remember how he promised at the end of that hearing to do everything in our power to make sure no family ever faces this situation again.

At that moment, Chairman Cummings was in the process of launching our committee on one of the most comprehensive and in-depth investigations of drug pricing ever conducted by Congress. Today, 18 months later, I am honored to report some of our initial findings.

At the outset, it is important to note that drug companies make products we all need. We rely on this industry to develop critical new therapies, treatments, and vaccines. But our committee's investigation has revealed deeply troubling facts about how these companies price the drugs we all rely on.

Our committee has now reviewed more than a million pages of documents from some of the largest and most profitable drug companies in the world. These include internal corporate strategy documents and communications among top executives. Let me briefly describe three main findings from these documents.

First, the documents show that these price increases are unsustainable either for government health programs or patients themselves. The documents have reviewed—that we reviewed show that drug companies continue to raise prices while raking in record profits and continue to put their products further out of reach for patients in need.

To start this week's back-to-back hearings, we will hear today from the CEOs of three companies. We will hear from the former CEO of Celgene and the former CEO of Bristol Myers Squibb, which acquired Celgene last year. These companies sell the cancer drug Revlimid. They have tripled the price of this drug since 2005. Today, a course of this drug is priced at more than $16,000 a month. That is just per month.

We will also hear from the CEO of the drug company Teva, which sells the multiple sclerosis drug Copaxone. The company raised the price of this drug 27 times in 1997. A yearly course is now priced at $70,000, nearly seven times higher than when it was first introduced. To put this in perspective, that is more than the median household entire income for the year in the United States.

Second, the document reveals—by the committee—show that these massive price increases are based on generating windfall profits for these companies, their shareholders, and their executives.

We have all heard the talking points from the drug companies and their lobbyists, claiming they need to raise prices to pay for research on lifesaving medications, that pharmacy middlemen are driving up the prices, or that they are committing significant funds to helping patients who can't afford the drugs. But the committee's investigation shows that those claims are utterly bogus. They do not hold water. The documents we reviewed show that time and time again drug companies hike prices to meet their earnings targets and in some cases so executives can get their personal bonuses for the year.

Finally, these documents show that drug companies are targeting the United States for the biggest price increases in the world. They know the Federal Government is currently prohibited by law from negotiating directly with drug companies to lower prices for Medicare beneficiaries.

This may be the starkest finding of all. I was astonished to see some of the new documents we will be discussing today. The United States is where the drug companies are increasing their prices much more than in any other country, and this is where they are making billions—billions—of dollars in profits.

Last December, the House passed H.R. 3, and we named it in honor of Elijah E. Cummings, Lower Drug Costs Now Act. This legislation would authorize Medicare to negotiate directly with drug companies for lower prices.

President Trump supported this change on the campaign trail. But unfortunately, he broke his campaign promise, and he now opposes the change. The White House issued a statement declaring that if H.R. 3 were presented to the President, "He would veto the bill."

Instead of taking on the pharmaceutical industry like he promised, President Trump appointed former industry executives to key positions. These included Joe Grogan, the former Director of White House Domestic Policy Council. Mr. Grogan personally wrote an op-ed opposing H.R. 3 one week before we passed it in the House.

Here is the bottom line. As a result of President Trump's reversal, drug prices have continued to skyrocket under his tenure, and drug company executives have continued to get rich. A recent report found that drug companies have raised the list prices of more than 600 single-source brand-name drugs by a median of 21.4 percent just between January 2018 and June 2020.

By any measure, President Trump has failed to rein in out-of-control drug prices. There is no doubt that he has been scrambling ahead of the election. He promised to hand out a paltry $200 dis-

count cards, but he has failed to explain how this will help people facing tens of thousands of dollars in drug costs.

The President also claimed he is banning U.S. companies from charging more than they charge abroad. But experts exposed this tiny demonstration project as a transparent and futile attempt to create the impression of action where there really has not been any.

Let me close with this. As Chairman Cummings would have wanted, we need to focus on the people this affects the most. I would like to place statements from two patients who want to share their experiences with us about these two drugs, and we will now play the patient videos.

[Begin video clips.]

Ms. HAMRIN. I am Ramae Hamrin. I am 50 years old, and I am from Bemidji, Minnesota. I am a single mom with two kids in college.

In 2018, I was diagnosed with an incurable cancer called multiple myeloma. Before my diagnosis, I was a high school math teacher and a long distance runner. But now I can no longer do either.

I rely on a drug called Revlimid to keep me alive. My out-of-pocket costs are around $15,000 a year, which is impossible for me to cover on my fixed income. In order to keep taking this drug, I will have to deplete my life savings, cash out my 401K, and sell my house. When those funds run out, I am not sure what I will do.

Usually, I am a planner, but I cannot plan for this. I am terrified for my future. My circumstances make me feel helpless at times, but I am grateful that I can share my story with all of you.

I urge you to consider patients like me as you work to hold drug companies accountable and fix this broken system.

Thank you.

Ms. HUMPHREY BALL. Hello, my name is Therese Humphrey Ball. I am 66 years old, and I live in Portage, Indiana. I spent my life working as a nurse, watching people struggle to afford prescription drugs. I never thought it would happen to me, until 2003 when I was diagnosed with multiple sclerosis.

Shortly after my diagnosis, I began taking Copaxone, which cost $1,800 per month at that time. After one year of paying for my treatment, I wiped out my savings. And after that, I had to rely on grants to cover the cost.

In 2017, I lost my grants, and at that time, the price of Copaxone had risen to $6,000 a month. I could no longer afford it. So, I went without the drug.

When I was not on the drug, I lost short-term memory and experienced other declines in my cognitive functions. This makes it difficult for me to enjoy the things that I love like spending time with my grandchildren.

My condition shouldn't progress faster just because drug companies want to make a few extra bucks. This drug company price gouging needs to change. As each of you works to reform this system, I hope you consider patients like me.

Thank you.

[End of video clips.]

Chairwoman MALONEY. Thank you, and I now recognize the ranking member for as much time as he would like for his opening statement.

Mr. COMER. Thank you, Chairwoman Maloney.

I appreciate you calling this very important hearing today on the issue of drug prices. This is a critical issue for my constituents, indeed for all of our constituents, and I am committed to working with you to identify and implement reforms that will improve access and affordability to prescription drugs.

This concern is also shared by the President. Over the course of the last three years, President Trump has taken bold steps to address drug prices.

Under the current administration, drug prices have fallen over 13 percent from the expected trend. Under President Trump, a record number of generic drugs have been approved, saving Americans tens of billions of dollars. Under the Trump administration, terminally ill patients are given a chance to explore innovative treatment options.

So, we are all in agreement that drug pricing is a crucial issue for us to consider. However, I am worried, Madam Chairwoman, about the apparent intentions of the majority in holding this week's hearings.

Instead of considering potential reforms in a productive and bipartisan manner, these hearings seem designed simply to vilify and publicly shame pharmaceutical company executives. A productive set of hearings would consider the pros and cons of various reforms and would seek to retain the positives from the current system while identifying improvements where necessary and possible.

Instead, Democrats seem eager to cast our witnesses as villains and to place all blame for cost and access issues on the private sector. The causes, I think, are far more complicated. Many of the greatest healthcare initiatives and innovations of the past 100 years have happened in America, and they have happened not because of government dictates, but as a result of the tireless work of individuals having the freedom to experiment and compete and improve all of our lives.

At this moment in time, the entire world is cheering on the pharmaceutical industry to find a safe and effective vaccine to stop COVID–19. That is the path to a more complete return to normalcy, to reopening our economy, to getting our kids back to school, and getting parents back to work.

Under the Trump administration, we are seeing the fastest vaccine development in history. It is unprecedented. A mere 43 days passed between sequencing of the coronavirus RNA and the start of vaccine development. As Dr. Fauci and others have testified, safety is not being sacrificed, but the financial risks are high. I am hopeful Democrats on this committee can stop the repeated attacks on the vaccine development process, which do nothing but undermine the efforts of so many government and private sector scientists.

Returning to the matter before us today, the policy challenge is ensuring we don't kill the motive to develop new cures while at the same time taking targeted steps to address specific concerns regarding cost and patient access. The problem, Madam Chair-

woman, is not that the free market has failed. Rather, the problem is that overly complex regulations and Government interventions in the market have distorted incentives and created barriers to competition.

I don't believe that more bureaucracy is the answer. We must rethink regulations that distort prices and ensure that adequate competition happens in the marketplace. And yes, we should consider any needed reforms to what the Founders envisioned as a limited guarantee to profit from an invention that at times has been distorted into an unlimited ability to exclude others from selling similar prescription drugs.

I look forward to hearing from today's witnesses about how best to ensure that America remains at the forefront of innovation and discovery while addressing prescription drug pricing and accessibility. I hope we choose to do that in a manner that takes into account the complexities of modern pharmaceutical development and the lifesaving innovations companies such as those appearing before us today have provided us all instead of creating false and simplistic narratives about the private sector.

Thank you, Madam Chairwoman, and I yield back.

Chairwoman MALONEY. Thank you. I now recognize Ms. Foxx, who is the ranking member of the Committee on Education and Labor, for her opening statement.

Ms. FOXX. Thank you very much, Madam Chairman.

Many Americans pay too much for prescription drugs. It is not right, and Congress needs to step up. Luckily, we have a solution that can lower costs at the drugstore for patients and seniors. This solution can be passed into law before the election.

The Lower Costs, More Cures Act, H.R. 19, the Republican alternative to Democrats' H.R. 3, combines many bipartisan reforms to lower out-of-pocket spending, protects access to new medicines and cures, strengthens transparency, and champions competition. To the contrary, Democrats' H.R. 3 would actually eliminate 38 new drugs over the next two decades, new drugs that could cure Alzheimer's, cancer, or COVID–19.

H.R. 19, the Republicans' bill, would make research and development more competitive by reducing companies' ability to game the system and engage in anti-competitive behavior. H.R. 3 would hide the cost of prescription drugs behind a wall of Medicare bureaucracy. The Republican bipartisan bill, on the other hand, would require insurance companies and PBMs to be more transparent where drug costs would be available to patients at the doctor's office before the prescription is even written.

H.R. 3 makes no effort to require pharmacy benefit managers to pass rebates from manufacturers to patients. H.R. 19 would require that a portion of rebates to PBMs be passed directly to the patient at the point of sale, saving seniors millions.

H.R. 3 attempts to use the power of the Government to steal companies' intellectual property to decrease the cost of the drug in the short run. H.R. 19 clears the way for more generics and biosimilars to come to market, increasing competition, rapidly driving down cost for patients, and ensuring access to new, innovative medications.

H.R. 3 ignores the cost of administering cancer treatments for Medicare beneficiaries. H.R. 19 cuts the cost of chemotherapy in half by providing incentives for high-quality care instead of merely giving priority to the location of treatments.

Instead of passing common sense reforms contained in Republicans' H.R. 19, Democrats have chosen to discard months of bipartisan work and conduct this partisan hearing to attack companies that are working to help the American people. Democrats had a choice to help Americans or help Speaker Pelosi. Sadly, they chose to help Speaker Pelosi.

Thank you again, Madam Chairman. I yield back.

Chairwoman MALONEY. Thank you. I now recognize Mr. Hice, who is the ranking member of the Subcommittee on Government Operations, for an opening statement.

Mr. HICE. Thank you very much, Madam Chair.

As my colleague from North Carolina just mentioned, H.R. 3 really would completely gut the pharmaceutical innovations which we all so desperately need and we rely upon. In fact, the Congressional Budget Office said that it would result in 38 fewer cures over the next 20 years. That is a significant number.

They also estimated that it would result in as many as 100 fewer cures from coming to the market. Now just think of that, 100 cures from coming to the market. We just saw a video. It could result in potentially a cure from deadly diseases like multiple sclerosis like we just saw, or ALS, or Alzheimer's, or even COVID–19.

We don't need to have cures that could potentially come in the market not coming to the market. But according to CBO, that is what would happen with H.R. 3. And by the way, these cures don't come cheap. It is not unusual for some of these medications to cost as much as $2.5 billion through R&D and so forth to even come to the market to begin with.

And that is not even to mention, it is not even to consider the fact that more than 90 percent of these drugs that enter into FDA clinical trials never gain FDA approval. So, we have got enormous expense with these companies trying to bring medication to the market, 90 percent plus of which never make it to the market.

So, listen, let me just be clear. The FDA's rigorous process is a huge reason why so many Americans trust that the medications and the vaccines that come to market are safe and dependable. And unlike many of my colleagues on the other side of the aisle, I trust the process, and I know that it will bring a safe and effective vaccine to the American people for COVID through Operation Warp Speed.

Biopharmaceutical companies are far outspending the Federal Government for R&D for cures for various diseases, and that is exactly why we need to be willing to work in order to make innovation easier so that more Americans can live fuller and happier lives, not killing innovation with too much government.

So, I am sad to see that today's hearing shows, frankly, at least in my opinion, that my colleagues on the other side of the aisle are not interested in a bipartisan solution to bring more cures to save American lives. Instead, they think it is more beneficial for their re-election campaigns to attack pharmaceutical executives, and I greatly think that is a huge mistake for the American people.

With that, Madam Chair, I appreciate the time, and I yield back.

Chairwoman MALONEY. Thank you. I now recognize Congressman Roy, who is the ranking member of the Subcommittee on Civil Rights and Civil Liberties, for an opening statement.

Mr. ROY. Well, I want to thank you, Chairwoman Maloney, and really seriously thank you for giving us time to have opening statements. You didn't have to do that, and we are grateful that you did so.

We all recognize that prices are and ought to be a major concern to all Americans because lives literally depend on their existence, their ability, and importantly, their effectiveness. Notably, the drug pricing issue is heavily focused on blockbuster biological drugs, and yes, that costs a lot of money.

Consider 0.4 percent of U.S. prescriptions are biologics, but 46 percent of drug spending. Ninety percent of the drugs sold in the United States are generics and relatively inexpensive. So, let us have hearings. Let us keep perspective on focusing them on solving the problem as a whole rather than vilifying certain actors.

Let us not play the game. The game in Washington is to clearly target one industry for political purposes who, of course—in this case you are talking about drug companies, of course, they have got plenty of blame to share for the high price of the drugs, but hardly all the blame. Let us look at pharmaceutical benefit managers, the Patent and Trademark Office and various patent holders, insurance companies, the FDA, hospital corporations, and of course, the Government regulations—Federal, state, and local.

Last year in a hearing, one of my colleagues who happens to no longer be part of the committee, Katie Hill, was eviscerating a drug company, Gilead, a company that makes HIV lifesaving drugs, for making profit. I said something to the effect of "I hope they do make a profit," but with the caveat that this kind of innovation saved my life when I was battling Hodgkin's lymphoma and the caveat that we root out the swamp games played that result in regulated corporate crony profit versus the kind of profit that drives innovation to save lives.

Many of us have had our lives saved by the innovative work of scientists all around the globe, likely many from drugs created by the companies represented here. I would note Chairman Cummings, whom we all miss—and I was glad you played that video—rightly noted that these companies often make money off of patents wrapped around Government research, and I agreed we should address that. I think most of us do.

But he also specifically gave me time to highlight my life story and perspective and pulled me aside after the hearing to agree that we must have innovation, that we must ensure we have the drugs to save lives. And I would note these are the companies we are hoping are working overtime to produce COVID vaccines as we speak.

Chairwoman MALONEY, you raised the issue about how these companies price their drugs, and indeed, it is a troubling situation. But it is heavily this body's fault. We have allowed a complex morass of Government regulations, coupled with insurance companies, to have total control of our healthcare system, empowering PBMs and major hospital corporations to roll over customers because

there is no market. There is no doctor-patient relationship that is sacrosanct and that enables patients to price things properly in a market.

This is a problem that Congress has largely created. If we want to address it, we need to look at the entire supply chain from top to bottom. If you look specifically, like in 2018, on patents, Sanofi's Lantus, a type of insulin, had 74 patents providing protection from competition, making it harder for diabetics to access cheaper insulin. This is what happens with limited competition.

Since 2016, the FDA has approved roughly 2,500 generic versions of 620 brand-name drugs. Pharmaceutical drugs with at least four generic competitors reduce the price of the brand drug by an average of 39 percent, but the FDA is costly and inefficient. On average, it can take more than a decade and $2.6 billion in research costs to get a new treatment through the FDA and to market. And only 1 in 1,000 drug formulas ever get to preclinical testing. Only eight percent of those get FDA approval.

And once the drug clears the labyrinth of patent law and the wisdom of the almighty FDA, the drug still has to make it on the formulary of your insurance plan in order for you to receive your discount. The healthcare bureaucracy this body has created is guilty of lining the pockets of these companies beyond what the market would demand, both insurance and pharma, and not to forget PBMs, who are far from innocent here.

In 2018, the United States spent $335 billion on retail prescription drugs, 10 percent of our national health expenditure. But we spent $1.2 trillion on insurance, 34 percent of the national health expenditure. So, where should the focus be? The healthcare system or just pharma?

As we all agree, our folks who require expensive drugs, our system should be able to help them defray cost. This is usually understood to happen through insurance and risk adjustment. But it has become too expensive for most Americans, and often it is this body's fault.

The ACA's regulation caused premiums to more than double from 2013 to 2017, increase overall by 60 percent from 2010 to 2017. Individual deductibles increased 76 percent.

Worse yet, CMS data shows that while premiums were spiking due to Obamacare, unsubsidized people on the individual market were losing their coverage. In just two years from 2016 to 2018, unsubsidized enrollment declined by 2.5 million people, a 40 percent decrease. This makes it harder to defray cost and forces many to pay the list price, which could be avoidable. There are always bad actors who take advantage of the vulnerable, but let us not forget Congress' role in creating the very system causing it.

I know I am running out of time. Chairwoman Maloney, I would also point out that each one of these companies are working today to engage in the fight to create a vaccine against the virus. Innovation in the pharmaceutical industry is critical. Without it, lives are literally lost.

None of us want unaffordable drugs. We want affordable drugs rather than expensive drugs that the rest of the world, frankly, piggybacks upon the back of the Americans. And to do that, let us do what this body literally never does anymore—roll up our

sleeves, restore personalized healthcare, empower patients and doctors, and remove all the bureaucrats and middlemen who are the ones driving up cost.

I look forward to hearing from the witnesses, and I appreciate, really seriously appreciate the time that you gave us this morning, Chairwoman Maloney.

Chairwoman MALONEY. Thank you. I now recognize my colleague and very good friend Congressman Welch, who worked very closely with Chairman Cummings on this issue, for his opening statement.

Mr. WELCH. Thank you very much, Madam Chair, and I thank my colleagues.

Every single American, every single taxpayer at one point or another is going to need pharmaceutical assistance. And every single American and every single taxpayer, everybody who pays a premium, every employer who pays premiums on behalf of his or her employees needs relief from prices that are absolutely beyond reach.

The question for this Congress is whether our Government will play a role, an active role to stop price gouging by the pharmaceutical industry? And let me be candid. There is a disagreement about that.

This legislation would enable the Government, on behalf of the people it serves, to negotiate prices when it purchases prescription drugs from the pharmaceutical industry. This is not a question of whether those are necessary. It is not a question of whether the investigatory and research work that pharma does is good. It is. It is about whether there is any limit on what the pharmaceutical industry can charge the taxpayer, the Medicare program, the Medicaid program, employers who provide insurance to their employees.

What Elijah understood is that the Government that is here to serve the people has a responsibility to do things that protect them from price gouging. And yes, it is true. Many of these pharmaceutical industries have come up with lifesaving and pain-relieving medications. But they are killing us with the prices they charge.

And what this report shows is that there is very clear strategy on the part of the pharmaceutical industry to boost its prices in the place where it can, and that is the United States of America. Ours is literally the only country where the government won't protect its citizens from price gouging.

Now the profits—no, nothing wrong with profits. But price-gouging profits, yes. And tactics used that are tried and true by the pharmaceutical industry to extend the life, that monopoly that they get granted by this Congress by making an ever-so-slight change in the medication itself and claiming that that entitles them to extend that patient, where you have companies that are charging like $70,000 for a drug, it helps. But who can pay that? Who can pay that?

And then we see the pharmaceutical industry coming up with very, very skillful ways to appear to be helping, like donations to third-party foundations that help patients to "afford." Well, they have done an analysis that you are going to see in this report where they very self-consciously realize that that boosts sales for them, and they make money by making that as an investment.

Now what has happened here is that that temptation that pharma has to use its uninhibited pricing power has transformed America's pain into pharma's profit. That is what has happened, and we can address many of the things that my colleagues have talked about with regulation and find ways to do things that will help on the margins.

But what Elijah knew is that the only way to really get fair pricing was to have negotiation. By the way, negotiation is core to a free market economy. A buyer and a seller have a discussion and decide what it is worth to the seller and what it is worth to the buyer. We are the only buyer, the Medicare and Medicaid program, where we don't negotiate. And when you negotiate, you save money, as Vermont has done.

Now when Elijah and I met with President Trump and Elijah was presenting his price negotiation plan, the President said he was for price negotiation and that pharma was ripping us off. And Elijah was hopeful. The President has failed to fulfill his promise. We are here to keep Elijah's commitment.

Thank you, Madam Chair. I yield back.

Chairwoman MALONEY. Thank you. I thank the gentleman for his hard work and statement.

Now I would like to introduce our witnesses. We are grateful to have their testimony, and I want to thank the witnesses for being so accommodating with their schedules so that we could have them here together.

Our first witness today is Mark Alles, who is the former chairman of the board and CEO of Celgene. Celgene sold the cancer drug Revlimid until November 2019. Then we will go to Dr. Giovanni Caforio, who is the chairman of the board and CEO of Bristol Myers Squibb. Bristol Myers Squibb has sold Revlimid since November 2019. Finally, we will hear from Mr. Kare Schultz, who is the president and CEO of Teva Pharmaceutical Industries. Teva sells the multiple sclerosis drug Copaxone.

The witnesses will be unmuted so we can swear them in. The witnesses will rise and raise their right hands.

And the witnesses, do you swear or affirm that the testimony you are about to give is the truth, the whole truth, and nothing but the truth, so help you God?

[Response.]

Chairwoman MALONEY. Let the record show that the witnesses answered in the affirmative.

Without objection, your written statements will be made part of that record.

And with that, Mr. Alles, you are now recognized for your testimony.

STATEMENT OF MARK ALLES, FORMER CHIEF EXECUTIVE OFFICER, CALGENE CORPORATION

Mr. ALLES. Chairwoman Maloney, Ranking Member Comer, and members of the committee, thank you for the opportunity to discuss Revlimid, a life-extending medicine approved by the FDA for the treatment of rare and incurable blood cancers.

My name is Mark Alles, and I've had the privilege of being part of the research-based pharmaceutical industry for more than 30

years. Before I joined this industry, I served in the Marine Corps and the Marine Corps Reserve, and before that, I taught junior high school. I've strived to bring the values of integrity, service, and respect to every part of my career.

Revlimid was discovered, developed, and brought to patients by my former employer, Celgene Corporation. Based in Summit, New Jersey, Celgene was a global biopharmaceutical company that specialized in the discovery, manufacturing, clinical development, and delivery of innovative medicines for the treatment of cancer and serious inflammatory diseases.

I joined Celgene in 2004, and after serving in multiple different roles in the company, I was appointed chief executive officer in 2016 and chairman of the board in 2018. My last day with Celgene was December 2, 2019, after Celgene was acquired by Bristol Myers Squibb in November 2019. At that time, the company employed more than 8,000 people worldwide, with approximately 5,600 employees in the United States.

One of the most clinically important therapies discovered by Celgene is the novel medicine lenalidomide, marketed as Revlimid. Revlimid's primary use is for the treatment of multiple myeloma, a rare and incurable blood cancer. Celgene invested approximately $800 million over 14 years to invent and develop Revlimid before its first FDA-approved use in late 2005.

Revlimid is a unique, patented molecule that required a completely independent development program and a full FDA approval process. Revlimid has become a standard of care for the treatment of myeloma, based on several large clinical studies that have demonstrated significant patient benefits.

Since Revlimid's initial FDA approval, the company continued to invest several hundred million dollars into the research and development of this medicine. At the time it was acquired, Celgene had and was sponsoring more than 50 additional Revlimid clinical studies for patients with different types of cancer.

As is common in drug development, some of these studies were not successful, did not succeed. However, several of these studies were successful and resulted in six additional FDA approvals, including the most recent in 2019. Since 2005, more than 700,000 patients have been treated with Revlimid worldwide.

At Celgene, pricing decisions for our medicines were guided by a set of long-held principles that reflected our commitment to patient access, the value of a medicine to patients and the healthcare system, the continuous effort to discover new medicines and new uses for existing medicines, and the need for financial flexibility. In 2018, the company publicly committed to full pricing transparency by limiting price increases to no more than once per year and at a level not greater than the Centers for Medicare and Medicaid Services' projected increase in the national healthcare expenditures for the year, absent exceptional circumstances.

To help ensure patient access to our medicines, the company's patient support programs provided copay assistance to eligible commercially insured patients and provided free medicine to eligible patients. More than 140,000 people in the United States prescribed a Celgene cancer medicine received some form of assistance.

Celgene sold and offered to sell samples of its patented medicines to generic manufacturers so long as those companies met critically important safety standards. These requirements were established to protect the public from the risk of severe birth defects associated with the known and suspected teratogenicity of some of its products, including Revlimid. In fact, multiple generic versions of Revlimid are licensed to enter the U.S. market within the next two years.

Celgene Corporation was a research-driven biopharmaceutical company, which invested heavily in the discovery and development of innovative therapies that are now helping to improve the lives of tens of thousands of people worldwide. In considering legislative changes, I urge Congress to maintain many of the strong incentives that currently exist to encourage and support medical innovation.

Finally, because my mother died from a neurodegenerative disease, my son lives with insulin-dependent diabetes, my daughter has autism, and my older brother is being treated for an incurable blood cancer, all of us are severely impacted by this pandemic. This issue matters to me at a deeply personal level. I hope and believe that these incentives will lead to new treatments that society and my family will benefit from today and long after these medicines become generic drugs.

Thank you, and I look forward to answering your questions.

Chairwoman MALONEY. Thank you. Thank you very much.

And we will now recognize Mr. Caforio. You are now recognized, Mr. Caforio.

[Pause.]

Chairwoman MALONEY. Mr. Caforio, are you unmuted?

Dr. CAFORIO. I am unmuted.

Chairwoman MALONEY. You are now recognized.

Dr. CAFORIO. Thank you. Can you hear me?

Chairwoman MALONEY. Yes, we can.

STATEMENT OF GIOVANNI CAFORIO, M.D., CHIEF EXECUTIVE OFFICER, BRISTOL MYERS SQUIBB

Dr. CAFORIO. Chairwoman Maloney, Ranking Member Comer, and members of the committee, thank you for the opportunity to join this important conversation begun by Congressman Cummings, who championed affordable healthcare and continued by Chairwoman Maloney. This is an important issue for all Americans.

Today, advances in medicine are progressing at remarkable speeds. As a physician, I'm excited by the science, but also concerned that without a system to protect all patients and enable affordable access, we risk these advantages being out of reach.

Medicines like Revlimid highlight these advancements and the challenges that come along with it. We have seen extraordinary gains in patients with multiple myeloma, the blood cancer treated by Revlimid. The five-year relative survival has doubled over the past 25 years, turning what was once a dire diagnosis into a manageable disease for some patients.

Revlimid is one of the most significant contributors to these improved survival rates. We continue to unlock our scientific understanding of multiple myeloma, and our research today is purely

next-generation treatments that build on Revlimid's success and progress.

For example, we are now on the cusp of personalized medicines for multiple myeloma that use patients' re-engineered cells to fight cancer. BMS and Celgene have exceptionally strong records in R&D. Both recognized for the highest R&D investments as a share of R&D across all industries.

This year alone, we expect to invest nearly $10 billion in R&D. As part of our efforts, we are conducting urgent research on COVID–19, providing 1,000 proprietary compounds to partners, examining two medicines in clinical trials, and enacting a robust philanthropic response.

The scientific and capital investment put toward developing Revlimid is instructive. Thalidomide, as you may recall, was prescribed outside the U.S. without a thorough understanding of side effects and caused tens of thousands of infant deaths and severe birth defects.

Celgene, however, continued to invest in its research and development for 14 years. Ultimately, this led to the invention of Revlimid. Revlimid's value to patients is truly immeasurable, and patients should have access regardless of ability to pay. For this reason, we have robust patient assistance programs providing financial support to hundreds of thousands of patients, with copay assistance and three medicines worth billions of dollars.

That being said, I do recognize that patient assistance programs are an imperfect solution to access challenges. I welcome the opportunity to work with you and others to advance critical reforms that more efficiently deliver care to patients and provide savings to the healthcare system.

We believe in the importance of a healthy generic market, and we applaud the administration's success with speeding the approval of generics and Congress' passage of the CREATES Act. At the same time, we must prioritize American innovation, which leads the world in developing new therapies for patients.

At Bristol Myers Squibb, we are committed to discovering, developing, and delivering innovative medicines that help patients. In an unprecedented year, our work has never been more critical. I look forward to answering your questions.

Thank you.

Chairwoman MALONEY. Thank you. Mr. Schultz, you are now recognized. Mr. Schultz, please unmute.

STATEMENT OF KARE SCHULTZ, CHIEF EXECUTIVE OFFICER, TEVA PHARMACEUTICALS

Mr. SCHULTZ. Thank you.

Chairwoman Maloney, Ranking Member Comer, and members of the committee, thank you for the chance to appear before you today.

My name is Kare Schultz, and I am the president and CEO of Teva Pharmaceutical Industries. I understand that the committee is interested in the pricing of Copaxone, the company's specialty medicine for the treatment of multiple sclerosis, or MS. But before I discuss Copaxone, I would like to tell you more about Teva and its role in the healthcare industry.

Teva is a global pharmaceutical company committed to helping patients access affordable medicines and benefit from innovations to improve their health. We were founded in Israel 120 years ago and operate worldwide, with a significant presence in the United States.

Teva is the global leader in providing affordable medicines, with the industry's largest portfolio of generic medicines and a strong portfolio of specialty medicines, including Copaxone. On the strength of our generic business, Teva drives access and provides direct savings to patients and healthcare systems around the world.

For example, in the United States, Teva saved the healthcare system $41.9 billion, including $5.9 billion in savings directly to patients in 2018. We also provided over $40 million worth of medicines to almost 13,000 patients in 2019.

Teva is committed to helping patients through rigorous and innovative scientific research, and we take great pride in that. This defines how we do business and how we approach medicine. In order for any pharmaceutical company to research and develop new drugs or improve old ones, the price of successful medicines must reflect the significant cost of ongoing research and development projects.

The public only sees and pays for the drugs that are ultimately approved by the Government, like Copaxone, but you have to expend a lot of resources and endure many disappointments before bringing to the market safe and effective medicines. Teva will continue to invest in new breakthrough treatments and find new ways to extend and expand patient care beyond medicine.

And Copaxone is one of the best examples of our dedication to innovative research and patient support. Our significant investment in researching, developing, and commercializing safe and effective treatments led us to introduce Copaxone in the United States in 1996. And since then, Copaxone has become a preferred treatment for MS.

Since first introducing Copaxone, we have continued our studies and most recently in 2014 introduced a more efficient version of that drug that only needs to be administered three times a week, as opposed to daily. This results in more than 200 fewer injections per patient each year. As a result, Copaxone has been competitively priced based on both the value it brings to the MS therapeutic area and the research and development needed for its continued advancement.

The historical Copaxone price increases of interest to the committee all predate my tenure at Teva, and Teva has not increased the list price of Copaxone since January 2017. Moreover, the net price of Copaxone has declined over the last several years, which is expected given our competitors' generic entry into the market, something we at Teva are very familiar with as a company primarily focused on generic drugs.

Teva is also dedicated to supporting our patients and improving patients' user experience in all the ways we can. For example, Teva spends a significant amount of resources on a program called Shared Solutions. Through Shared Solutions, we provide both medical and financial assistance to Copaxone patients.

Teva also provides patients with 24/7 access to phone support from MS-certified nurses, a range of peer resources, and educational programs for patients and MS professionals. These comprehensive benefits represent substantial cost to Teva, and the price of Copaxone reflects the product value, including these patient support services.

But Teva is also committed to ensure that patients have affordable access to their MS therapy. For example, Shared Solutions have a team of dedicated benefit specialists who help research patients' coverage and insurance benefits so patients are able to receive the most affordable care possible. Teva acknowledges that the pharmaceutical industry as a whole needs to be mindful and responsible about the pricing of medications and understands that each company plays a role in keeping down healthcare costs.

Teva renews its commitment today to continue to provide access to high-quality generic medicines, to create innovative solutions for patients, and to strive to make healthcare more accessible and affordable. We appreciate the continued efforts of the committee to understand the overall value of specific medications and look forward to working with the committee and answering your questions.

Thank you very much.

Chairwoman MALONEY. I thank all of you for your testimony.

I now recognize myself for five minutes for questions.

I want to talk about internal documents our committee obtained as part of our investigation showing that drug companies are targeting the United States for their biggest price increases anywhere in the world.

They do this in part because Federal law currently prohibits the government from negotiating directly with drug companies to lower prices on behalf of Medicare beneficiaries.

So, Mr. Alles, I would like to start with you. I would like to put up a slide that we obtained from your company, Celgene. Please put the document up.

[Slide.]

Chairwoman MALONEY. And do you have a copy of it now, Mr. Alles, that you can see it?

This document that is in the reports that we gave you, this is an internal presentation from October 2018 and it was made to your company's corporate market access committee. That is the committee that is responsible for approving your company's price increases.

Can you see the document, Mr. Alles? Do you have it?

Mr. ALLES. Madam Chairwoman, I see the document on the Webex but I am looking for a copy of it here in the room, and I have it——

Chairwoman MALONEY. Well, this document——

Mr. ALLES. I have it now.

Chairwoman MALONEY. Yes, you have got it? OK.

Mr. ALLES. Yes.

Chairwoman MALONEY. This document, basically, gives your company's view of the world and how much money you can make in different countries. I want to ask you about the United States, on the bottom left, and compare that to the European Union on the top right.

If you look at the U.S. it says, and I quote, "highly favorable market with free market pricing," end quote. Now you say free market pricing but the government, the Federal Government, can't negotiate with you to lower prices under Medicare.

So, that is absolutely terrific for your profits, and I understand why you think it is highly favorable. But then if you look at the EU, you say things are only, quote, "manageable," end quote, and then you highlight, quote, "stagnated price growth," end quote, as a result of price negotiations.

Now, you call it stagnated price growth. But the rest of us call it negotiating to bring prices down for people, for our patients.

Your company loves the U.S. because you can keep increasing prices here as high as you want, and Medicare, which covers millions of Americans, isn't allowed to negotiate.

But in the EU, where they do negotiate price increases, are, in your own words, stagnated or not increasing.

So, here is my question. Isn't it true that for the past decade you targeted the United States for the biggest prices and the biggest price increases in the entire world?

Mr. ALLES. Madam Chairman, thank you for the question.

As I look at this slide, it seems to accurately reflect our assessment of the market access and the pricing environment in the different regions of the world at that time.

I think it also speaks to that the United States is the world's leader in medical innovation and the free market pricing opportunity in the U.S. continues to drive much of the research and development and medical innovation for the world.

So it also, I think, describes not as well as I would like that there are fundamental differences around the world with economies and countries and the systems. But in the end, it does highlight that the United States is the home of medical innovation and that is a free market environment.

Chairwoman MALONEY. But since launching Revlimid in 2005, you raised the price 22 times. In the 10 years from 2009 to 2018, your company reported $51 billion in net worldwide revenues from this drug alone and $32 billion of that came from the United States.

You charge more for this drug here in the U.S. and you made more money from this drug here in the U.S. than in every other country combined.

Let me turn to Mr. Schultz. I have an internal document from you company, Teva, that also shows how executives view the U.S. Let me put this document up on the screen. This is Exhibit 32.

[Slide.]

Chairwoman MALONEY. This is an internal presentation from September 2016. The top of the slide reads, and I quote, "What does Teva do well in pricing," end quote.

The first bullet on the slide says, quote, "Pricing negotiation strategy and able to increase prices successfully." And underneath that bullet it reads, and I quote, "Influenced heavily by U.S. being allowed to hike prices," end quote.

And below it, it says, and I quote, "We apply more frequent price changes once, twice a year, and many on a continuous basis," end quote.

Let me repeat this. You say, "We apply more frequent price changes in the U.S. once, twice a year, and many on a continuous basis."

Mr. Schultz, this presentation seems clear. You are highlighting your ability to raise prices here in the United States because you are allowed to do so, where in other countries you are forced to negotiate prices down for patients and for people.

Isn't that right?

Mr. SCHULTZ. Madam Chairwoman, thanks for that question.

As you might know, I joined Teva as CEO on the 1st of November 2017, which means that I haven't seen this document before and I am not aware of actually what happened before I joined.

I can assure you, however, that since I joined Teva Pharmaceuticals in November 2017 there has been no changes, no price increases, to the list price of Copaxone, and in the same period there has been a dramatic reduction of the actual net pricing that Teva Pharmaceuticals sells the product for to the tune of a price reduction in 2018 of more than 20 percent, again in 2019 of more than 20 percent. So, that is really what I can comment on.

Chairwoman MALONEY. Well, this document, clearly, shows why we need to pass and sign into law H.R. 3. Chairman Cummings was right and President Trump was right, before he broke his promise and reversed his position.

We need to get rid of this ridiculous law that says the government cannot negotiate drug prices.

I now recognize Mr. Palmer for his questions.

Mr. PALMER. Before I begin, Madam Chairman, I would like to say that I do miss Elijah and miss him calling me brother. No disrespect to your chairmanship, but he was, in my opinion, a good man.

Chairwoman MALONEY. Thank you. We all miss him. Thank you.

Mr. PALMER. If I may reclaim that time.

I think it is obvious that we don't want to do anything to stifle research and innovation that has brought us—literally, brought us miracle drugs. I think we are about to see that with the COVID–19 vaccine.

We have got members of this—of Congress, including Mr. Roy and others, that have had drugs have a major impact in their lives. It was mentioned multiple myeloma.

I am happy to hear about the advances there. That cancer took my father-in-law's life in 2000. I think all of us have stories like that and I think the fact is that we want to encourage innovation.

We want to encourage this research that can bring us these miracle drugs. But that will do people little good if they can't afford those drugs.

And one of the things that my colleague, Chip Roy, mentioned was patents, and we have seen situations where the patent protections are so short that it seems obvious, or at least to me from a business perspective, that some of the price hikes are forced upon the companies to try to recover their cost because there is billions of dollars that are invested in the development of a drug, and many of these drugs never come to fruition. They never get to market, and companies have to take that into account in their pricing.

But what I want to know is, is if extending patent protections would be of any value to reducing the cost of drugs. Mr. Alles, if you wouldn't mind responding.

Is it Elles, or how do you pronounce that? Celgene.

Mr. ALLES. Yes. Thank you for the question. It is Alles, sir, but I will answer to anything that sounds like my last name. So, no worries.

Mr. PALMER. Well, I started calling you Mark but that is inappropriate.

Go ahead.

Mr. ALLES. The question is very complicated but it is a critical question. I believe that if patent reform extended the patent life of a medicine, coupled with modernizing these reimbursement access challenges, for example, capping the out-of-pocket cost for Medicare beneficiaries, along with the CREATES Act that passed at the end of 2019 that did tighten up some of the areas that could have been used to extend the existing patents under existing law.

So, I think there are a combination of things that could happen together that would have the opportunity to lower pricing.

At Celgene we also thought that managing the company's patented medicines where we took into account the lifetime value of the medicine with its initial approval versus what has historically been the pricing practice, which is, over time, increasing the price in the U.S. to, as you say, offset failures, offset clinical research costs, offset other unexpected or sometimes expected expenses, one finds a different relationship in how to manage price.

And that is actually what we did at the beginning of 2018 with our pledge to use medical inflation as a marker for annual price increases.

Mr. PALMER. Let me suggest to you—I appreciate the answer. I would like to hear from the industry what incentives the Federal Government could provide to help address some of these issues of stranded cost, and maybe extending patents and tax incentives and other things like that so that we can make sure that these drugs are available to the people who need them.

And one of the things that concerns me is a report that came out of England that the British National Health System was denying coverage to 25 cancer drugs that included drugs for treating breast cancer and bowel cancer and prostate cancer.

We don't want to have that happen here. We also—I think we are going to have to address the issue of overregulation, particularly with common drugs that should be very inexpensive like insulin, like the EpiPen, where we have literally regulated the companies into shutting down and it left the production of those drugs to just one or two companies that had a monopoly.

And the last thing, if I may, Madam Chairman, if you will extend my time just a little bit, is when we start looking at covering drugs through a national health care system, I want us to avoid situations like occurred in Oregon and California where you had Barbara Wagner, who had treatable cancer but the Oregon health plan would not cover it.

Instead, offered to pay for her hospice or assisted suicide drug, and then Stephanie Packer in California, 31 years old, mother of four children, and her insurance company wouldn't pay for it but

they would pay the assisted suicide drug, and her co-pay would only be $1.20.

We want to avoid that. We want to incentivize companies to continue to do this fabulous research.

I think we ought to have an Operation Warp Speed for cancer drugs, Madam Chairman. I think we see an example of how this could work if we all get our minds around it and get committed to it.

With that, I yield back and I thank you for your indulgence.

Chairwoman MALONEY. Thank you.

I now recognize Ms. Norton. You are now recognized for questions.

Congresswoman Norton?

Ms. NORTON. Thank you very much, Madam Chair. I want to thank you for this very important hearing, and I note that it is a two-day hearing, signaling the importance of this hearing on drug pricing to the American people.

I want to say that the notion of negotiation is very close to me. I taught negotiation when I was a tenured professor at Georgetown Law School.

So, the notion that in a market system we are having to debate the notion of negotiation for any market item is very peculiar to me.

Mr. Alles, Mr. Caforio, Mr. Schultz, I want to thank you, all three of you, for joining us today and I want to acknowledge and let you know that I appreciate the innovative work you are doing, the life-saving drugs that your companies are producing, and even, as you have testified, the assistance you are granting some patients.

You, of course, understand from the videos the chair played that there are millions of Americans who cannot afford these drugs. Your companies are crucial lifelines, which is why I appreciate what you are doing so much.

For that reason, though, every time your companies raise prices, you push these lifelines and opportunities for good health even further out of reach.

Now, because I have a limited amount of time, I am going to have to ask you not to give me an extended reply but to give me a yes or no answer.

I am simply trying to establish for the record the answers to the questions I am asking. So, please abide by the discipline I have been submitted to and the amount of time that I must, therefore, submit you to.

Mr. Alles, I understand that your company, Celgene, raised the price of Revlimid more than 20 times since it came to market in 2005.

I also understand that Celgene generated $32 million in net income from U.S. sales of Revlimid between 2009 and 2018, and that over that same period of time Celgene's annual profits have increased from $780 million in 2009 to $4 million in 2018.

Do these numbers sound correct to you, yes or no?

Mr. ALLES. I would just make one correction for the record. Thirty-two million would be $32 billion.

Ms. NORTON. Billion. I am sorry. Billion.

Mr. ALLES. That is fine. I just—I believe those numbers would be correct. I believe they would be.

Ms. NORTON. Thank you very much.

A monthly course of Revlimid is about $16,000. That is triple the price it was in 2005.

Mr. Caforio, after Bristol Myers Squibb acquired Celgene in 2019, you raised the price yet again. Is that right?

Dr. CAFORIO. Yes, Congresswoman. We increased the price by six percent in January of this year.

Ms. NORTON. Turning to you, Mr. Schultz, I understand that your company, Teva, has raised the price of Copaxone 27 times since bringing it to market in 1997.

I also understand that the same monthly course of Copaxone is now seven times more expensive than it was in 1997 and that since 1997 Teva has collected more than $34 million in U.S. net sales for Copaxone.

Mr. Schultz, do these numbers sound correct to you?

Mr. SCHULTZ. I wasn't there at the time but they sound correct to me.

Ms. NORTON. Thank you.

Mr. Schultz, are you aware that nearly one in four Americans taking prescription drugs report difficulty in affording their medicine?

Mr. SCHULTZ. I am very aware of that and, therefore, I am also very thankful for providing nearly one out of 10 generic prescriptions in the United States market.

Ms. NORTON. Thank you very much.

Mr. Caforio—thank you. My time is running out.

Mr. Caforio, are you aware of that, that nearly one in four Americans taking prescription drugs report difficulty affording their medicines?

Mr. Caforio?

Dr. CAFORIO. Congresswoman, I am aware of that and that is why we very actively support every patient we can with a number of patient assistance programs.

Ms. NORTON. Pardon me. Are you aware of that number, Mr. Alles—Mr. Alles, that one in four Americans taking prescription drugs report difficulty in affording them?

Mr. ALLES. I am aware of that number, yes.

Ms. NORTON. Thank you very much, and I see my time has expired.

Thank you, Madam Chair.

Chairwoman MALONEY. The gentlelady yields back.

Ms. Foxx, you are now recognized for questions.

Ms. FOXX. Thank you very much, Madam Chairman.

This—my first questions will be for any or all of the witnesses. I understand that your industry and companies are working to develop new treatments, therapies, and vaccines to fight the spread of COVID–19.

What country do you expect to deliver the first credible and widely used vaccine for COVID–19?

[No response.]

Ms. FOXX. Could the witnesses answer, please?

Dr. CAFORIO. Thank you, Congresswoman. This is Giovanni Caforio.

Thanks for your question. I know that companies around the world are working day and night to develop not only vaccines but also treatments for COVID–19 and we are cooperating like we have never done before to shorten what is typically a 10-to 15-year processing to, potentially, one to two years, and we are working 24/7, which is really what we do as an industry.

As has been said before, innovation in our industry happens primarily in the United States. Many of the companies that are working on treatments and vaccines are U.S. companies.

A lot of the research is happening in the U.S. But there are companies from, of course, other parts of the world that are working on this as well.

What I know is whether it is a new medicine or a new vaccine, whenever innovation is made available to patients, it is available right away.

In our country, it is sometimes delayed in terms of its access outside of the U.S. We are working to make sure that doesn't happen in the case of COVID.

But I am confident that we will accelerate the development of treatments and vaccines for the U.S. and for U.S. patients.

Ms. FOXX. Well, we know that the United States is the most likely country to develop the first credible vaccine. So, if one of the other witnesses could say, what are the best incentives for developing these new treatments, therapies, and vaccines?

Mr. ALLES. Congresswoman, this is Mark Alles.

It is very clear that the ability to have flexibility, financial flexibility, built into the innovation cycle allows for the multi-national companies that Dr. Caforio was speaking about to shift those resources when crises occur and, certainly, COVID–19 is a crisis.

So, I think the innovation cycle that is representative of the U.S. market does two things. It allows for that shift and it also provides access more often than not to these new medicines in the United States first.

For example, one of the indications for Revlimid that was available to the U.S. citizens immediately upon approval took 13 years longer to be available to patients in the United Kingdom.

So, these structural issues are accompanying some of the development issues, and then the economic challenges of how innovation is rewarded in the United States but not necessarily in the rest of the world.

Ms. FOXX. OK.

Mr. Schultz, let me ask you the next question. If the United States had implemented the same drug price controls that many of our European allies have in the last few decades, would we be more or less likely to develop a vaccine for COVID–19?

Mr. SCHULTZ. I would say you would definitely be less likely simply due to the fact, as my peers from the industry mentioned, that the financial incentives would be less.

But one interesting fact which is in line with this whole problem of access to new medicines is that nearly all new kinds of drugs are available in the United States, more than 95 percent of them.

I think if you just go to Canada it is something like 56 percent only of the recent innovations in the cancer medication that is available in Canada.

So there is, of course, a clear link between financial incentives and the motivation to do research and development in a certain geography and launch products in a certain geography.

In the long run, of course, 10, 20 years out, most of these drugs will, of course, be available all over the world also as generics.

Ms. FOXX. Thank you very much. I think anybody who has had any kind of experience with capitalism or any kind of reward system understands that human beings respond better to rewards than to punishment.

I mean, we have known that for a long time. Thank you all very much.

Madam Chairman, thank you very much for recognizing me.

Chairwoman MALONEY. Thank you.

Mr. Connolly has generously offered to handle our committee's work on the floor. So, we are going to recognize him now so that he can go to the floor.

Mr. Connolly, you are now recognized for your questions.

Mr. CONNOLLY. I thank the chairwoman and I thank her very much for holding this hearing.

I do want to preface my questioning by, frankly, taking issue with my friends on the other side of the aisle. If you listen to their narrative, you would never know that 600 single-source brand name drugs—brand name, not blockbusters, not newly developed drugs—went up in price for the American consumer by 21 percent in just a two-year period between 2018 and 2020.

You would never know, listening to their narrative, that longtime drugs a hundred years old like insulin, which is not a new drug and not a dime of new R&D went into it, increased and skyrocketed in price, threatening the health of American diabetics and prediabetics into the tune of millions.

You would never know, in their rushing to defend CEOs against attacks by this side of the aisle, apparently, that only a few years ago we had Martin Shkreli at that table, a man who bought a company that had—was the sole source for a lifesaving drug, and gouged the price not because of the need to reinvest or to have a return on investment, but because he could and he had no conscience. And he went to jail.

That is the CEO we want to look at. We want to protect the American consumer, and if my friends on the other side of the aisle decide they don't want to do that, I think they are taking a bad step.

And that is what this hearing is about and I commend you, Madam Chairman—Chairwoman, for holding it.

Mr. Alles, if we could put up the graph showing the historic price evolution between Europe and the United States—not that one—on your drug, Revlimid, if I am pronouncing it directly.

[Slide.]

Mr. CONNOLLY. And if we—yes, if we look at that graph, when you introduced Revlimid in Europe, it actually cost a little bit more than it did here in the United States. And yet, over time a huge

divergence occurred. So, the European price kind of straight lined. But the American price went up and up.

And that is because you described—your company described this as saying that the United States was a free market investment and Europe was something else. Do you make a profit on that drug in your sales in Europe or is it a loss leader?

Mr. ALLES. We do make a profit on the drug in the aggregate European Union.

Mr. CONNOLLY. OK. So, I guess that capitalism my friend, Ms. Foxx, was just talking about is alive and well in Europe.

It is just you can make even more profit here in the United States because of the free market environment, which I think means we don't negotiate that price in a lot of public programs. Would that be a fair statement?

Mr. ALLES. I think in the aggregate, Congressman, what we are seeing is the innovation cycle and R&D that goes into developing a cancer medicine like Revlimid worldwide in this window of time.

Mr. CONNOLLY. Is there a different—I am sorry. I am running out of time. Is there a difference between the R&D investment in Europe versus the R&D investment—I mean, it is the same drug.

Mr. ALLES. It can be quite different. Clinical trials can be wrong more completely in the United States or more could be happening here than across Europe. So yes, those R&D expenses could be quite different.

Mr. CONNOLLY. Well, with respect to that, if we look at Exhibit 7, your own forecast said that you were going to have modest price increases in this drug here in the United States through 2018, independent of volume, and that you would stabilize the price of a pill at $470 by 2019.

Instead, that pill went up to $750. Was that also because of unanticipated R&D costs? How could you get that price per pill so wrong?

Mr. ALLES. I am looking at the document that you are describing and I don't know that we got the estimate of R&D wrong. But the opportunity for increased investment and the opportunity for new drugs is, clearly, there.

Mr. CONNOLLY. No, you got the price of the pill wrong. You got the price of a pill wrong. That is a pretty big differential, especially when it hits the pocketbook of an American consumer. Would you not agree?

Mr. ALLES. I see the difference between the European Union price and the forecast that is here. But I also don't see the increase investment in R&D. For example, in 2018 it approached $5.7 billion. So, I can see here these are numbers that are forecast.

Mr. CONNOLLY. Well, I will just end here. That difference—that difference means that for an American consumer dependent on this lifesaving drug, it can cost more than $16,000 a month, and I don't think that is an appropriate cost.

It is not a bearable cost for most Americans, and that gives them the kind of choice the chairwoman showed us in the videos, heartbreaking videos of American consumers who are forced with kind of price escalation to make the terrible choice between controlling their illness or letting it go, and that ought not to be the kind of Sophie's Choice any American faces.

I yield back.

Chairwoman MALONEY. The chair now recognizes Mr. Hice.

You are now recognized for questions.

Mr. HICE. Thank you, Madam Chair, and I want to thank all of our witnesses for being here today as well and for the difficult task that you have of working through R&D and trying to make a profit while at the same time provide medications not only here in the United States but abroad.

I do wish that my friends on the other side of the aisle, if they were serious about true reform and lowering prices we would be looking at something like H.R. 19 instead of pushing something like H.R. 3, which we all know would not help lower drug prices and, again, as I mentioned earlier in my opening statement there would be fewer drugs available as a result of H.R. 3.

And this is not just me saying words. This is according to the CBO, and they confirmed that there would be a loss of cures available on the market, and I don't know why that in any shape, form, or fashion is considered to be a good idea. Seems like a poor idea. In fact, it seems like a dangerous idea to go down that path.

So, for whatever reason, some of my friends on the other side, at least the appearance is that it is worth it to lose cures, potential cures, in order to push H.R. 3 through as opposed to H.R. 19, the Republican legislation which addresses many of the issues, frankly, that we are talking about today without destroying the market the free market, innovation, the ability to get drugs through the process and to people who need it.

I mean, just think of it. Again, eliminating any cure, any cure, for whatever the disease might be, from Alzheimer's to sickle cell to various cancers, ALS. I mean, you name it.

Which one of these diseases with a possible cure that could not come to the market would—that is unsatisfactory. We just simply cannot go down that path of eliminating any potential cure for some of these serious diseases.

H.R. 19 would have capped seniors' out-of-pockets costs. It would have required insurance companies to make information about drug costs available while in the doctor's office, and a host of other things.

So, I want to thank each of the companies who are here today. I know every one of you are involved in developing treatments and vaccines for—potentially, for COVID–19 and this, again, highlights how important the investments are that you make, and policies that incentivize investment in pharmaceutical innovation is a good thing, and that is where we need to be focused.

Of course, right here in the United States no doubt this is the epicenter of research and development for a host of diseases and that includes COVID–19.

And, finally, I want to just acknowledge and thank the administration for the great work that they have done in lowering drug prices.

As you can see from the poster behind me, there has been drastic decrease in prices, and you look at this and beginning—and by the way, this is stats from the Bureau of Labor Statistics, but in June •19 the U.S. saw the largest single year drop of prescription drug prices since 1967. This is great progress in the right direction.

The FDA approved a record number of affordable generic drugs last year for the third consecutive year. That would be under this current administration.

In October 2017, the FDA published a list of brand drugs that are off patent and off exclusivity without any generic competition and they announced that they will expedite a review of the generics submitted on that product list.

In October 2018, the FDA approved 110 generic drugs and tentatively approved 18 more. All of this results in a $26 billion reduction in cost. Twenty-six billion dollars in cost savings.

And then we have also some executive orders from the president, four of them, to lower the cost of drug prescription prices. So, this is a huge issue.

We are moving in the right direction and, again, I want to thank our witnesses and these companies for being here. I think we need to get beyond talk and look at actual action that is taking place to lower prescription drug costs.

And with that, Madam Chair, I will yield back. Thank you very much.

Chairwoman MALONEY. Thank you.

Mr. Cooper, you are now recognized and you must turn your video on.

Mr. Cooper, you are now recognized.

[No response.]

Chairwoman MALONEY. OK. We are having some technical difficulties.

I now recognize Mr. Raskin. You are now recognized. We will go back to Mr. Cooper later.

Mr. Raskin?

Mr. RASKIN [continuing]. So, I used that by contrast to a majority of all the states shall be necessary. It is your choice.

So, you know, I am not saying what——

[Inaudible.]

Chairwoman MALONEY. OK. We are—we are now—we have some technical problems. We are now going to Ms. Wasserman Schultz. You are now recognized.

[No response.]

Chairwoman MALONEY. Robin Kelly, you are now recognized.

Ms. KELLY. Thank you, Madam Chair, and I thank the committee for bringing us together to discuss drug affordability, and I thank all of our witnesses for being willing to testify today.

The medications each of your companies make are critical to the patients they serve. Yet, the cost of these medicines can make them unaffordable, putting lives at risk.

Dr. Caforio, does your company have any programs or initiatives to help patients afford Revlimid? Have you expanded these programs during the current COVID–19 discussion? If not, can you share why not?

[No response.]

Ms. KELLY. Can't hear. You are on mute.

Dr. CAFORIO. Can you hear me, Congresswoman?

Ms. KELLY. Yes.

Dr. CAFORIO. Thank you for your question.

Yes, I would like to say, first of all, that it is absolutely important, essential for us, that any patient that needs one of our medicines has access to it. In answering your questions, we have a number of programs to help patients and I will just mention a few examples.

Through our foundation, we provide free medicine to patients that are in need and eligible. These are mostly uninsured or under insured patients.

In one year, Bristol Myers Squibb provides approximately $2 billion of free medicine for patients. In the U.S., we help 100,000 patients every year.

For Revlimid specifically, in 2019 we provided, in that case through Celgene, approximately $500 million worth of free products.

We also provide a co-pay assistance program support to patients that have commercial insurance and have challenges with paying their co-pay, and for Revlimid specifically that support was approximately $20 million last year.

We did act quickly at the beginning of the COVID pandemic because we thought it was really important to do that. So, we expanded our program, and for any U.S. patient that lost their job or insurance because of COVID, they are receiving any Bristol Myers Squibb medicine for free.

Additionally, we do make contributions to independent charitable organizations because we do know that there are patients we cannot help directly and we do make those contributions so that patients can have access to grants and support their out of pocket cap.

We do understand, and I do, that all of those are solutions that may help some of the patients. When you look at the totality of our program we believe we have a program that is as broad as we can implement.

We definitely would like to do more, and I would like to work with the committee to think about policy reforms that can help companies like Bristol Myers Squibb help even more patients.

Ms. KELLY. I know Bristol Myers Squibb has expressed a commitment to addressing health disparities including a $300 million investment announced last month.

But with the skyrocketing prices, you know, that could exacerbate the same health disparities and, specifically, Revlimid can be used to treat multiple myeloma. Incidence of multiple myeloma in African Americans is two to three times that in whites. A $300 million investment does not erase the health care disparities issues.

So, what impact have you seen with the increasing price? What impact has it had on minority communities in particular, and does increasing the price lead to less access for those groups?

I am not sure if you track it or not.

Dr. CAFORIO. Well, Congresswoman, we do know and I think the COVID pandemic this year has demonstrated very clearly to all of us that some communities are disproportionately more impacted, and we try to help in many different ways.

As I mentioned, we expanded our support programs that are able to provide our medicines for free to many more patients this year.

That includes underserved communities and those communities that have been impacted more.

Ms. KELLY. Do you track that? Do you track how many in those communities are taking advantage?

Dr. CAFORIO. I don't have exactly the statistics yet. But we are tracking the utilization of our programs and I would be happy to followup with you because——

Ms. KELLY. Yes, I would love to see that.

Dr. CAFORIO [continuing]. It is really important.

Ms. KELLY. I would love to see that.

Dr. CAFORIO. Absolutely.

Ms. KELLY. Thank you. My time is up. Thank you, Madam Chair.

Chairwoman MALONEY. Thank you.

Congressman Cloud, you are now recognized.

Congressman Cloud?

Mr. CLOUD. Thank you. Appreciate you holding this hearing. This is, certainly, extremely important to the people we all represent and something we know we have needed to deal with for quite some time now, the extraordinary increase in drug pricing.

Dr. Caforio—really, probably any of you could speak to this, but Dr. Caforio, could you speak to—this is a hearing on drug pricing.

Could you speak to the pricing system, so to speak? The difference between what you price a drug at and what the customer pays and kind of the process it goes through, kind of a brief explanation?

Dr. CAFORIO. Yes. Thank you, Congresswoman. I would be happy—Congressman, sorry—I would be happy to do it.

Let me just start by saying that the pricing systems in the U.S. are very complex, and one of the objectives we should have working together is to resolve some of that complexity and realign the incentives to make sure we help the patients better.

We do price our medicines in the U.S. based on the value they deliver to patients, to health care systems, to society, and we do take patient affordability aspects into consideration because they are very important to us.

The system, as I said, is complex in the commercial space, so for patients that have insurance through their employer, of course, we work with insurance plans and PBMs to ensure that our products are reimbursed and often provide very significant rebates and discounts. We would like to see those transferred to patients and they often are not. This is an area that is important to us.

Of course, the focus of today is primarily on the important government program Medicare, and in Medicare as well across many areas, there are, of course, plans that manage that program and there is significant competition in Medicare as well and for some products that results in——

Mr. CLOUD. I am going to—I am going to break in here for a second because we got—running out of time here. But, basically, this is—would you say this is somewhat an accurate chart as to drug pricing scheme?

Dr. CAFORIO. Congressman, it is difficult for me to see it. But——

Mr. CLOUD. OK. Well, the thing that I would note is that there is manufacturers, drug wholesalers, pharmacies, PBMs, pharmacy

benefit managers, and we are speaking only to the manufacturers today.

And I would just suggest that while there is definitely a lot we need to talk to manufacturers about if we are going to come up with a good pricing—if we are going to have a true discussion about that that we probably need to bring these other elements into the discussion as well.

Over the last few years, of course, we know that the Trump administration has produced record number of generics. They have approved a number—they have approved three years in a role a record number of generics. Do generics generally bring the pricing down for the consumers?

Dr. CAFORIO. Yes, Congressman, and in fact, 90 percent of prescriptions in the U.S. are for generics.

Mr. CLOUD. OK. And the other two CEOs would agree with that?

Mr. SCHULTZ. This is Kare Schultz. Thank you for that question, Congressman Cloud.

Yes, generics definitely brings down the price dramatically, and as it was just stated by Dr. Caforio, more than 90 percent of the prescription volume in the United States is from generics. We are very proud to, basically, provide one out of 10 prescriptions of generics in the U.S.

The pricing typically drops by somewhere between 60 and 99 percent within a year from the launch of a generic version of a drug.

Mr. CLOUD. OK. And we also know President Trump also passed an executive order dealing with most favored nation status to gauge our pricing more on an international price index.

And then as Mr. Hice mentioned, 2019 was the largest drop since, I think, 1967 for prescription drug pricing. It is also interesting to me that, you know, while we have H.R. 3 out there, which is, again, an attempt to kind of take over this from a government standpoint, we have another option out there, H.R. 19, which does address pay for delay, product hyping, patent evergreening, which are serious issues that need to be dealt with.

And, certainly, you know, I think we all agree it is a bipartisan issue that we want to lower drug pricing. But as we have seen with the Obamacare and Affordable Care Act, the intentions don't necessarily turn into actual policy. When we saw the attempt to get everybody health insurance actually led to extraordinary increase in health insurance with actual decrease in actual care.

So, it is extremely important that we make sure that we are equipped to deal with this properly.

Now, one question I do have—oh, my apologies, Chairwoman. I read the clock wrong.

Chairwoman MALONEY. OK.

Mr. Raskin, you are now recognized.

Mr. RASKIN. Thank you very much, Madam Chair, for calling this extremely important hearing.

Mr. Schultz, I have questions for you. The prices of your product, Copaxone, have gone way up over the last two decades. It is more than 10 times what it used to cost. Your profits have been soaring. It is in the billions.

The executive compensation has increased dramatically. I understand your top executives are all making $4 million, $5 million, $6 million.

By the way, what is your salary, Mr. Schultz?

Mr. SCHULTZ. I have a salary which is combined of different elements. But, basically, my sort of the basic salary would be $2 million and then I would have——

Mr. RASKIN. What is your total compensation package you negotiated for when you accepted the job?

Mr. SCHULTZ. The ongoing compensation package was in the range of $12 million——

Mr. RASKIN. Twelve million. OK. So I want to ask about R&D because we have heard already today inevitably that the exorbitant prices that d,rug companies are charging for medication in America are necessary to invest in research and development.

In just a little example, Copaxone cost our constituents $126 a day, which is four times what it costs in Germany, $33 a day, five times what it costs in the United Kingdom, $25 a day, and seven times what it costs Vladimir Putin's constituents in Russia, $18 a day.

But we are told if we put any limits on price increases in America, which is the only country on Earth which doesn't limit drug prices, we will stifle innovation. We will deprive our people of the next cure, and we take that seriously.

That is a sobering answer to us when people complain about the skyrocketing price of prescription drugs because R&D is costly and critically important to discovering the next treatment or next cure of the killer diseases.

But our examination of your company data, Mr. Schultz, reveals that Teva is not investing nearly as much in R&D as big pharma might lead the American people to believe and, certainly, not enough to justify the extraordinarily high prices our constituents are paying while, you know, there is something of a bonanza for the salaries of the executives of the company, and so on.

Your companies raised the price of Copaxone 27 different times since bringing it to market more than two decades ago. Its current price is $7,114 for a monthly course.

Has your company ever justified these price increases by claiming that its Copaxone revenues are used to invest in scientific research and development?

Mr. SCHULTZ. Congressman, thank you for that question.

The way that pharmaceutical products are priced, and let me just state up front that I was not there during this time you are referring to for Copaxone. I only started late 2017.

Since then, we have not increased the price of Copaxone and we have actually significantly decreased the next sort of——

Mr. RASKIN. OK. Forgive me, because I am running out of time.

So, the fact is that your company's talking points that were produced to this committee—it is page 5 of Exhibit 57 in the materials—show your executives being directed to justify price increases for Copaxone on exactly this basis, quote, "so the company can invest in researching new developments that directly translate to increased options for Copaxone patients." In other words, it is an echo of what we have heard from some of our colleagues today.

But other documents your company produced to the committee directly contradict those talking points. Take a 2016 internal presentation to the board of directors, which indicated that Teva spent the least amount of money on R&D among all major pharmaceutical companies. I want to put that slide on the screen, Madam Chair. It is Exhibit 56.

[Slide.]

Mr. RASKIN. And, Mr. Schultz, do you know how much your company has spent on Copaxone R&D compared to what it has made in profits on Copaxone? And I understand that you are relatively new to the company.

Mr. SCHULTZ. Yes. So, I wouldn't know the details of that. No, I don't know——

Mr. RASKIN. All right. Let me—let me give you the details then.

Your company has made more than $34 billion—$34 billion—from Copaxone but it reported to the committee that it has spent two percent of that on R&D expenditures for Copaxone patients. So, in direct contradiction to the talking points that we got from your company and that we are hearing today, Teva could not report to the committee a single R&D expenditure that took place after 2015.

Yet, there have been multiple price increases since 2015. How would you justify that to the kind of patients that we saw on the video at the beginning of our hearing who cannot make ends meet, who are desperate, who are talking about selling their cars, selling their houses, having to move?

How can you justify increasing the prices of this desperately needed drug while there have been no investments in scientific research and development while those price increases are being imposed?

Mr. SCHULTZ. First of all, as you know, I didn't join the company until the end of 2017.

Mr. RASKIN. So, you don't justify it. You think it was wrong. And have you been brought in to clean house?

Mr. SCHULTZ. I have been brought in because the company came into financial trouble for a number of reasons, one of them being the patent expired for Copaxone and the associated price decline, the other one being having put on major debt and that meant that I was brought in to, basically, restructure the company and reduce costs so that the company could honor its commitments in terms of its financial——

Mr. RASKIN. So, the company got addicted to the cash cow of Copaxone——

Chairwoman MALONEY. The gentleman's—the gentleman's time has expired.

Mr. RASKIN [continuing]. And when there was some competition, then at that point it became a crisis.

Chairwoman MALONEY. The gentleman's time has expired.

Mr. RASKIN. Madam Chair, this is precisely why we need to give the government and Medicare the power to negotiate for lower drug prices because our patients and our taxpayers are getting ripped off by big pharma.

I yield back.

Chairwoman MALONEY. I agree.

Mr. Norman, you are now recognized for questions.

Mr. NORMAN. Thank you, Ms. Chairman. I just want to thank you for holding this hearing.

You know, one thing is you hear both sides discuss the problems we face with high drug costs. Here is what we agree on. Miracle drugs that cure cancer, cure a lot of the illnesses we have, are no good if our patients can afford it.

Second, I agree that the price of insulin, as an example, which has been around a hundred years or more, that doesn't require any research and development, that ought to be stopped.

And the difference, I think, in both—in my friends on the other side of the aisle, they look to just government. Let us let government get involved.

Now, on our side, you have heard a lot of different testimony about H.R. 19. Let us look at the one thing that helps this great American system thrive is the competition will bring down pricing.

So, I would ask my friends on the other side of the aisle, H.R. 19, take a look at it. It stops companies from withholding generic drug samples.

It stops the exclusivity of products as insulin that has been around for a long time, for prices to be hiked up. It stops product hopping where a company will say that one—they introduce a drug that has—there is no difference in getting a higher price when the drug does exactly the same thing as the old drug.

That is the type thing we ought to be looking at, and I would urge my colleagues on the other aisle to take a look at this. Public disclosure of pricing ought to be highlighted.

So, I would urge you to look at H.R. 19. One of the things I am really interested in is the PBMs. Could any of the panelists, any of our witnesses, go into the effects that—of pharmacy benefit managers and how it affects the drug prices?

Anybody?

Dr. CAFORIO. Congressman, thank you. I am happy to provide my perspective.

First of all, let me say that as I mentioned earlier the pricing system in the U.S. is really complex, and I do agree with you that our objective is that every patient that needs one of our medicines has access to it.

Specifically——

Mr. NORMAN. I agree with you. But it is at an affordable price. Every patient needs it, but if you can't afford it what good is a drug?

Dr. CAFORIO. I agree with you, and that is why we do everything we can to help patients with affordability programs to be able to afford their medicines.

There is one area where we would like to be able to do more, which is to provide patients with Medicare co-pay assistance. That will be extremely helpful for patients that are struggling to afford their out-of-pocket costs.

We also support measures such as introducing out-of-pocket caps in Medicare, which would be, again, really helpful to some of the patients that are struggling with our medicines.

Specifically to your question on PBMs, PBMs play an important role. At the same time, our concern is that the significant rebates

and discounts that the industry provides for some medicines in order to have formulary listing don't make their way to patients at the pharmacy counter, and our perspective is that patients should be benefiting from those rebates and discounts and our industry would be supportive of reform that looks at that anomaly and realigns incentives so that the discounts we provide can make a real difference in terms of affordability for patients.

Mr. NORMAN. Then I would ask your company to lead the way. Get us a blueprint what would do just what you said where patients can afford drugs, as an example, insulin, that is unaffordable for so many families. How about you leading the way with that?

Let me hear from the other witnesses.

Mr. SCHULTZ. This is Kare Schultz from Teva. Thank you for that question, Congressman Norman.

The PBMs, they play a significant role in that they consolidate and negotiate on behalf of managed care plans and other customers that they had who, again, of course, take care of the patients that are insured under those schemes.

It is correct that over the lifetime of a pharmaceutical product the rebates typically increase as time goes on and more competition enters into the marketplace, and it is not abnormal to see rebate levels somewhere between, let us say, 25 percent and 65 percent.

And, of course, it matters a lot to patients that the rebates are actually passed on to the patients and, therefore, there has been a lot of debate and pharma has also been supporting that the rebate structure could be more transparent than it is today. So, I think that is the difference in——

Mr. NORMAN. Transparency. Let me—I am running out of time. Transparency. Help us do that. Help us see what PBMs negotiate and what they charge the groups that they are selling products to. Help us more—have more transparency with that.

I yield back.

Chairwoman MALONEY. The gentleman's time has expired.

The gentleman's time has expired.

Mr. Mfume, you are now recognized.

Mr. MFUME. Thank you very much, Madam Chair. I am particularly thankful that you are holding this hearing.

Five months ago, I was re-elected again to fill this seat, a seat that was previously held by my dear friend of 42 years, Congressman Elijah Cummings, and I appreciate the comments that I have heard earlier with respect to those of you who served with him and miss him like we all do.

Congressman Cummings represented Maryland's Seventh congressional District for 23 years, and throughout his time in Congress, he championed a lot of things, but nothing more dedicated than this effort to lower cost of prescription drugs. In fact, on March 8, 2017, Congressman Cummings went to the White House to meet with President Trump about this and to talk about a key piece of legislation that we are here talking about today that would give the Federal Government the authority to do a number of things, but most of all to drive down the price of prescription drugs. That legislation would guarantee real price reductions on what was then and what continues to be now soaring prices of these drugs.

According to his own statement following the meeting that day, Chairman Cummings said the President "seemed enthusiastic about the idea and pledged—pledged—to work together to pass the legislation." But despite numerous good faith efforts by Chairman Cummings to followup, President Trump never responded. He abandoned his commitment to work jointly, and he instead issued a statement saying, and I quote, if the bill were presented today in its current form, he would, in fact, veto it.

So, in many respects, we are here today because President Trump failed to fulfill his promise. As a result, seniors and retirees and others continue to face immeasurable suffering simply because they can't afford to buy a pill or to take a shot. Their pain and their suffering can't be quantified, but the collective costs of the greed of big pharma can be calculated.

Take, for example, the Teva Pharmaceuticals company, which we have heard from today, and their CEO. A drug, as we all know and has been mentioned, has been used effectively to treat multiple sclerosis. Since 1997, Teva has raised the price of the drug 27 times, 27 times, to its current price of $5,800 a month. That is nearly seven times more expensive than when it was first introduced. Between 2002 and 2016, Teva's U.S.

[inaudible] $11 million to $3.3 billion.

So, Mr. Schultz, I would like to start with you, and I know we are challenged by time here. We are all limited. The good thing is that this hearing will go on for a while. It is my understanding, sir, that Teva negotiates directly with Government players like Veterans Affairs. Is that correct?

Mr. SCHULTZ. That's correct, sir.

Mr. MFUME. And it is also my understanding that Teva does not directly interact with or negotiate with Medicare. Is that correct?

Mr. SCHULTZ. We do negotiate with Medicare plans. So, the way it works is that we will negotiate with a Medicare plan, which would be run by an insurance company typically. So, not directly with Medicare, per se, but with a Medicare plan represented by an insurance provider——

Mr. MFUME. And that is indirectly. So, if Teva negotiated directly, which is what I am asking, would that, in your opinion, lower the cost of Copaxone?

Mr. SCHULTZ. Now that's a very complex question to answer because it could go both ways, and the reason why it could both ways is that it really depends on the circumstances—how many competitors are there in the market for the drug, how many patients are there in that plan that you are discussing. So, it is very complex——

Mr. MFUME. But Mr. Schultz, in all likelihood, the answer probably would be yes. I think you would agree with that. I mean, otherwise, why even enter into the negotiations?

Let us talk about 2013. That year, the average net cost, meaning the cost after discounts, that the VA paid for Copaxone was $2,019. Do you know the average paid that same year by Medicare for the drug, sir?

Mr. SCHULTZ. No, I don't know that, sir.

Mr. MFUME. It was $4,200, twice as much. So, that is quite a difference in a drug going to two different agencies within the Gov-

ernment simply because the Government prohibits one of the agencies from not negotiating at all.

My time is just about expired, sir. But can you give us, in your opinion, since you have been with the company now for the last 30, 36 months, what do you suggest we do at this particular point in time as a legislative body, and what do you suggest Americans do, whose hands are tied and who need the drug?

Mr. SCHULTZ. So, I would like——

Chairwoman MALONEY. The gentleman's time has expired, but Mr. Schultz may answer the question, please.

Mr. SCHULTZ. Thank you very much, Chairwoman.

So, I'll need to give you two different answers because there are two parts in your question. The first part is what do I suggest that could be done to the U.S. healthcare system? This is a very difficult question about a very complex system, which is a huge organism, as we just saw, with many, many different players taking part in it.

What is important is, of course, to secure innovation and secure access. I think we can all agree to that. But I also think it's important to try and make the system slightly less complicated because it's very difficult, even for a pharmaceutical manufacturer as we are, to see through the system and understand what is actually happening.

And one of the reasons why you might see let's say more preferential access in time of negotiations, as you saw with the VA, is also because they offer a very simple model. They will offer and say, OK, we will buy X million of X doses of something. And then, of course, just like if you go to a big store that sells 1,000 pieces at a time, you get a cheaper price than if you buy one at a time.

So, the whole complexity of the system is a part of what is driving overall cost, where some—other healthcare systems are less complex. So that's one element.

The other element to your question is what about Copaxone right now? And I'm sorry that I have to repeat myself, but the price of Copaxone has collapsed. The revenues of Copaxone for Teva Pharmaceuticals has collapsed. The irony is that's the reason why I came into the job I have today, because we've been lowering the price of Copaxone ever since I joined the company at the end of 2017.

So, the price you mentioned before——

Mr. MFUME. Madam Chair, I know I don't have any time here.

Chairwoman MALONEY. OK.

Mr. MFUME. But to use the word "collapse" after you have raised the drug price 27 times. So, did it collapse by two percent? Is that a real collapse? I think we ought to be careful with the way we use wording here, and to suggest to the American public, after you have raised the price 27 times, that it collapsed is a little bit misleading.

I yield back, Madam Chair.

Chairwoman MALONEY. Mr. Keller, you are now recognized for questions.

Mr. KELLER. Thank you, Madam Chair.

Americans pay too much for their healthcare, and the rising cost of prescription drugs needs to be addressed through bipartisan co-

operation. Now more than ever, we need to ensure that patients, especially those with preexisting conditions, have access to affordable prescription drugs.

Having traveled around northeastern and north central Pennsylvania meeting with patients, hospital administrators, and medical professionals who have repeatedly told me, among other things, that the best way to tackle the issue is to address patient reform and get generics to market faster, pursue price transparency solutions so consumers know the true cost of their medication, and incentivize innovation to help find new cures.

There has been some discussion today around H.R. 3, a partisan Government-centric approach that would allow the Government to set prices through forced negotiation, resulting in fewer cures and less innovation in the pharmaceutical drug market and ignoring the good bipartisan work done on this issue that would make significant progress toward lowering drug prices. H.R. 19, the Lower Costs, More Cures Act, introduced by Energy and Commerce Committee Ranking Member Walden, would improve price transparency so that patients can have access to more information and shop the marketplace as a true consumer, get generics to market faster, and encourage innovation, instead of stifling it as H.R. 3 does.

I do have a question for Dr. Caforio. Some of my colleagues in Congress support moving toward socialized medicine. Can you speak to the effects of socialized medicine on the pursuit of medical innovations such as Revlimid and other drugs designed to treat cancer?

[Pause.]

Chairwoman MALONEY. Can you please unmute so you may answer the question?

Dr. CAFORIO. Yes, Congressman. Can you hear me?

Mr. KELLER. Yes, we can now.

Dr. CAFORIO. Thank you. Thank you for your question.

Well, let me start by saying I am a physician by training. I was trained in Europe. I had the opportunity to live in multiple countries, and I've been working and living in the U.S. for most of my career. And I've had experiences with multiple healthcare systems around the world, and access to new medicines for patients is the number-one priority.

I want to emphasize that when we develop and introduce a new cancer medicine in the United States, that is available to patients immediately. And of course, we need to work to make sure it is affordable to some of the patients that are struggling today.

I do have experience with countries where there is a significant delay with new patients having access to medicines. I can tell you that one of my experiences is in multiple myeloma, where innovative cancer medicines have increased the survival of patients with multiple myeloma after five years from 10 percent to over 50 percent in the last 10 years. And I do know that the medicines that are responsible for this improvement are still not available in more than one country around the world.

So, I think our objective should be to address the challenges that exist with the affordability of medicines for patients in the U.S., of course. We must be working together to make sure that no patient

has the experience we heard earlier this morning. But it is absolutely essential that we continue to reward innovation and that we are able to provide a new medicine when it is available to every patient immediately.

Mr. KELLER. Thank you. I appreciate that.

I have heard several times during the hearing this morning that the pricing system in the United States is very complex, and my colleague from Texas, Representative Cloud, had a chart that shows the many different parts of the system, from manufacturers to the PBMs and so on. And the people I see in the room today, you are just one part of the entire system, from manufacturing the drugs or producing the drugs to getting it to the patient.

None of you witnesses with us today have any other role other than being the manufacturer of the drugs? Is that correct?

Dr. CAFORIO. That's correct.

Mr. KELLER. So, I would think that if we have a complex system and there are many parts to it, if we really wanted to get down to making sure that the drug was produced and delivered to the patient in a cost-effective way so that it was affordable, instead of having just one part of the supply chain in the room today, the committee—the majority in the committee would have invited everybody in that supply chain to make sure we could come up with a solution that would benefit us and get toward a real solution, rather than just some messaging.

So, I yield back. Thank you.

Chairwoman MALONEY. The gentleman's time has expired. The chair recognizes Ms. Wasserman Schultz. You are now recognized for questions.

Ms. WASSERMAN SCHULTZ. Thank you, Madam Chair.

Encouraging generic competition is crucial to ensuring that brand-name drugs become more affordable, but some drug companies have resorted to exploitative tactics that delay generic competition, which is——

Chairwoman MALONEY. Representative, would you turn your video on so we can see you? By law, we have to have your video on as you speak.

Ms. WASSERMAN SCHULTZ. My video is on.

Chairwoman MALONEY. Thank you.

Ms. WASSERMAN SCHULTZ. At least on my end, my video is on. All right. Can you see me now?

Chairwoman MALONEY. Yes, we can see you now. Thank you.

Ms. WASSERMAN SCHULTZ. All right. Let me begin again.

Encouraging generic competition is crucial to ensuring that brand-name drugs become more affordable, but some drug companies have resorted to exploitative tactics that delay generic competition, which, in turn, keeps drugs high for patients.

Mr. Alles, I would like to ask you a few questions about Celgene's use of its safety program as it relates to Revlimid, the oral chemotherapy treatment. As a breast cancer survivor, the high cost of cancer treatment is very personal to me. A Risk Evaluation and Mitigation Strategy, or REMS, is an FDA-required program that ensures that high-risk drugs are used safely.

Mr. Alles, I am sure you are familiar with this program and that manufacturers are not allowed to use REMS to impede generic manufacturers' applications to FDA. Is that right? Mr. Alles?

[Pause.]

Ms. WASSERMAN SCHULTZ. Madam Chair? Mr. Alles?

Chairwoman MALONEY. Mr. Alles, please unmute and answer the question.

Mr. ALLES. I did hear the question, and you are correct, Congresswoman.

Ms. WASSERMAN SCHULTZ. OK. FDA required Celgene to implement a REMS safety program for Revlimid due to its risk for use by pregnant women. As a mother of three, this is something that I can certainly appreciate, and still, I think it is important to understand implementing this program for its intended purpose.

This program is supposed to be used to protect patient safety. Correct, Mr. Alles?

Mr. ALLES. That is the goal of the program, yes.

Ms. WASSERMAN SCHULTZ. OK. And Mr. Alles, did Celgene also view the REMS program as a way to delay generic entry?

Mr. ALLES. We did not. As I said in my prepared testimony, we did offer to sell and would sell samples of our products to generics once they agreed to our common sense safety standards and an indemnification process.

Ms. WASSERMAN SCHULTZ. Thank you. Let us take a look at a slide from a Celgene internal presentation about its REMS program. This is Exhibit 11.

See the second key discussion point. Celgene viewed the program as useful for the "prevention of generic encroachment."

Mr. Alles, prevention of generic encroachment just means to delay generic competition. There is just no other way to read that. So, I will ask you again. Did Celgene use its REMS program to try to prevent generic competition, yes or no? And you are looking at a document that whose definition, "prevention of generic encroachment," would seem to be exactly that.

Mr. ALLES. I see the slide, and I understand some of the words, but I don't know the context. And what I can say——

Ms. WASSERMAN SCHULTZ. Oh, come on. Come on.

Mr. ALLES [continuing]. Is that a generic—a generic manufacturer would need to replicate the exact same standard in the branded version of the REMS program. So, as long as the generic, with their abbreviated application, would, in fact, meet that same rigorous standard——

Ms. WASSERMAN SCHULTZ. OK.

Mr. ALLES [continuing]. Then, yes, it would be approved.

Ms. WASSERMAN SCHULTZ. Thank you. Reclaiming my time, according to the FDA, Celgene's REMS program delayed 14 generic manufacturers from purchasing enough samples of Revlimid to obtain FDA approval. And while these samples were eventually provided, an expert analysis estimated that the delay cost consumers as much as $637 million.

Who knows how many cancer patients skipped, split, or rationed the medication because you were able to keep competitors at bay and prices high with these anti-competitive tactics.

Isn't it also true that Celgene even tried to obtain usage of safety—isn't it also true that Celgene even tried to obtain additional patents on the REMS program itself?

Mr. ALLES. I'll begin with the second question, Congresswoman, and in fact, we listed, pursuant to statute and regulations, a patent on the REMS program that we created in conjunction with the FDA for the safe distribution of medicines that you know one dose in a pregnant female would lead to severe birth defects.

Ms. WASSERMAN SCHULTZ. No, no, no——

Mr. ALLES. So, we did—we did patent that——

Ms. WASSERMAN SCHULTZ. Reclaiming my time——

Mr. ALLES [continuing]. Pursuant to regulation.

Ms. WASSERMAN SCHULTZ. Reclaiming my time, the FDA very specifically said that they did not think that providing samples to generic manufacturers would create a safety concern, and you very clearly in the company's own presentation define "generic encroachment" as a key goal. There is no—anyone with common sense understands that generic encroachment meant that you were trying to block other generic companies from being able to get access to develop the drug.

Thankfully, Congress has created—has acted to address inappropriate usage of safety programs through the CREATES Act last year. But this example demonstrates how drug companies will continue to exploit loopholes unless and until Congress acts to close them, regardless of whether these strategies inflate the cost of medications for people living with cancer. And that is exactly what your heinous policy that your company has followed has allowed.

It is unacceptable. It is offensive to me as a cancer survivor, and I really strongly suggest that you take back to your company just the things that have come to light here and rethink the way you handle the process of approving generic competitors to access the materials they need to produce the drugs.

Thank you, Madam Chair. I yield back.

Chairwoman MALONEY. Congressman Grothman?

Mr. GROTHMAN. Can they hear me? First of all, for Dr. Caforio, when did BMS acquire Celgene?

Dr. CAFORIO. Congressman, in November 2019.

Mr. GROTHMAN. Two thousand and when?

Dr. CAFORIO. Nineteen. Last year.

Mr. GROTHMAN. OK. And what was the list price for Revlimid immediately prior to the acquisition?

Dr. CAFORIO. I don't have that figure in front of me, Congressman. I know we had provided it, and it has been mentioned before in the hearing. I'm happy to give you some information that show up on all the lists, list prices.

Mr. GROTHMAN. I guess what I am looking for, did the price increase dramatically in January 2020?

Dr. CAFORIO. In January 2020, we looked at the price of all of our medicines. When we do that, we consider multiple factors—the value of Revlimid, our investment in R&D in this area, considerations related to affordability. We did increase the price by six percent.

Mr. GROTHMAN. That is all, six percent?

Dr. CAFORIO. Six percent, yes.

Mr. GROTHMAN. OK. Have there been any price increases this year?

Dr. CAFORIO. That was the—that was the one price increase. Our practice has been, since 2018, to limit price increases to only those medicines where we have active and significant clinical research programs ongoing, limit it to six percent. And when you look at the net price of our total portfolio in the U.S., since 2018, it has been flat.

Mr. GROTHMAN. OK. Mr. Schultz, I have a question for you. As I understand it, Teva entered into an agreement with Amgen, which appears to be a pay-for-delay sort of contract. Is that accurate?

Mr. SCHULTZ. I really wouldn't know. If it happened, it must have happened way before I joined the company.

Mr. GROTHMAN. I am sorry. Was there a payment made to delay the introduction of a generic?

Mr. SCHULTZ. No, I'm not aware of that, but it's an allegation which I guess is linked to the period before I joined the company. So, I don't know anything about it.

Mr. GROTHMAN. OK. So, you don't know for sure whether there was such an agreement or not?

Mr. SCHULTZ. No, I'm sorry. I don't.

Mr. GROTHMAN. OK. That is almost incredible, but OK. I will come back to Mr. Caforio. Is there generic competition for Revlimid currently on the market?

Dr. CAFORIO. Congressman, there is not because Revlimid is still protected by patents until 2027. So, its exclusivity has not expired, and the patents expire beginning in 2027.

What I can tell you is that those patents were reasserted last year by the Patent Office, which denied secondary review because of their strength. And they protect important innovations surrounding the invention and development of Revlimid. And there will be patents, patents of Revlimid—sorry, there will be generics of Revlimid in the next few years, beginning in 2022.

Mr. GROTHMAN. Some critics have said that Revlimid is essentially the same as a drug called thalidomide. Can you tell us, is it essentially the same or not?

Dr. CAFORIO. Congressman, that's not my understanding. Revlimid is a completely different medicine that Celgene developed with a 14-year program that started synthesizing hundreds of compounds. It is—belongs to the same class as other medicines, but as it always happens in our industry, every new medicine is developed as a new medicine. It is—it has a different safety profile. It has a different efficacy profile.

It has clearly advanced in the treatment of multiple myeloma. It is an independent medicine.

Mr. GROTHMAN. OK, I will give you a broader question here before I run out of time. Right now, it seems to me from what we see on the Internet that in the United States, per capita, we pay about 50 percent more for pharmaceuticals than Canada, Japan, or Germany, and about twice as much as Italy and Ireland.

To what do you attribute that? It is kind of a dramatic difference.

Dr. CAFORIO. Well, Congressman, the difference comes from the fact that innovation is recognized and rewarded in the United

States, and this is the reason why innovation-based industry is primarily a U.S. industry, and much of the research we do takes place in the U.S. Medicines are readily available to many patients in the U.S. I can tell you in the case of Bristol Myers Squibb, we invest almost $10 billion a year as a U.S. company in research and development, that there are 13,000 dedicated scientists that work at the company, and the reward of innovation for us is really important in order to continue to fund R&D.

We are discussing multiple myeloma, where Revlimid has made a very big difference for patients. At the same time, in the next three years, we will invest more than $2 billion in the development of the next generation of multiple myeloma medicines, and some of them represent extraordinary innovation. And the reason why we can do that is because we have a system that rewards innovation, and that system is one we should be working together on to make sure that——

Chairwoman MALONEY. The gentleman's time has expired. OK, thank you.

Mr. GROTHMAN. Thank you.

Chairwoman MALONEY. I now recognize Mr. Sarbanes. You are now recognized for questions, Mr. Sarbanes.

Mr. SARBANES. Thank you, Madam Chair. Can you hear me OK?

Chairwoman MALONEY. We can hear you, and we can see you.

Mr. SARBANES. Thank you. Thanks for the hearing.

I want to echo those who indicated that we sorely miss Chairman Cummings. On this issue, he was a bulldog. He never let go.

And unfortunately, the President talked a good game. He often talked about how he was going to take on the pharmaceutical industry, but in the end, it turned out he was weak-kneed. He ended up being a pushover. He caved to the industry. And we know that Elijah Cummings wouldn't have done that, and you are not doing that either, Chairwoman Maloney. So, thank you for calling this hearing.

I wanted to just take a moment to address an argument that we heard articulated today by these companies, which is that the pharmacy benefit managers are the ones responsible for these rising drug prices. And look, there is no love lost between me and the PBMs. I know that they dropped the ball on pricing as well, and frankly, I think from the standpoint of the average consumer and patient out there, the pharmaceutical companies and the PBMs and a lot of other players are part of a really kind of broad conspiracy to hike up these prices of prescription drugs.

But nevertheless, I don't think it is fair to try to push the blame off particularly onto the PBMs. It is the pharmaceutical companies.

So, Mr. Alles, let me ask you this. In 2009, the average net price of a unit of Revlimid, meaning the price after removing discounts and rebates, was $294. In 2014, it went up to $396. And in 2018, it was $598. So, your net price more than doubled in just that period of time.

Is it fair to say that Revlimid's price increased at a faster rate than any discounts or rebates provided to PBMs or to others in the supply chain? Mr. Alles?

Mr. ALLES. Can you hear me, Congressman?

Mr. SARBANES. Yes.

Mr. ALLES. Yes, thank you.

I don't have the numbers in front of me, but I trust that the numbers that you've provided are accurate, and it would represent a rapid increase in the net price, as you describe.

Revlimid is a unique molecule, as you heard from Dr. Caforio, in the treatment of rare blood cancers, and in the marketplace, the use of discounting or other contracts or work with PBMs was really not required. It's such a specialty cancer drug for this orphan disease, which affects on average about 50,000 patients a year in the United States, the incidence of new cases of about 25,000 to 30,000 a year. So, it's very much one of those products that is available, and medical hematologists will prescribe it as we distribute it through specialty pharmacies.

So, there really isn't the complexity other than the risk management program that you see with other products like——

Mr. SARBANES. Well, in that case—just to reclaim my time. In that case, you are not really using the rebate or PBM or other mechanics as an excuse for why the price had skyrocketed and more than tripled between 2005 and 2019. That is what we saw in terms of the price hike around Revlimid. So, that really falls on the company. I mean, you are in the position to having to explain why there was such a significant increase there.

But let me go to Mr. Schultz because I am going to run out of time here. Unlike Revlimid, Teva has provided significant rebates for your drug Copaxone. Is that correct?

Mr. SCHULTZ. That's correct, yes.

Mr. SARBANES. Yes. But even with these rebates, before generic competition entered the picture, Copaxone's net price, again after rebates and discounts, increased by more than 75 percent in just eight years. Is that right?

Mr. SCHULTZ. I'm not really aware of that because I wasn't there at the time. So, I only really know——

Mr. SARBANES. OK. Well, it is the case, and I just want to congratulate you on being able to answer, from my estimate, about 50 percent of these questions by saying you weren't there at the time. I understand and appreciate that, but it would have been nice to come maybe equipped a little bit better with what the situation was at the company with respect to these drugs prior to entering there because in some ways, you have a responsibility to have a historical perspective.

But in any event, the net price jumped from $2,214, $2,214 in 2009. It then went to $3,113 and, in 2017, $3,886. And it only decreased, as we discussed, when the generic option came in. So, PBMs had some role in the pricing, and again, I don't let them off the hook. But clearly, the pharmaceutical companies are still a major culprit when it comes to the price gouging, and that is why we are bringing this attention to your activity.

And with that, I yield back, Madam Chair.

Chairwoman MALONEY. Thank you. The gentleman's time has expired. Mr. Higgins, you are now recognized for questions. Mr. Higgins?

Mr. HIGGINS. Thank you, Madam Chair and Ranking Member. Thank you for holding today's hearing, which is focused on a subject that affects everyone in the country.

We are hearing today from my colleagues across the aisle that the solution to the issue of high drug costs is their bill H.R. 3. I have issues with H.R. 3. H.R. 3 would result in a huge expansion of Government control over patients' healthcare that would result in actually fewer cures and less access for Americans to drugs and treatments.

If we were genuinely worried about this issue, then we would work on compromise legislation that would have a chance of making it to the President's desk rather than messaging bills that never had a chance of getting consideration by the Senate, with zero bipartisan input and some very unconstitutional language, in my opinion.

Now that being said, we must recognize as a nation that it is part of a legitimate narrative across the country, the citizens that I serve, we have genuine complaints about the price of pharmaceuticals. So, you gentlemen that appear on this panel today have to answer some difficult, but legitimate questions.

Introduction of generic drugs, I am going to ask Mr. Caforio. Regarding generic drugs, introduction into the marketplace generally produces positive economic benefits for consumers. Would you at least—by the essence of that statement, would you agree with that, sir?

Dr. CAFORIO. Congressman, I fully agree.

Mr. HIGGINS. OK. In the interest of time, it is understood across the board that when generic drugs are introduced into the marketplace, then needed pharmaceuticals become more affordable for regular Americans. And this is the cornerstone of our concern and why you are here today.

So, you had stated in response to another colleague who was questioning you that, the note that I took, you mentioned, good sir, that the drugs that you introduce are unique. They are each unique.

And generally, we would agree with that, but would you please address pharmaceutical companies' tendency to make very small changes in the formula of a drug and, therefore, extend their period of protection and delay the introduction of generic drugs or market that very slightly changed Rx formula through the insurance companies and through the management system that exists. Just talk to us about the just slight change of the formula of the drug and why should that stop a generic drug from being introduced? To me, that is gaming the system.

Dr. CAFORIO. Thank you, Congressman.

Let me just start by saying that our policy is to patent meaningful innovations, and our patents reflect meaningful and important innovations. In many cases, it's about new diseases, new treatments. In some cases, it's about new dosing, the use of different manufacturing technologies. But our approach is to patent meaningful innovation that is beneficial for patients.

Mr. HIGGINS. Would you say that meaningful innovation in the formula of an existing drug that is approaching the expiration of its protection on the patent and you are looking at the introduction of generic drugs with that same formula, would you say a meaningful change in the formula that is not recognized across the board by the medical field and by doctors? If the doctor says it is not a

meaningful change, then how is it that the board of directors in a pharmaceutical company would determine that it is a meaningful change?

Explain to us what you mean, good sir, by a meaningful change.

Dr. CAFORIO. Sure. I believe that for most pharmaceutical products at the time in which we introduce a new medicine, we are just at the beginning of a development program that lasts for many years. And the way we think about meaningful changes are changes that are recognized as innovation that can be patented and innovation that is, therefore, protected.

We think about across the entire period in which we invest in a medicine, and we do that in context in which I and we recognize the importance of generics. In fact, it is a fact that 90 percent of drugs are generics in the U.S. that allows us to be able to continue to have sort of room for innovation.

So, I think that the patent system is designed in order to protect innovation that is meaningful that's determined by us as researchers. It's determined by the Patent Office that grants us with patents. And the objective is to protect and reward the investments we made——

Chairwoman MALONEY. The gentleman's time has expired. Mr. Welch, you are now recognized for questions.

Mr. WELCH. Thank you. Thank you, Madam Chair.

I think one of the reasons that a lot of us are focusing on the executive compensation is that the model is higher prices, higher profits, and higher bonuses. And it is not just that the individuals that are making significant amounts of money, the executives, it is about a significant burden on taxpayers, on the companies that are purchasing employee-sponsored healthcare—or employer-sponsored healthcare, and I want to ask a little bit about that.

First of all, Dr. Caforio, between 2006 and 2017, according to the committee report, the Celgene—the top Celgene executives were paid $400 million. Can you address that?

Dr. CAFORIO. Congressman, as you—as you know, we acquired Celgene in 2019. I'm not familiar with all the details of past compensation of Celgene executives. I'm sure they will——

Mr. WELCH. No, that's in the—yes, that is in the report. Here is my question. Does that in any way seem like a little on the high side to you?

Dr. CAFORIO. Congressman, I cannot comment on those figures. I'm not familiar with them. I do not know what they—what they cover.

Mr. WELCH. It is in the report. So, assuming the report is correct, I am asking your opinion about whether that amount of compensation, $400 million, is on the high side?

Dr. CAFORIO. Congressman, I have received the report just a few minutes before the beginning of the hearing. I don't know what the figure refers to. That would have been a decision of the board of directors of Celgene, and it is not a topic I'm familiar with.

Mr. WELCH. All right. Yes, I am telling you, first of all, what is in the report. So, it is $400 million during that period of time. Executive pay at Teva between 2012 and 2017 was $119 million.

Now sales of your product Revlimid have increased as a result of the Medicare Part D program. Correct?

Dr. CAFORIO. Sales of Revlimid have increased for a number of reasons. The primary reason is the number of indications and diseases the product is used for.

Mr. WELCH. But you are familiar with Medicare Part D that is a benefit to seniors and then enables them through the Government to purchase that product. Correct?

Dr. CAFORIO. Absolutely.

Mr. WELCH. Yes. And the price of one pill is about $719. Is that correct?

Dr. CAFORIO. I am sure it is correct. Yes, Congressman.

Mr. WELCH. Let me go to Mr. Alles. Is it true that Celgene raised the price of Revlimid 23 times after it was brought to market in 2005, including as many as three times in one year?

Mr. ALLES. I will agree that the price has gone up in the 20-time range, Congressman. I don't have the number in front of me. But specific to 2017, I do recall that there were three price increases that year, yes.

Mr. WELCH. OK. And Dr. Caforio, Bristol Myers Squibb increased the price of Revlimid again after acquiring Celgene. Correct?

[Pause.]

Chairwoman MALONEY. Mr. Caforio, would you unmute yourself and answer the question?

Dr. CAFORIO. Thank you, Chairwoman. I'm sorry, but it appears that I need to be unmuted centrally.

Yes, we did increase, Congressman, the price of Revlimid at the beginning of 2020.

Mr. WELCH. And do you know how much the out-of-pocket expense is to a Medicare beneficiary after the Government pays these increased prices?

Dr. CAFORIO. Yes, Congressman, I know. And I know it can be significant. We have looked at that and——

Mr. WELCH. It is $15,000 a year, and the average Medicare beneficiary probably gets a Social Security of about $22,000 or $23,000. Do you know how much Revlimid costs the Federal Government through Medicare Part D?

Dr. CAFORIO. I know, Congressman, that it is a widely used medicine, that it has significant——

Mr. WELCH. Well, it is $4 billion. I really don't understand why you don't know these numbers because these are the numbers that come down to the individual patient who can't afford the out-of-pocket, even with the help of the Medicare Part D.

Did Celgene—Mr. Alles, did Celgene provide discounts to Medicare Part D plans for Revlimid?

Mr. ALLES. We provided all discounts by statute, Congressman, yes.

Mr. WELCH. I don't know that we have any of that information. Would you provide the contracted price reductions information to this committee?

Mr. ALLES. If there were statutory discounts, we provided them. We did not discount Revlimid through commercial plans widely. But yes, we'll followup with any of that information. I don't have it with me today.

Mr. WELCH. All right. Dr. Caforio, has Bristol Myers Squibb begun providing any discounts to Medicare for Revlimid since it acquired Celgene?

Dr. CAFORIO. Congressman, we have continued to provide all statutory discounts.

Mr. WELCH. I do want to go back to this executive pay. Ultimately, that is paid for by taxpayers, employers, and by individual patients. Do you have any reservations about $100 million being paid to six executives over two years?

Chairwoman MALONEY. The gentleman's time has expired, but the gentleman may answer his question, please.

Dr. CAFORIO. Congressman, I—with respect to executive compensation, what I can tell you refers to Bristol Myers Squibb. I'm grateful to be well-compensated. The decisions about our compensation are made by our board of directors, and whether it's about our executives or any employee in our company, they are really structured in a way that looks at compensation across our industry and other industry and creates the conditions for us to be able to attract and develop talent in the company.

Chairwoman MALONEY. The gentleman's time has expired. Mr. Comer, you are now recognized, and you may go over as much time as you need because Mr. Welch did go over time, too.

Thank you.

Mr. COMER. Thank you, Madam Chair.

And I don't believe we can have a credible hearing on unsustainable drug prices without mentioning PBMs. I know a few people have mentioned that today, but PBMs are unnecessary levels of bureaucracy, which, according to every independent pharmacy in my congressional district, have no rhyme or reason for the bills they send to the pharmacies. I think that is something that this committee needs to look into, and I hope, Madam Chair, moving forward that that is an area where we can have bipartisan agreement in exploring what role they play in unsustainable drug prices.

But we are talking about drug prices, and obviously, it is a concern for all of our constituents, regardless of who we represent. But our constituents also rely on new treatments and cures being developed.

Today's witnesses represent two sides of this debate. Teva is the world's largest manufacturer of generics, and Bristol Myers Squibb is one of the largest brand-name manufacturers. So, I would like to ask Dr. Caforio and Mr. Schultz the same question. How do we balance these two objectives?

And Dr. Caforio, representing Bristol Myers Squibb, you can go first.

Dr. CAFORIO. Thank you, Congressman.

I think that balancing the two objectives of continuing to invest in research and development and bringing new treatments and cures to patients with the need to ensure that medicines are affordable to patients is really important. And I would say the most important part for my answer is that I do agree that our system requires change, and I know that Bristol Myers Squibb and the industry is really open to working with this committee, with Con-

gress, with the administration to find ways of evolving our system to become less complex and help patients more.

It is possible to find that balance, and there are some measures we could take immediately. Allowing companies to provide Medicare patients with support, financial support for their copay would be helpful to patients. That could be done very rapidly.

Similarly, introducing an out-of-pocket cap in Medicare would alleviate a lot of the burden that exists today in patients. Ultimately, I think we need to work together to think about how the system evolves to account for the speed at which innovation has happened.

Mr. COMER. From a generic manufacturer standpoint, how would you address that?

Mr. SCHULTZ. Mr. Comer, thanks for the question.

I'd like to give a slightly broad answer, and I apologize if it takes a little while. So, I think the system basically works well, and you can address that from the fact that most of the innovation in modern pharmaceuticals really takes place in the United States. And a lot of new medications have been introduced over the last, let's say, 40 years due to this system. And of course, the system basically rewards innovation by granting patents, which means that for a period of time, the pricing is not the normal competition where everybody can join.

And the reason why that's necessary is that less than 1 out of 100 initial projects actually make it through all the way to the marketplace. The rest, they fail on the way, and that means that that risk nobody would take. If they launched the product, everybody would be copying, and they would never make back their investment.

So, the basic idea about patents works, I think, extremely well, as has been seen by the many, many innovations and the prolonged life span in the big picture of Americans over the past 40 years, which has partly been due to better pharmaceuticals. That being said, of course, you cannot keep on getting that sort of benefit of a patent which gives you a better pricing situation when you launch this product that you've developed over 15, 20 years. That has to stop at a certain point in time, and then prices have to come down for Americans.

I'm happy to report that the generic industry does work very well. It provides high-quality medications based on the initial innovations, and it provides these products at a high quality and at a fraction of the price. And when I talk about very dramatic price reductions, I think that is really the case because most of the generics in the United States today, they probably had a price, a net price which is less than 10 percent of the list price of the originator. So, a price drop of more than 90 percent, that is substantial.

And that system also basically rewards—we saw a graph earlier today of how the total pricing is actually trending downwards in the United States. Now that's a combination of competition on innovative drugs, but also of the competition from generic drugs. Because every time the new drug enters the market, of course, it has some benefits, but the benefits have to be seen in relationship to the pricing. And therefore, the presence of many high-quality generic drugs in the marketplace is a part of balancing the whole market.

So, I believe in a free market——

Mr. COMER. But Mr. Schultz?

Mr. SCHULTZ. Sorry.

Mr. COMER. Mr. Schultz, let me interrupt and ask you this because we are on a clock here, and I have gone over a little bit. What is an adequate amount of time for a brand-name company who invents and gets a patent on a new drug, what is an adequate amount of time, in your opinion, for the patent to exist before generic manufacturers can come in there?

Recognizing the fact that obviously the brand-name company spend a lot of money on research and development. We have all gone over that. But from your standpoint, what is an adequate amount of time before the generics can come in in the marketplace?

Mr. SCHULTZ. Thank you, Mr. Comer.

I believe that the current regulation in the United States is a fair amount of time for the original innovation and for the original patent and, thereby, if they are creating them for the innovation. I think the issue is that sometimes—I'm not saying in any way that any of the companies present would ever do that. But some companies have been seen to make a lot of patents which are not that substantial.

And they have had to be challenged. That's part of the generic business model that we have to challenge these many patents that are often not really living up to the innovation standard that should be in a patent, and then those patents eventually get revoked or turned down. And then the generic can launch.

So, you could argue that somehow it's not the original patent that's the problem. It's not the patent life of the original patent, but it's sometime the sort of exuberance of many surrounding minor patents that really do not have the innovation in them that they ought to have. And that's maybe something you would say that could be looked at more holistically to avoid that you get so many patents around a product that it delays the generic competition.

Mr. COMER. Thank you, Madam Chair. My time has expired, but I look forward to working with this issue—working with you on this issue moving forward. I certainly hope we can examine the PBMs and every other factor that contributes to skyrocketing drug prices for our constituents.

Chairwoman MALONEY. I look forward to working with you.

Congresswoman Speier, you are now recognized for questions.

Ms. SPEIER. Thank you, Madam Chair, and thank you for hosting this hearing.

And to our three panelists, let me start off by saying that what you do is remarkable. You are saving lives with these innovative drugs. Fifty thousand Americans who have blood cancers that Revlimid can assist is remarkable.

But here is the issue. As the President often says, who is the sucker here? The United States is the biggest spender, the Government of the United States is the biggest spender of drugs. We are at 44 percent. In a number of years, we will be at 47 percent. So, the taxpayers are picking up the tab for all of the expenditures of drugs in this country.

If we look at that and then we look at Celgene, which in 2017—in just that one year raised the cost Revlimid 15 percent, 15 percent in one year, that was $3.3 billion in Medicare spending in that one year for that one drug. Between 2009 and 2018, half of all the revenues generated for Celgene in the world came from the United States, $33 billion. And we represent four percent of the population in the world. So, at one point or another, we have got to say are we just suckers?

Now, Mr. Alles, you have a remarkable drug, but your price increases have put this wonder drug out of the reach of most Americans. I would like to first put up on the screen a graph that shows Revlimid's price per pill since 2005. It has gone from $215 a pill to the price today of $765—or $763.

The price for a monthly course in 2005 was $4,500. Mr. Alles, do you what the price of a monthly course of Revlimid is today?

Mr. ALLES. I believe, Congresswoman, it's in the $15,000 range. We heard that number today from a number of people.

Ms. SPEIER. It is actually $16,000. So, why did Celgene raise the price of Revlimid by more than 250 percent over the last 15 years?

Mr. ALLES. During that same period, Congresswoman, the portfolio of Celgene drugs grew from two medicines—are we—I think I'm muted.

Ms. SPEIER. No, you are not muted. We can hear you.

Mr. ALLES. Oh, OK.

Ms. SPEIER. I am specifically asking you why you increased the price of Revlimid 250 percent from 2009 to—over the course of 15 years.

Mr. ALLES. To fund what became a very important portfolio of cancer drugs. Two products are now 10 products, including products that treat pancreatic cancer, breast cancer, lung cancer, different forms of blood cancers, and severe inflammatory diseases. So, approximately 30 to 35 percent of that revenue and the price increase that accompanied the generation of that revenue was reinvested into research and development that has produced some of the most important cancer medicines that we haven't talked about today, outside of Revlimid.

Ms. SPEIER. OK. Reclaiming my time. Sir, you evidently received remarkable compensation in the last two years that you were the president or CEO of Celgene. You and I believe six of your colleagues—or five of your colleagues received upwards of $400 million.

Why are the taxpayers of this country picking up the tab for those extraordinary salaries on top of picking up a tab for an increase in a drug that went up 250 percent so you can fund other drugs? At some point, the Federal Government cannot be the ultimate sucker here.

Mr. ALLES. With respect to Revlimid, the success of one medicine in a pharmaceutical company is often the drug and the revenue that pays for the innovation and the failures across a number of years of development. With respect to compensation, as my colleague Dr. Caforio spoke to, those compensation packages are arrived at through competitive analyses and from our independent board of directors.

In order to build a company that could discover drugs——

Ms. SPEIER. All right. Let me ask you——

Mr. ALLES [continuing]. Like Revlimid, we need a competitive compensation plan to be able to sustain the company.

Ms. SPEIER. I think my time has expired, but Madam Chair, if I could just ask one more question?

Chairwoman MALONEY. One more question.

Ms. SPEIER. I want to know what each of you are willing to do to bring down the cost of drugs to the U.S. taxpayer.

Mr. ALLES. May I go first?

Ms. SPEIER. Of course.

Mr. ALLES. Thank you.

I think that the discussion today is illustrative in that all stakeholders—industry, the PBM insurance industry, and of course, all of you—we need to come together and find as an objective and an outcome of legislation how to cap out-of-pocket costs for patients/beneficiaries so they have the predictability and the affordability that we all want.

I think the way to do that is for industry, along with the insurance industry, to come together with Congress and work together on that goal. The way we pay for that, of course, requires a lot of give-and-take. But if that was the goal of H.R. 19 and H.R. 3, I think we would really be helping the American consumer and the American taxpayer.

Dr. CAFORIO. Congresswoman, from my perspective, I would like to commit to two things. First of all, working with the committee to understand how we can evolve policy in a way that is more helpful to patients.

Specifically, I am supportive, as I have mentioned before, of a company like ours to provide financial assistance to patients in Medicare, to support them with their copay and out-of-pocket exposure, if that will be possible in the future. It's not possible today. I am supporting of working on the establishment of an out-of-pocket cap in Medicare as well.

Ms. SPEIER. Thank you. Yield back.

Chairwoman MALONEY. And thank you. Go ahead.

Mr. SCHULTZ. This is Kare Schultz. So, from Teva Pharmaceuticals, we would be committed in the future to continue to be committed to two main things. The number-one thing is to ensure that we remain the leaders in generics in the United States and keep on supporting patients by always developing and launching generics or biosimilar versions of originator drugs so that they can become accessible and affordable for all Americans.

Besides that, we would also love to work with the committee on increasing transparency and reducing paid by patients in the different channels, be it Medicaid, Medicare, or the managed care segment.

Thank you.

Chairwoman MALONEY. Thank you. We now recognize Congresswoman Lawrence. You are now recognized.

Mrs. LAWRENCE. Thank you, Madam Chair.

I would like to ask a question to doctor—Mr. Caforio. In July 2018, Celgene announced a pricing policy that would limit the price increases to, and I quote, "no more than once a year at a level no

greater than the Centers for Medicare and Medicaid Services' projected increases in the national health expenditures of the year."

So, my question, Dr. Caforio, in the beginning of this year, Bristol Myers raised the list price of Revlimid to $763 per pill, and that was a six percent increase. The projected increase in the national health association for 2020 was 5.4. So, it appears that you have already failed to meet that part of Celgene's pricing pledge.

So, I ask this question. Has Bristol Myers Squibb committed to not taking any further price increases for Revlimid this year?

Dr. CAFORIO. Thanks, Congresswoman.

We are not taking—we will not take additional price increases for Revlimid this year. Our practice has been to look at a number of factors and limit price increases in our medicines to a maximum of six percent and only to those medicines where we have active research and development program ongoing. And that practice has resulted in our net price for the total portfolio of our medicines in the United States since 2018 to be flat.

Mrs. LAWRENCE. So, my question to my colleagues and to you, Doctor, is do we need to set some regulations on R&D? Because it seems like that is the invisible line, how the industry defines R&D, what we see as lay people on the other side trying to protect the American public. Because a drug that is not changing, how are you increasing it, saying it is R&D when it has been approved, the trials have been done, and you are selling it?

So, where is this R&D increase? And my question will be will you commit here today to stop raising the price, moving forward, of Revlimid?

Dr. CAFORIO. So, Congresswoman, there are two important considerations with respect to R&D. First of all, and importantly, when a medicine is first approved and introduced in the marketplace, it's often the beginning of a research and development process. In fact, we heard today that Revlimid was approved in 2005, and it was approved for three indications in a different disease.

Research continued, and it's only thanks to research that happened later that we discovered its role in treating multiple myeloma. The last indication for Revlimid was approved last year for a form of lymphoma where it wasn't approved before.

I think what's most importantly is that research and development expenses we have, the investments we make are actually directed at the totality of our portfolio, and 90 percent of the programs we work on will not work. So, when we think about research and development choices and the research and development investments we make, they're really directed at the total of our science.

As I mentioned earlier, in multiple myeloma, we are currently investigating 13 new medicines that will take what Revlimid has accomplished and take it one step further. And we have plans to invest over $2 billion in the next three years in new medicines for multiple myeloma beyond Revlimid.

So, that's our strategy. That's the way we think about research and development.

Mrs. LAWRENCE. So, this is where the confusion comes in. So, if you are testing other medicines, if they are implemented, you will charge the R&D to that. So, how does that R&D cost get placed on Revlimid?

And what I need to know, does that mean that this medicine will continuously keep moving up and increasing in cost, although you will—if you implement another drug, you are going to tack onto that drug the R&D cost. So, it seems like double dipping here, and that is the part I just—I am so frustrated with and I don't understand, sir.

Dr. CAFORIO. Yes, Congresswoman, I'm happy to provide my perspective.

You know, what I know is that of the new medicines in development that I described, many will not work and will never be approved by the FDA because this is the nature of our business.

Mrs. LAWRENCE. So, then do you put that, do you put the cost of that R&D——

Chairwoman MALONEY. The gentlewoman's time has expired. He may answer her question, but your time has expired.

Mrs. LAWRENCE. Does that mean that the drugs that you are testing that fail, that you put it on an existing drug to cover the cost of that? Is that what you are saying?

Dr. CAFORIO. No. We look at our total investment in R&D, and then we look at our total portfolio market in medicines. And our objective is to have a system in which the reward for the investments we make in R&D is recognized. And that's—that's the way our industry works, and that's how we can fund very high-risk lengthy and costly R&D programs.

Chairwoman MALONEY. The gentlewoman's time has expired.

Mrs. LAWRENCE. We need change, Madam Chair. Thank you.

Chairwoman MALONEY. Thank you. Mr. Gomez, you are now recognized for questions. Mr. Gomez?

Mr. GOMEZ. Thank you, Madam Chair.

I want to move, go back to the issue of patent protection. I think everybody recognizes the development of a new formulation of existing drugs can improve patient outcomes and expand treatment options. But we have also seen that drug companies use newer versions of the same drug to extend their monopoly pricing power.

I mean, the gentleman from Louisiana even was asking question about it, and he is not considered a liberal by any stretch of the imagination. And monopoly pricing power was also a key focus of the USMCA negotiation. I was one of the eight negotiators from the Democrat side to negotiate with the White House, and we successfully eliminated the 10-year guarantee of market exclusivity for biologics, which would have enshrined these monopoly prices that companies often seek to extend in perpetuity.

And we actually turned it into one of the most progressive trade deals in the history of this country, and it passed 385—385 to 41 in the House, Republicans and Democrats, 89 to 10. So, this issue is a big issue.

So, I want to ask Mr. Schultz, I would like to ask you a few questions about Teva's decision to develop and launch the 40-milligram version of Copaxone. Unlike the original 20-milligram version, which was taken daily, Copaxone's 40-milligram is taken three times a week.

Teva originally tried to develop a daily 40-milligram version of Copaxone. However, studies showed no difference in efficacy be-

tween the daily 20-milligram dose and the daily 40-milligram dose. Is that correct?

Mr. SCHULTZ. Unfortunately, part of that development was way before my time at Teva.

Mr. GOMEZ. OK. There is actually a press—reclaiming my time. Actually, it is a yes or no question, and it is actually yes, right, because Teva issued a press release. And if you need a copy of it, we can send it to you.

After these findings, Teva began to develop a 40-milligram dose to be taken three times a week, but the documents reviewed by the committee suggest that many of Teva's own scientists opposed pursuing this research. One scientist reported that members of the company's Innovative Research and Development Division were "strongly against the study since they had no scientific rationale/value." This is Exhibit 47 in your materials.

The same scientist noted that the company's lifecycle management team was aware of and even agreed with the scientists' concerns but thought that "such a study had its business value."

Mr. Schultz, the lifecycle management team is on the business side of the company, isn't it?

Mr. SCHULTZ. No, I'm not aware of what that situation was——

Mr. GOMEZ. I am not asking about that. I am asking the lifecycle management team is on the business side of your company. Correct?

Mr. SCHULTZ. Not necessarily, no. Typically, lifecycle management is taking part in the R&D conversation. So, the lifecycle projects would typically be organized within the R&D organization, but I'm not aware of the particular exhibit you're referring to.

Mr. GOMEZ. OK. Well, we will get you the exhibit as well. When a marketing team later analyzed the new dose in 2010, they highlighted that it would result in "patent protection extension" and be a "barrier to generic entrants." This exhibit is Exhibit 15 in your materials. We should get that one to you as well.

These documents show that Teva executives viewed the new 40-milligram dose as a way to extend Teva's monopoly in the market. The market analysis also noted that the 40-milligram dose provided no scientific advantage over the 20-milligram dose.

Teva has claimed that it developed the 40-milligram dose because it is more convenient for patients than the daily 20-milligram dose, and you described Copaxone as one of the best examples of Teva's dedication to innovation and research and patient support in your written testimony. But documents produced by the committee show that Teva has decided against researching the efficacy of administering the 40-milligram drug once per week, which would have been more convenient, right? Less frequent, more convenient. That is basically how it goes.

Mr. Caforio, earlier you said that when you were getting questioned, "meaningful innovation." Do you believe it is meaningful innovation when there is no scientific improvement in the dosage? Is it a meaningful innovation to do it three times a week?

Dr. CAFORIO. I don't know Copaxone and the issue you're referring to.

Mr. GOMEZ. I take back my time because I—Teva's internal documents show that Teva's CEO at the time worried it would lead patients to take two injections of a cheaper generic version of Copaxone's 20-milligram rather than Teva's Copaxone's 40-milligram. I am assuming, Mr. Schultz, you are going to say "I wasn't aware of that." So, I am not even going to bother asking you. You might as well get off the screen.

So, in summary, you guys, all you were doing was trying to find a way to extend the patent protection of a particular drug. That is all you were doing. Not based on that it was going to improve the outcomes for patients. It was just going to improve the outcomes for your bottom line for the long term, right?

Even your scientists said don't do it because it doesn't improve the outcomes. And if you had a choice to make it more convenient, you chose not to followup on that study to make it once a week, right? Once a week injection is more convenient than three times or daily.

So, that is the problem, that nobody—nobody believes the fact that you are trying to improve the outcomes for patients. They believe that you are trying to improve your bottom line, and you are undermining not only—not only your own business, but you are undermining the American public's confidence that when they take a drug and they pay more for it, it is actually going to be beneficial.

With that, I yield back.

Chairwoman MALONEY. The gentleman's time has expired, but you may respond, if anyone would like to respond to his question.

Mr. SCHULTZ. Yes, I would like to just give a quick response. So, I worked 30 years in pharmaceuticals and developed a lot of medications in the space of CNS, in the space of diabetes, and many of these drugs have to be injected.

And over the course of 30 years, the potential in this technological development, which has not come cheap and not come easy, years ago, it would be normal to have a product that was freeze-dried. You would have to reconstitute it in a vial. You would take it out with a syringe, and you would be injecting yourself with a syringe. Once a day, twice a day, three times a day. This would be quite inconvenient, socially not very easy, and it would reduce the quality of life in patients in those different disease areas, including MS.

Now over the period of time, a lot of work has been put in by the pharmaceutical industry to make it easier for people to take their drugs. And some people who do not know about chronic disease, they'll say what's the difference if you take it three times a day from a syringe and a vial, or you take an injection once a week or once a month?

I can tell you it's a huge difference to people's quality of life and their treatment because what happens if it's inconvenient, unpleasant to take your medication, then you skip dosing. And that's proven in many, many trials. And when you skip dosing, you don't get the efficacy of the drug you need.

That means that people have an inconvenient way for the drugs to get——

Chairwoman MALONEY. The gentleman's time has expired.

Mr. SCHULTZ [continuing]. And that's why treatment——

Chairwoman MALONEY. Thank you very much.

Mr. SCHULTZ [continuing]. Look at better delivery mechanisms. Thank you.

Chairwoman MALONEY. OK. Thank you. Mrs. Miller, you are now recognized for questions.

Mrs. MILLER. Thank you, Chairwoman Maloney and Ranking Member Comer, and thank you to all of our witnesses for being here today.

We can all agree that patients need access to lifesaving cures, and they need these drugs at a cost that will not break the bank. I am a cosponsor of H.R. 19, the Lower Costs, More Cures Act, which would help accomplish these goals.

Last year, the House passed H.R. 3. The Congressional Budget Office estimated that at the low end, this legislation would prevent 38 new cures from coming to market, while other estimates said it would put more than 100 fewer cures in the hands of patients. Either way, just one less lifesaving drug on the market is one too many.

What if the cures that were taken out in H.R. 3 is the cure for leukemia or ALS? We must be able to encourage innovation without the heavy hand of the Federal Government and put lifesaving prescriptions in the hands of the patients at a reasonable price. H.R. 19 would do all of this.

Dr. Caforio, how much does your company spend yearly on research and development?

Dr. CAFORIO. Congresswoman, approximately, $10 billion.

Mrs. MILLER. Thank you. Mr. Alles, now I am going to pose the same question to you. How much does your company spend yearly on research and development?

Mr. ALLES. In the last year before Bristol Myers Squibb acquired Celgene, my recollection is that the total R&D spend was $5.7 billion, which was 37 percent of our revenue that year.

Mrs. MILLER. Mr. Schultz, how much money does your company spend yearly on research and development?

Mr. SCHULTZ. Teva Pharmaceuticals spends approximately $1 billion per year.

Mrs. MILLER. OK, thank you. Now I am going to ask you all the same question again.

Dr. Caforio, how does the cost of research and development affect the pricing of new drugs?

Dr. CAFORIO. It does affect it, Congresswoman, because as I mentioned earlier, our investment in research and development is extremely significant. It's one of the highest in the industry. We know that many of the programs that we work on will ultimately not work, and I have many examples of large, long, and expensive clinical development programs in brain cancer, lung cancer, prostate cancer, and other diseases that have failed.

So, the need to obtain a return on our research and development investment is one of the important factors impacting the way we think about the price of medicines. Of course, the other one is the usual patient affordability and making sure that every patient can have access to our medicines. But R&D is an important factor.

Mrs. MILLER. OK. Mr. Alles, how did the cost of research and development affect the pricing of your new drugs?

Mr. ALLES. In fact, the scenario at Celgene was quite unique in that almost every disease that we researched was considered an orphan disease. That is fewer than 200,000 patients in the United States per year.

So, the diseases we've been talking about today, multiple myeloma, myelodysplasia, leukemia, et cetera, these are very rare diseases. In fact, one of our medicines that was approved during the time we were taking price increases on Revlimid is a drug called Idhifa, which is for a subset of acute myeloid leukemia, and approximately 4,000 people in the United States per year are afflicted by that biomarker-driven disease.

So, we targeted these rare, unmet needs on the belief, first by the Orphan Drug Act, that we would over time be able to recoup our investment and build a successful company. So, it had everything to do with our direction, our strategy to invest in and develop drugs for very small, rare, difficult cancers.

Mrs. MILLER. Thank you. Mr. Schultz, how does the cost of research and development affect the pricing of your new drugs?

Mr. SCHULTZ. It does, of course, affect it directly and indirectly. About half our research actually goes into generic biosimilars. And of course, that research is less costly because the drug has already been proven by the originator to work. So, there we save money getting new high-quality biosimilars or generics into the marketplace. We're solving these, same as I mentioned before, to the tune of more than $40 billion U.S. per year for the U.S. healthcare system.

But the other part is similar to what happens at BMS and what used to happen at Celgene. It is much more high-risk, innovative research, and as I said before, out of 100 projects you start, on average 1 of them makes it finally to the marketplace. So, of course, there is a cost for all the failures that also gets allocated to the products that do make it to the market.

Mrs. MILLER. Thank you. Many of my colleagues here today would have us believe that march-in rights are necessary for the well-being of the American public. This means that the Government could essentially come in at any time and take back patents from drug companies. How do you all think march-in rights, do you think they would show innovation?

Dr. CAFORIO. Yes, Congresswoman. I think that continuing to recognize and reward innovation through the patent where we currently have an intellectual property protection is the reason why our industry can make long-term investments in research and development.

Mrs. MILLER. Anyone else?

Mr. SCHULTZ. This is Kare Schultz. Yes, I would support that. It's basically the foundation for the innovation in pharmaceuticals is the patent system. If there were to be no protection after 10, 15, 20 years of hard R&D work, then nobody would undertake the risk because then there would simply be no balance between the risk and the reward.

Chairwoman MALONEY. The gentleman's time has expired. Congresswoman Tlaib, you are now recognized for questions.

Ms. TLAIB. Thank you so much, Chairwoman Maloney, for this important hearing and for our committee staff for all their hard work.

Mr. Schultz, I am sure serving as the CEO, you may have little to no contact with how your actions hurt real people, like my residents in 13th District Strong. Your actions have consequences, as you have heard from many of my colleagues. It has hurt people like Ms. Lisa McRipley, who lives with MS in my district. Lisa pays $6,000 per month for her MS medication and about an additional $1,000 just to treat her symptoms of pain, fatigue, and balance.

Now, Mr. Schultz, I know $7,000 per month may not seem like much to you as the CEO of Teva Pharmaceuticals. But Lisa doesn't have $7,000 of disposable income per month. The vast majority of Americans don't.

I understand that Copaxone, the drug used for MS, was first introduced on the market in 1997, and the wholesale acquisition at that time was only $8,000 annually. Today, it is $70,000. So, Mr. Schultz, yes or no, do you believe it is reasonable for Lisa in my district and others like her to pay nearly $70,000 a year to access Copaxone?

Mr. SCHULTZ. No, I would not think that would be reasonable at all, but fortunately, there would not——

Ms. TLAIB. Thank you. I just asked for a yes or no. It is not reasonable. So, let us talk about other items that your company does.

So, I also know that the drug companies frequently mislead the public by claiming charitable programs help ensure that patients who need medications can get them. But those programs do not cover everyone, and they are not reliable for patients, and they actually drive up the cost for many of my residents. In fact, I actually asked Lisa, who is on Social Security, if she was able to access such charitable relief, and she had no luck.

Documents obtained by this committee, Mr. Schultz, suggest that these programs actually serve drug companies' own financial interest. Mr. Schultz, does your company donate to third-party independent charities which cover Medicare beneficiaries' out-of-pocket cost for Copaxone?

Mr. SCHULTZ. We do contribute to charities——

Ms. TLAIB. Thank you.

Mr. SCHULTZ [continuing]. To further secure access.

Ms. TLAIB. Great. So, Mr. Schultz, yes or no, would you consider donation to these foundations to be financial investments?

Mr. SCHULTZ. No. I would not consider it to be, no.

Ms. TLAIB. OK. Well, let me tell you why you are misleading us right now. Internal documents provided to the committee show that Teva company did view these programs as financial investments, even described them that way.

In your own 2008 Copaxone work plan, which is Exhibit 37 in your materials, estimated that the company would lose over $11 million in sales if it reduced its "investment in Medicare Part D grants by $44.3 million," as you can see here. The work plan also estimated that Copaxone net sales would decline by $45 million in 2011 if your company were to "eliminate Medicare PAP investment."

So, Mr. Schultz, it seems that Teva company expected Copaxone sales to decline if it decreased donations to these grants. Is that correct?

Mr. SCHULTZ. This is more than 10 years before I joined the company, and I wasn't there. So, I did not——

Ms. TLAIB. No, it is pretty clear. It is pretty clear, Mr. Schultz. In my district, Mr. Schultz, we call this a "side hustle." Your pharmaceutical company makes these so-called charitable donations so you look like you give a shit about sick people. But in reality, these are just another scheme by your corporation to make money off of sick people, Mr. Schultz. Lisa needs her medication to live. She is not part of a hustle and should not be one.

Let us turn to Teva's program to cover the copays of Copaxone patients with commercial insurance. Again, this is how you are misleading the public. According to Teva's own internal analysis, the company spent $54.6 million on commercial copay program in 2014. But in return, you all got $257 million back. That is 371 percent profit, Mr. Schultz.

Mr. Schultz, these are companies' own estimates. I am not making—this is your own documents, and they suggest that what you and other corporate executives claim to be charitable-type programs are actually profit-motivated efforts to retain patients and generate sales.

I want to close off with Lisa's words, and this is so important because rarely do we put a human face behind so much of the actions by these corporations. Lisa said, "We need this medication to have a decent life. There is no cure right now to MS, so we need this because we want to continue to contribute to society. We want to make an impact."

So, Mr. Schultz, you need to go back and actually stop misleading the public and making sure that these drugs, again, have people's quality of life in jeopardy, their right to live in jeopardy. I ask all of you and for my colleagues to please pay attention to many of these documents again submitted to the record.

Thank you so much. I yield.

Chairwoman MALONEY. Thank you. I now recognize Ms. Pressley. You are now recognized for your questions. Ms. Pressley?

Ms. PRESSLEY. Thank you very much, Madam Chair, and I so appreciate that we can continue the work started by our beloved colleague, our former chairman Elijah Cummings, in investigating drug pricing.

Now I represent the Massachusetts Seventh congressional District, a diverse, dynamic, and vibrant district, and one of the most unequal in our country. And we certainly see those disparities play out when it comes to health and economics. So, let me be clear. The lack of access to affordable lifesaving medications is an injustice. It represents an act of economic violence and an attack on the basic principle that healthcare is a fundamental human right.

Across the Commonwealth of Massachusetts, the Massachusetts Seventh congressional District, which I represent, has the highest rate of new diagnosis of multiple myeloma, and black residents are more than twice as likely to die from the disease than white residents. Now multiple myeloma is a cancer that compromises an in-

dividual's immune system and places them at increased risk, especially during the ongoing coronavirus pandemic.

Revlimid is a drug used to treat multiple myeloma. Unfortunately, due to no reason other than greed, the company Celgene raised the price of this lifesaving drug from $215 to $719.

Mr. Alles, I appreciate your succinct answers with my colleagues, and so I will ask the same from you in my line of questioning. So, Mr. Alles, for the record, yes or no, do you believe that pharmaceutical companies should prioritize people over profit?

Mr. ALLES. We can only do well by doing good.

Ms. PRESSLEY. Yes or no?

Mr. ALLES. We have to take care of people for us to be able to be successful. So, we have to prioritize people and the medicines we develop for the diseases they have if we're going to be successful.

Ms. PRESSLEY. Over profit. OK. Well, that wasn't a yes or no. So, I will take that as a yes.

According to documents from our investigation, from 2009 through 2018, Revlimid generated $51 billion in net revenues, including $32 billion from the U.S. alone. Now to understand how Celgene accumulated such massive revenues, let us follow the money from the beginning.

So, Revlimid was developed from a precursor drug called thalidomide, which Celgene acquired in 1992. Mr. Alles, was thalidomide a new drug when Celgene acquired it?

Mr. ALLES. Thalidomide was not a new drug when we licensed it from Rockefeller Institute.

Ms. PRESSLEY. OK.

Mr. ALLES. In fact, it was an old drug that had a very notorious history of causing birth defects.

Ms. PRESSLEY. So, it has been used since the 1950's, and in 1996, a researcher found that the drug was effective in treating multiple myeloma. So, Mr. Alles, did you know this study was funded by a grant from the National Institutes of Health with taxpayer money?

Mr. ALLES. I was not aware specifically that the only funding was an NIH grant, but I would not be surprised——

Ms. PRESSLEY. OK.

Mr. ALLES [continuing]. In 1996 if some funding was provided by the Government.

Ms. PRESSLEY. Reclaiming my time. I am sorry, I am running out of time. So, then through three different studies, researchers found that a chemical variation of thalidomide, which would later be named Revlimid, was even more effective in treating multiple myeloma. So, later, more investigators working with the Mayo Clinic and a cancer research collaborative showed that Revlimid worked with another drug to treat newly diagnosed patients.

So, Mr. Alles, did you know these studies were also funded by NIH with, once again, taxpayer money?

Mr. ALLES. Congresswoman, I do not know the studies you're referring to specifically, but what I can say is that the development of Revlimid and the discovery of Revlimid in its initial form was something that Celgene uniquely discovered.

Ms. PRESSLEY. So, just reclaiming my time. I am sorry. So, it was only after——

Mr. ALLES. After that, I agree with you that most of those studies were done——

Ms. PRESSLEY. Just reclaiming my time. It was only after these numerous federally funded studies that Celgene invested in the trials needed to obtain FDA approval. Isn't that right, Mr. Alles?

Mr. ALLES. The studies that were sponsored by Celgene that led to the newly diagnosed approval, the study was a large randomized trial that was run globally and included——

Ms. PRESSLEY. Just reclaiming my time because——

Mr. ALLES [continuing]. Institutions in the U.S.

Ms. PRESSLEY. Because we have the timeline, which bears out what I am asserting in this moment. It was only after these numerous federally funded studies that Celgene then invested in the trials to obtain FDA approval.

So, by the time Celgene decided to invest its own money in Revlimid, taxpayers had already contributed significantly, and your company was confident of its future billion-dollar success. We know this because an internal memo from your company stated as much.

In fact, Mr. Alles, you wrote that the company's analysis "grossly underestimated the cumulative annual sales potential for Revlimid." Do you recall writing that to a colleague?

Mr. ALLES. I saw that document this morning, and I did remember writing that. It accompanied a paper that described a study.

Ms. PRESSLEY. OK, thank you for acknowledging that you wrote that. So, despite the taxpayer investment in its development, Celgene reported to the committee that it does not provide any negotiated documents or Revlimid counts to Revlimid to Government healthcare programs. So, this is a classic example of profits over people.

So, while the occupant of this White House does not pay Federal income taxes, my constituents in the Massachusetts Seventh do. Veterans, immigrants, single parents, and we have paid to develop Revlimid, and your company charged those same taxpayers hundreds of dollars to use this lifesaving medication.

So, although you are no longer with Celgene, I hope that you will discourage the companies you advise from showing the same greed and contempt for the taxpayers that underwrite these various estimates. We live in the richest country on the planet, yet drug prices are so high that people cannot afford to stay alive. This is about the right to live, and the American public deserves better.

Thank you, and I yield back.

Chairwoman MALONEY. Thank you. The gentlewoman's time has expired. Ms. Ocasio-Cortez, you are now recognized for questions. Ms. Ocasio-Cortez?

Ms. OCASIO-CORTEZ. Thank you, Madam Chairwoman, for holding this incredibly important hearing and one that, as many others have noted, was an issue that was

[inaudible] to our former chair, Chairman Elijah Cummings.

And thank you, Mr. Schultz, for participating in today's hearing and offering your expertise and insight.

I want to talk today about my constituents with multiple sclerosis and the exorbitant costs that they have been—that they have been facing in their diagnosis and their disease. And I would like to start by putting up on the screen two graphs that show the net

price per day of Copaxone 20-milligram and 40-milligram in five different countries in 2015.

Now these graphs were created by our team here on the committee using data that your company provided. And as you can see here that the daily net price of Copaxone 20-milligram was just $29 in Spain, $33 in Canada, $40 in Germany. But it was more than double that, $97, in the United States. That is per day, $97 to live per day.

And we have similar information for Copaxone 40-milligram, which, in 2015, cost $33 in Germany per day, $29. But more than almost four times that, $129, in the United States.

So, Mr. Schultz, why is the price of Copaxone so much higher for people with multiple sclerosis in the United States than those in other countries?

Mr. SCHULTZ. Now the data is, of course, from before I joined. So, I don't know exactly how the pricing was back then. But I can give a general comment on it that, as has been discussed earlier in this hearing, there is very early access and very broad access in the United States, and it often comes with a higher list price than the price you see in Europe.

So, that's just a fact, and that's what you see in these numbers.

Ms. OCASIO-CORTEZ. OK, well, thank you, Mr. Schultz. I am sorry I have to reclaim my time because it is so limited.

But your company's internal documents seem to tell a different story. The explanation provided by those documents for these price discrepancies was that you were forced to charge lower prices abroad. In fact, one of your company strategy plans obtained by the committee noted that from 2007 to 2009, they faced "downward price pressures in Europe."

Mr. Schultz, do you know whether Teva was, in fact, pressured to lower the price of Copaxone in Europe in those years?

Mr. SCHULTZ. No, I have no knowledge of that. That's more than 10 years before I came to the company.

Ms. OCASIO-CORTEZ. But that is quite all right, thank you. Thankfully, we do know, and the answer is that it was.

And while Teva was forced to put pressure, was forced to lower the price in Europe, in that same two-year period, the company raised the price on U.S. multiple sclerosis patients by 60 percent in the same two years that they were reduced in Europe. And when generic products entered the market in 2017, the U.S. list price started to finally steady. But outside of the United States, the availability of generics actually resulted in a decrease in the list price.

So, Mr. Schultz, isn't it the case that most European countries use some form of price negotiation based on external reference pricing?

Mr. SCHULTZ. That's correct. There are differences from country to country, but many countries use some kind of reference pricing, and other countries use some kind of value based.

Ms. OCASIO-CORTEZ. I see. And is that why Teva lowered prices abroad, but not in the United States?

Mr. SCHULTZ. No, you can't look at it that way because in the United States, you have this strange system that you have a WAC price, which is a list price, which is a price nobody ever pays. You

have a patient that pays maybe, you know, $10 to $50 on a WAC price that might be

[inaudible].

And then you have a lot of rebating going to PBMs——

Ms. OCASIO-CORTEZ. I see.

Mr. SCHULTZ. So, it's very opaque in the U.S.

Ms. OCASIO-CORTEZ. So, it is my understanding that your testimony today is that European countries having price negotiation and the United States not having price negotiation has nothing to do with the fact that Copaxone is almost four times the price in the United States than it is in countries like Spain or Germany or Canada?

Mr. SCHULTZ. No, I wasn't saying that. I was saying that the system is different. And in the U.S., you have many different parties negotiating. Whereas in many European countries, you're only negotiating with one party.

And typically, there's a big volume on the table, and of course, your negotiation position will change. That's also why the consolidation of PBMs has led to higher discounts.

Ms. OCASIO-CORTEZ. Thank you. And Mr. Schultz, sir, I have one last question. Even with charging those lower prices, does Teva turn a profit in Europe?

Mr. SCHULTZ. Yes. Teva has, overall for the total business, a profit in Europe, yes.

Ms. OCASIO-CORTEZ. Thank you.

Chairwoman MALONEY. Ms. Porter? Ms. Porter, you are now recognized.

Ms. PORTER. Thank you.

Mr. Alles, you were CEO of Celgene until fairly recently and, as my colleague Ms. Tlaib was showing, Celgene makes Revlimid, a cancer drug. Do you know what the price of Revlimid was when it first hit the market in 2005?

Mr. ALLES. I don't remember the number, but it was 200——

Ms. PORTER. Reclaiming my time. Reclaiming my time. It was $215 for one pill. Do you know what the price of Revlimid was in 2013?

Mr. ALLES. I can look it up, but I don't recall. I don't have it in front of me.

Ms. PORTER. Four hundred 12 dollars per pill. How about the price—let us get into more recent where your memory may be jogged. How about 2017?

Mr. ALLES. I would say approximately $700 a pill. But again, I don't have it in front of me.

Ms. PORTER. Seven hundred 19 per pill. And today, Revlimid costs $763 per pill. I am curious. Did the drug get substantially more effective in that time? Did cancer patients need fewer pills?

Mr. ALLES. During that time, the development of Revlimid included six additional indications, some in lymphoma and the balance in patients with different segments of multiple myeloma.

Ms. PORTER. Reclaiming my time. So, Mr. Alles, you discovered more patients who might benefit from paying $763 a pill, but being able to use the drug for more patients doesn't necessarily more price. Did the drug start to work faster? Were there fewer side ef-

fects? How did you change the formula or production of Revlimid to justify this price increase?

Mr. ALLES. The indication changes are for subsets of different patients with disease.

Ms. PORTER. Reclaiming my time. Mr. Alles, I understand that. What I am trying to understand from you is how did the drug improve? If I were to look at a pill and analyze it from 2005, when it cost $215, and I looked today when it costs $763, would that pill be the same?

Mr. ALLES. I understand your question about the pill. The pill, the manufacturing for it, would be the same.

Ms. PORTER. Right. Thank you. So, to put that in perspective, you hiked the price by $500, when the average Orange County senior only has $528 left in their bank account after they have paid their basic monthly expenses. The average Orange County senior can't even afford one pill.

And you said recently that nobody pays the list price, but that is not correct. Do uninsured patients sometimes pay the list price?

Mr. ALLES. I can imagine there are circumstances where underinsured or uninsured patients would be paying close to or at the list price. I don't know of any specific circumstances, but I would guess that they do exist.

Ms. PORTER. Reclaiming my time, Mr. Alles. I want to turn to one other number, if you would help me. Do you know what this number is?

Mr. ALLES. I—I don't, but——

Ms. PORTER. Does it ring any bells?

Mr. ALLES. I think you're referring to my compensation in some way.

Ms. PORTER. In some way. This was your compensation in 2017 for being CEO of Celgene, and that is a lot of money. It is 200 times the average American's income and 360 times what the average senior gets on Social Security.

Now of that $13 million, about $2.1 million came from your company hitting yearly earning targets, and more than half of the bonus formula was based on those targets. Any increase in the price of Revlimid would also increase your bonus by increasing earnings. Isn't that right, Mr. Alles?

Mr. ALLES. If revenues increased and expenses did not, then earnings would be enhanced——

Ms. PORTER. Thank you. Mr. Alles, in fact, the Oversight Committee——

Mr. ALLES [continuing]. And that was a part of the calculation of my compensation.

Ms. PORTER [continuing]. Found that if you hadn't increased the price of Revlimid, you wouldn't have gotten your bonus. Mr. Alles, do you know how much you personally received in bonuses over two years, the last two years, just because Celgene raised the price of this one drug, Revlimid?

Mr. ALLES. I received very generous compensation, but I don't know the exact number that you're referring to.

Ms. PORTER. In fact, you personally received $500,000 personally just by tripling the price of Revlimid.

So, to recap here, the drug didn't get any better. The cancer patients didn't get any better. You just got better at making money. You just refined your skills at price gouging. And to be clear, the taxpayers spent $3.3 billion on Revlimid, $3.3 billion—Medicare, $3.3 billion.

Mr. Caforio, Bristol Myers Squibb, your company, acquired Celgene and its drug Revlimid. Is that correct?

Dr. CAFORIO. That's correct, Congresswoman.

Ms. PORTER. If the price of Revlimid had only been increased to reflect inflation, the cost would be about $286 today, according to the Fed's inflation calculator, $286 per pill. Will you commit to lowering the price of Revlimid to $286 per pill?

Dr. CAFORIO. No.

Chairwoman MALONEY. The gentlewoman's time has expired, but the gentleman may answer the question. Please respond to the question.

Dr. CAFORIO. Yes. No, I can't commit to that. We—we did look extensively at the price of Revlimid and the value of Revlimid when we acquired Celgene. And I can commit to continuing to work to ensure that patients that need Revlimid have access to Revlimid, and we are doing all we can in order to make that happen.

Ms. PORTER. Mr. Caforio, I just would like, for the committee's clarification, a yes or no. Will you commit to lowering the cost of Revlimid——

Mr. COMER. Madam Chair, her time has expired.

Chairwoman MALONEY. Your time has expired. But the gentleman may answer if he would like.

Dr. CAFORIO. I already answered. I can't commit to that.

Chairwoman MALONEY. All right, thank you.

Thank you. The gentlelady's time has expired.

Before we adjourn, I want to address the members on the other side of the aisle who have stated repeatedly throughout this hearing that we should be working in a bipartisan basis, and this is a critical issue to the people of America, I agree. And we want to work on a bipartisan basis.

And Chairman Cummings tried to do so. He was one of the first senior Democrats to go to the White House after the election, and he met with President Trump on March 8, 2017. He took the President's campaign promises at face value, that he wanted the U.S. Government to finally be able to negotiate for lower prices. He ran on that platform.

Chairman Cummings gave the President a copy of his draft bill that would do just that. He asked for his input on the draft bill, which turned into H.R. 3. He asked to work together, and he asked repeatedly for the President's support. But President Trump fell off the face of the Earth. Chairman Cummings sent letter after letter after letter to the President in good faith and a bipartisan way.

He sent on one April 20, 2017, reiterating his request to work together. I have a copy of it right here. He sent another one on June 21, 2017, and I have a copy right here. And then he sent a third

letter, and this was on October 25, 2017, and I have a copy of that letter.

And I would like to ask unanimous consent to place all of these letters in the record.

Without objection.

Chairwoman MALONEY. Do you know what President Trump's response was? Zero. He never responded to Chairman Cummings again. He broke the promise he made during the campaign to support legislation to finally let Medicare negotiate, and he broke the pledge he made directly to Chairman Cummings in the White House to work together in a bipartisan way.

So, to my colleagues who are complaining that we didn't work on a bipartisan basis, you should be directing your criticism directly to the President. He is the one who went back on his promises, and he is the one that refused multiple times the efforts by Chairman Cummings to work together.

In closing, I want to thank all of our panelists for their testimony, and I want to commend my colleagues on both sides of the aisle for participating in this very important conversation.

Mr. COMER. Madam Chair?

Chairwoman MALONEY. You will be recognized.

Tomorrow, we will continue this conversation with Part II of our hearings on the skyrocketing price of prescription drugs, and at that hearing, we will finally hear from three more drug company executives from Amgen, Mallinckrodt, and Novartis.

So, I look forward to seeing all of you tomorrow at 10 a.m., and I recognize for comments my distinguished colleague and note that, without objection, all members have five legislative days within which to submit additional written questions for the witnesses to the chair, which will be forwarded to the witnesses for their response. And I ask the witnesses to respond promptly as they are able.

And I recognize my good friend and colleague, the ranking member of the committee, for his closing comments and thank him for his participation and his willingness to work in a bipartisan way.

Mr. COMER. Well, thank you, Madam Chair.

And that is true. We sincerely want to work together. I think this is a bipartisan issue. But with respect to the letters that you mentioned, that this committee, that former Chairman Cummings, yourself, and all the members of the committee have sent the President, you all have sent so many letters from this committee to the President, I would say that they view that as junk mail because they get so many letters from this committee.

I think moving forward, we need to pick some issues where there is bipartisan agreement, and this is an issue. Republicans have already passed—proposed a bill, H.R. 19, that does many of the things that many of your members reference during this hearing. So, I think that the potential is there.

I recognize the fact that there is probably not going to be any mood for true bipartisanship over the next 30 days, but hopefully, after the election, we can work together and move forward to try to do what our constituents want, and that is to try to get some type of reform with respect to drug pricing.

With that, I yield back.

Chairwoman MALONEY. Thank you for your participation, your comments, and I will see you tomorrow at 10 a.m.

This meeting is adjourned.

[Whereupon, at 1:54 p.m., the committee was adjourned.]

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