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

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BEFORE THE

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

Thursday, October 1, 2020

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

The committee met, pursuant to notice, at 10:04 a.m., in room 2154, Rayburn House Office Building, Hon. Carolyn Maloney, Chairman of the Committee, presiding.

Present: Representatives Maloney, Norton, Clay, Lynch, Connolly, Raskin, Rouda, Wasserman Schultz, Sarbanes, Welch, Speier, Kelly, DeSaulnier, Plaskett, Gomez, Tlaib, Porter, Comer, Jordan, Gosar, Foxx, Massie, Grothman, Palmer, Cloud, Gibbs, Higgins, Miller, Steube, and Keller.

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 welcome to Day Two of our landmark series of hearings with drug company CEOs. Yesterday we heard from the CEOs of three drug companies: Celgene, Bristol Meyers Squibb, and Teva. And what we learned was shocking. Drug companies are hiking their prices higher and higher, and placing an even greater burden on the very patients who rely on these drugs to survive. We learned that these skyrocketing prices are simply unsustainable, both for government programs and American families.

We also learned that claims by drug companies that their price increases are necessary for research and development are completely bogus. The internal company documents we obtained show that drug companies hike prices almost entirely for selfish reasons. They do it to meet internal revenue targets, or to increase their own bonuses, in some cases. Drug companies certainly spend some funds on research and development, but nowhere near the windfall profits they are bringing in as a result of their massive price increases.

Finally, in the cases we examined yesterday we learned that drug companies target our country for their biggest price and for their biggest price increases, charging the American people more than the entire rest of the world combined.

They do it simply because they can, because Federal law currently bars our government from negotiating directly with drug companies to lower prices for Medicare. According to the non-par-

tisan CBO, allowing the Federal Government to negotiate directly with drug companies could lower spending on brand name drugs by about $456 billion. So, let that number sink in. It is nearly half a trillion dollars.

Today is Day Two, and we will hear from three more executives. We will hear from the CEO of Amgen, which repeatedly raised the prices of two drugs: Enbrel, which is used to treat rheumatoid arthritis and other painful inflammatory diseases, and Sensipar, which is used to treat the effects of kidney failure and parathyroid cancer.

We will hear from the top U.S. executive from Novartis about the company's massive price increases for Gleevec, a drug that treats chronic myeloid leukemia, a rare form of cancer of the blood and bone marrow.

And we will hear from the CEO of Mallinckrodt about the pricing of its drug called H.P. Acthar Gel, which is used to treat a rare seizure disorder in little babies.

We are going to keep our opening statements short because we want to hear the testimony from our guests. But I would now like to turn to our ranking member for his opening statement.

Mr. COMER. Thank you, Madam Chairwoman, for holding this hearing. I would like to reiterate a few points brought up at yesterday's hearing.

First, Republicans have introduced legislation, H.R. 19, full of bipartisan provisions that the House could pass today and could be signed into law by the end of the week, to decrease the cost of prescription drugs for all Americans.

Second, pharmaceutical innovation is vital to enabling Americans to live longer and healthier lives, but we must ensure those innovative products are accessible and affordable for all Americans.

Third, while brand pharmaceutical manufacturers play a significant role, we must look at the entirety of the pharmaceutical marketplace, including PBMs, health insurers, generic manufacturers, and wholesalers, to truly solve this problem permanently.

At this time, Madam Chair, I would like to yield the balance of my time to Representative Massie.

Mr. MASSIE. Thank you, Ranking Member Comer, and thank you, Madam Chairwoman. I anticipate today's discussion and testimony will involve the U.S. patent system, and so in this opening statement I want to read the patent and copyright clause that is in the Constitution. This clause was so uncontroversial that it was accepted by all of those who were drafting and voting on the Constitution, unanimously and without debate.

It says, "The U.S. Congress shall have power to promote the progress of science and useful arts by securing, for limited times, to authors and inventors the exclusive right to their respective writings and discoveries."

So, some people who haven't studied this issue too much think that perhaps patents are the reason that drug prices are high, but the reality is on a lot of the drugs the patents have expired and there is no restriction from the Patent Office to keep somebody from making the generic versions of the drugs. But there are other impediments not involving patents that stop these generics from coming to market. So, I hope we find out what those are about.

Then I also want to say that our Founding Fathers were really smart here. They knew that if the owner had a limited period to recoup their investment, the inventor and the owner, then they would be able to find the capital and the backers to develop these ideas and discoveries. So, even if you had scientists who would come up with new drugs, for free—let's say they just gave the idea away—these new drugs require millions, hundreds of millions in some cases, of development in order to bring them to market, and without a patent, which is the equivalent of a deed, like a deed to a piece of property—nobody would develop a piece of property if they couldn't get a secure title to the property—patents work the same way. They allow the investors to get secure title to the idea so that they can then invest the money that is required to bring that to market and to test it and make sure it is safe for all human beings.

So, I look forward to a robust discussion on that, and with that I yield back.

Chairwoman MALONEY. I want to thank my colleagues, and with your indulgence, because of my cough, I would like to just lead up to the video that we want to play before we go into it. But I did want to respond to my good friend and colleague, Mr. Comer. I agree we should work on this issue. It is important to the American people. It should be bipartisan. But since you mentioned your bill, I am going to mention mine, H.R. 3, which would merely allow our country to negotiate for lower drug prices for Medicare, as we do with the Veterans Association. It has passed the House. It is now in the Senate.

But what I would really like to do right now is to honor and remember our former chairman, Elijah Cummings, who launched this investigation 18 months ago. His No. 1 priority then, and our No. 1 priority now, is the health and the well-being of the American people, who are being harmed on a daily basis by these astronomical price increases.

So, I would like to conclude my statement by playing a clip of three individuals, patients and doctors, who are being directly and negatively affected by the actions of these three drug companies. And if could now play that video and move quickly forward.

[Video shown.]

Chairwoman MALONEY. Thank you. Thank you very much. I will now introduce our witnesses, and we are grateful for their attendance today and for their testimony.

Our first witness today is Mr. Robert Bradway, who is the Chairman and CEO of Amgen. Amgen sells the anti-inflammatory drug, Enbrel, and the chronic kidney disease drug, Sensipar. Then we will go to Mr. Mark Trudeau, who is the President and CEO of Mallinckrodt Pharmaceuticals. Mallinckrodt sells the autoimmune and inflammatory disease drug, H.P. Acthar Gel. Finally, we will hear from Mr. Thomas Kendris, who is the U.S. Country President of Novartis. Novartis sells the cancer drug, Gleevec.

The witnesses will be unmuted so we can swear them in. Please raise your right hands.

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. Thank you. Let the record show that the witnesses answered in the affirmative.

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

With that, Mr. Bradway, you are now recognized for your testimony. If you could unmute your mic.

STATEMENT OF ROBERT BRADWAY, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, AMGEN INC.

Mr. BRADWAY. OK. Thank you. Good morning, Chairwoman Maloney, Ranking Member Comer, and other members of this committee. My name is Bob Bradway and I am the CEO of Amgen, a leading biotechnology company based in Thousand Oaks, California.

Before I begin my formal remarks, I want to acknowledge the work of Elijah Cummings on drug pricing issues as chairman of this committee. I know he is sorely missed by his former colleagues and I wanted to recognize his work dedicated to improving access and affordability for patients.

For 40 years, Amgen's unwavering mission has been to serve patients. We do that through innovative medicines and high-quality biosimilars that treat many of the world's most serious and costly illnesses. We are also engaged in the fight to understand, treat, and prevent COVID–19.

We employ nearly 14,000 people here in the U.S., where we conduct a vast majority of our cutting-edge research and eco-friendly manufacturing.

Amgen is deeply committed to meeting the needs of every patient, every time. Therefore, it is of great concern to us when patients who might benefit from our medicines can't get them.

We are committed to responsible pricing. A few recent examples: In 2018, we launched a new migraine prevention treatment called Aimovig, at a price that was between 20 and 65 percent below market expectations. We also made Repatha, a medicine proven to reduce heart attacks and strokes in patients with stubbornly high cholesterol levels, available at a 60 percent reduced price. This helped lower out-of-pocket costs for patients, especially seniors on Medicare.

Over the last two years we have launched biosimilars to some of the top-selling medicines in the country, and plan to bring more to market over time, providing patients with more affordable treatment options.

Overall, the average net price for Amgen medicines across our entire portfolio in the U.S. declined in 2018 and 2019, and we are on track for further declines this year.

Enbrel is an Amgen medicine that treats patients with autoimmune disorders such as moderate to severe rheumatoid arthritis. Enbrel highlights the tension between ensuring patients have access to critical, innovative medicines and the out-of-pocket costs they are also required to pay. Physicians tell stories of how their waiting rooms were cluttered with canes, crutches, and wheelchairs. Thanks to Enbrel, countless patients have been given a new lease on their lives.

Since Enbrel's approval, we have invested hundreds of millions of dollars in studies for additional uses and to make it more patient friendly. As an example, we recently introduced an easy-to-use self-injection device designed for Enbrel patients whose disease has sapped the strength in their hands.

But innovations like this cost money, and that is partially why we have increased the list price of Enbrel in the past. But what has driven up the list price more than any other factor is the pressure we face to match the price increases of the market leader. I know this sounds strange. Companies in virtually every other industry compete by offering the lowest price. Unfortunately, the current rebate system in the U.S., created with good intent, now often leads to a situation in which not getting kicked off formulary requires matching a competitor's higher price. These higher prices increase the already significant rebates paid to the middlemen, who largely dictate which medicines patients can access, regardless of which medicines their physician prescribes.

Worst still, these rebates, paid on all our medicines, do not translate into lower costs for patients, and that is because they don't get passed on to patients at the pharmacy counter. There is no question that the present rebate system is dysfunctional and does little to serve the very patients it was designed to benefit.

As we wrestle with the worst public health and economic crises of our lifetime the time is now and the place is here to craft the changes that are needed. Innovative biopharmaceuticals are part of the solution to the burden serious diseases impose on patients and society. Amgen can strive for reforms to improve affordability for patients. However, a single manufacturer cannot make that happen alone.

We stand ready to work with members of both parties, the administration, and other stakeholders to develop policy solutions, help improve access and affordability for our patients without stifling innovation. There are so many diseases to confront and patients to help. If we all stay focused on what is best for patients, I am confident we can end up in a better place.

Thank you for the opportunity to speak to you this morning.

Chairwoman MALONEY. Mr. Trudeau, you are now recognized.

STATEMENT OF MARK TRUDEAU, PRESIDENT AND CHIEF EXECUTIVE OFFICER, MALLINCKRODT PHARMACEUTICALS

Mr. TRUDEAU. Chairwoman Maloney, Ranking Member Comer, and members of the committee, thank you for the opportunity to be here today.

I started in the pharmaceutical industry as a research and development engineer nearly 40 years ago. Over the course of my career I have worked on pioneering treatments for several critical diseases, including some of the very first for HIV. The leadership roles that I have had in other regions of the world have allowed me to better understand both the strengths of the U.S. health care system and its challenges. I have devoted myself to this industry because, like the nearly 3,300 employees of Mallinckrodt I know that the therapies that we make improve the lives of patients and their families.

This has been a year of unprecedented challenges. When COVID–19 hit we mobilized to identify therapies to combat the diseases. We consulted with the FDA and NIH regarding potential evaluation of INOmax, our inhaled nitric oxide therapy for the treatment of COVID–19-related respiratory complications, and supported an independent clinical trial being coordinated by Mass General. As of today, nearly 250 hospitals and U.S. health systems have used INOmax as an experimental treatment for COVID–19 patients.

We also secured our supply chain to avoid manufacturing interruption for the critical medications we make and donated 54,000 pieces of PPE, several ventilators, and more than 16,000 gallons of hand sanitizer manufactured in our Missouri plant. We also engaged with Members of Congress and Federal agencies like BARDA to discuss leveraging our extensive experience making high-quality, U.S.-made generics at our plants in Missouri, New York, Illinois, and North Carolina, to bring home the manufacturing of essential medicines and active pharmaceutical ingredients.

Today we are the only American manufacturer of acetaminophen, a key active pharmaceutical ingredient in many medicines, which we proudly make in Illinois and North Carolina.

Our resolve to help patients with critical conditions has never been stronger, and we understand and share the American people's concerns over the availability and affordability of prescription drugs. Mallinckrodt is steadfastly committed to knocking down barriers to patient access. That is particularly true with Acthar Gel.

Acthar is a complex injectable biopharmaceutical product, FDA approved for 19 serious conditions, including infantile spasms, lupus, multiple sclerosis, nephrotic syndrome, and rheumatoid arthritis. Acthar is life-changing therapy for a small group of patients for whom other treatment options have failed, or patients whose conditions, if left untreated, may lead to physical and developmental impacts requiring life-long care, causing great financial strain on families and the American health care system.

Acthar is not patent protected. We do not block generic competitors from entering the market. It is our policy to provide reference samples to generic manufacturers upon request, and we have supported legislation like the CREATES Act to ensure appropriate access to those samples.

Since we acquired Acthar in late 2014, we have invested more than $660 million into modernizing the product, including over $470 million in R&D activities and close to $190 million in manufacturing advancements. We have initiated nine clinical trials with targeted combined enrollment of nearly 1,100 patients, a large number given the rare or complex conditions Acthar typically treats. Results from one study of patients with persistently active rheumatoid arthritis showed that treatment with Acthar resulted in low disease activity for an astounding 62 percent of patients for whom standard treatments did not work.

Since we have owned Acthar, the list price has increased, on average, around five percent annually, not factoring in inflation or significant discounting that we started when we acquired it. In two of the last six years we didn't take any price increase, and last year the net price of Acthar went down, as it will again this year. We

have also improved the ability of patients with a prescription to obtain Acthar through our robust free drug and commercial copay assistance programs, which lead to many patients paying nothing out of pocket.

Like all of Mallinckrodt's employees, I am dedicated to bringing more breakthrough treatments to the market, including Terlipressin, one of two treatments we are developing for patients with advanced liver disease; StrataGraft, our investigative regenerative skin therapy, which may reduce the need for autografting in certain burn patients; and Adrabetadex for Niemann-Pick Type C disease, a high mortality rare disease affecting children and adolescents.

We will not waver in our commitment to serving patients with critical conditions who need better options. Thank you again for the opportunity to be here today.

Chairwoman MALONEY. Thank you. Mr. Kendris, you are now recognized.

STATEMENT OF THOMAS KENDRIS, U.S. COUNTRY PRESIDENT, NOVARTIS AG

Mr. KENDRIS. Thank you, Chairwoman Maloney. Chairwoman Maloney, Ranking Member Comer, members of the committee, thank you for the opportunity to speak with you today.

My name is Tom Kendris and I am the U.S. Country President for Novartis, a leading global medicines company. We use innovative science to develop transformative medicines that improve and extend people's lives. We also develop generics and biosimilars through our Sandoz division, the second-largest generics company in the United States. Our medicines reach close to 800 million people every year. Globally, we are over 100,000 people, with approximately 15,000 employees in the United States. Our global R&D headquarters is in Cambridge, Massachusetts, and we have several manufacturing sites across the U.S.

I have been with Novartis for 25 years, and I still marvel at the passion of our people to tackle the most complex medical challenges. Gleevec was one of the most significant medical advancements in recent history. It revolutionized targeted therapy for cancer. Before Gleevec was introduced in 2001, the five-year survival rate for a patient with chronic myeloid leukemia was only 30 percent. Now the vast majority of CML patients have a normal lifespan. What's more, Novartis continued to study whether the drug could treat other diseases, and today it is approved for six other rare cancers, saving tens of thousands of lives.

A more recent example of our transformative treatments is the development of a gene therapy to treat spinal muscular atrophy, a rare genetic neuromuscular disease that affects primarily babies. The treatment is one of the first gene therapies to be approved in the U.S., with a single injection. Some babies who would otherwise have died by the age of two or three are now going to kindergarten and growing up like other children.

In cell therapies we developed the first CAR-T therapy to treat a rare form of pediatric and young adult leukemia. This therapy can bring a patient from the brink of death to remission. The first patient ever to receive this therapy has been cancer-free for eight

years and is now going to high school and leading a normal life. Spending time with this young patient's family is one of the great privileges of my career.

Beyond rare diseases and cancers, we are reimagining how innovative medicines might improve public health broadly, particularly in sickle cell anemia, malaria, and cardiovascular disease.

I would like to be clear with the committee, however, that at Novartis we recognize that these innovations don't matter if patients cannot afford or get access to them. In the U.S., issues of price and access present systemic challenges that must be addressed together by industry and policymakers, and Novartis is committed to being part of the solution. While CMS predicts national health spending to grow at an average rate of 5.4 percent through 2028, the average net price of our medicines is expected to decrease by 2.5 percent in 2020.

Value-based pricing is a critical tool in addressing affordability and access. When setting prices, we at Novartis consider multiple factors, including the improvements the medicines offer patients, both clinically and in terms of their quality of life, and the benefits that the medicines offer to the health care system and to society.

The industry should adopt a similar approach, and patients should have access to treatments with low cost-sharing, to encourage the use of the most cost-effective options available. We also seek to lower costs by developing low-cost biosimilars and generics through our Sandoz division, which brought the first biosimilar to market in the U.S.

Over the past five years, Novartis has provided medications at no charge to nearly 300,000 U.S. patients experiencing financial hardship or who have limited or no prescription drug coverage. Eligible patients with commercial insurance often pay less than $30 for a 30-day prescription for the vast majority of Novartis' products.

The pharmaceutical industry used to be revered. That trust has eroded, however, and our industry must work to regain it. At Novartis we understand that this trust is earned, not just from bringing breakthrough medicines to patients but by pricing these medicines responsibly and ensuring broad access. While we live in an incredible era of progress in human health, we will only be successful if we can make both of these goals a reality. At Novartis we are passionately committed to doing so.

Thank you for your time this morning and I look forward to answering your questions.

Chairwoman MALONEY. Thank you. I thank all of you.

I now recognize myself for five minutes for questions, and I thank Mr. Comer for allowing me to go over a little of my time. I certainly grant the same to him, and more, to his colleagues on your side of the aisle.

Yesterday we heard the CEOs claim over and over again that they had to raise drug prices to help pay for research and development and promote innovation. But the internal documents we obtained showed that these claims were false. Instead, they showed that these price increases are intended to generate more and more revenues for the drug companies.

Mr. Trudeau, let's start with you. In your written statement today you made the statement, and I quote, "At Mallinckrodt we

believe that pricing for an innovative therapy should reflect the value that the treatment brings to patients, providers, and the health care system as a whole," end quote.

But your company didn't acquire Acthar Gel because you thought it was an innovative therapy. It was a very old drug. You acquired it to meet your financial objectives.

I would like to go through three quick slides with you. First is Exhibit 66, and it is up on the screen.

[Slide.]

Chairwoman MALONEY. This is a slide from a presentation that was prepared when you were considering the acquisition of Questcor, which made Acthar. As a preliminary matter, these talks about Quincy, Quincy was just the code name you used for your real company, Questcor, right?

Mr. TRUDEAU. That is correct, Madam Chairwoman.

Chairwoman MALONEY. Thank you. The title of the slide says, and I quote, "Questcor is a rapidly growing specialty pharmaceutical company with a premium-priced product."

Mr. Trudeau, the premium-priced product was Acthar, and premium-priced just means really expensive. Right?

Mr. TRUDEAU. That is actually not true. What it refers to is that it was priced at a premium to other competitive therapies.

Chairwoman MALONEY. Well let's look at the next slide, Exhibit 67.

[Slide.]

Chairwoman MALONEY. If you look at the fourth bullet, this slide says your acquisition would allow Mallinckrodt to, quote, "achieve aspirational goals with a single transaction," end quote. By "aspirational goals" you are talking about huge revenues, and that is exactly what you got. Acthar sales accounted for a third of your company's net sales from 2017 through 2019. Isn't that right?

Mr. TRUDEAU. The sales are roughly correct, but our aspirational goals were actually to transform the company. Mallinckrodt was originally a generics and imaging company and we were looking to make a transformation to a company that was focused on research, investment, and the opportunity to address patients with severe and critical conditions who are underserved by current therapies.

Chairwoman MALONEY. Well, let's now look at Exhibit 68.

[Slide.]

Chairwoman MALONEY. Mr. Trudeau, I will just read the headline. It says that your modernization strategy will define the future of Acthar as either a growth asset or a, and I quote, "cash cow," end quote. Isn't it true that this is how you really see this drug, not as an innovative therapy but as a "cash cow"?

Mr. TRUDEAU. No, that is not true, and this document, which I was just recently made aware of, actually was a draft document that was never shown to our board.

But that term is typically applied to products for which no investment is likely to be going forward, and, in fact, that is exactly the opposite with what we have done with Acthar. We have invested nearly $660 million since we acquired the product in 2014.

Chairwoman MALONEY. OK. A cash cow is a profit-making thing. What is a cash cow? That is what you said. I think the document speaks for itself.

Mr. Bradway, may we turn to you? Your company's talking points claim, and I quote, "At Amgen we price our products to reflect the economic value that is delivered to patients, to providers, and payers, the unmet medical need, the size of the patient population, the investment and risk undertaken, and the need to fund continued scientific innovation," end quote.

But your internal documents tell a very different story. So, let's look first at Exhibit 36.

[Slide.]

Chairwoman MALONEY. This is a pricing committee presentation from December 2016. In this document your pricing committee is basing its decision not on innovation or research and development but on what another company, AbbVie, might do with a similar drug. Isn't that right?

Mr. BRADWAY. Yes, Madam Chairwoman. That is correct, and it is important to note what is happening in this discussion. What this reflects is the nature of the—the structure of the biopharmaceutical industry through which we compete for formulary position for our medicines with other molecules in the same therapeutic category. So, what you are seeing here is a snapshot of a discussion about how we position Enbrel versus other molecules that we compete against in this anti-inflammatory category.

Chairwoman MALONEY. Well, this document, it has three scenarios for what AbbVie might do, and it plans out what your company will do in response. Mr. Bradway, these pricing executives are not discussing any of the things that you mentioned in your talking points. They are not discussing research and development, unmet needs, investments, risk undertaken, innovation. Instead of competing with other companies to beat their prices you are all increasing them in lockstep. Isn't that right? That is what the document says, and I think it is scandalous.

Mr. BRADWAY. What you see here is a document that illustrates the competition that exists to keep medicines like Enbrel on formulary. Again, if I may be allowed, Madam Chairwoman, let me say a few words about the structure of the market that requires the kind of rebating that is implied in this document.

As I said, Enbrel competes against 20 different molecules in the anti-inflammatory space. We offer rebates which secure our position on the formulary of the intermediaries who determine which medicines are available for patients to use, and what the effects are of the scenarios that the team is considering in order to make sure that this medicine remains available for those patients who are already on it and those patients whose physicians want to add them to their therapy. So, they are looking at a range of scenarios, and implicit in this is the rebate that would be associated with those scenarios for the product.

Chairwoman MALONEY. Well, let's move on to Mr. Kendris. In your written testimony you say, and I quote, "Given its life-changing attributes we have committed to making Gleevec accessible to patients who need it," end quote. But one of the documents obtained by the committee shows that executives priced Gleevec as high as possible, and they priced it so high, from the documents, to meet revenue targets without triggering negative backlash.

Let's put the slide on the screen, and this is Exhibit 3.

[Slide.]

Chairwoman MALONEY. This is a slide of Gleevec's pricing scenarios, including the risk to Novartis' strategic financial plan, quote, "if action not taken in 2013," end quote. If you look in the top right-hand box, the description of the aggressive pricing model says, quote, "delivers greatest upside while keeping single increases below the 10 percent threshold," end quote. This aggressive model recommends five price increases of 9.9 percent over the course of three years.

Mr. Kendris, my question is, your company chose the most aggressive pricing model, didn't it?

Mr. KENDRIS. Madam Chairwoman, in the next sentence, right after the one you read, the document which I am seeing this morning recommends enhancements to our patient support programs. So, Madam Chairwoman, what I would say is that over the years since Gleevec was introduced onto the market its value increased exponentially, because of the five new indications that we obtained for Gleevec in rare cancers and the tens of thousands of patients whose lives were saved. Over time it became clear that the remissions, not only in CML but in all of those cancers, were robust and long-lasting.

In 2001, we didn't know that. We didn't know how long patients would live and survive after they were given Gleevec. But over time we found out that they did. And we turned cancer, all of these six cancers, from a fatal condition first to a chronic condition and then, with a follow-on product, Tasigna, we turned it into a treatment-free remission condition, basically a cure. They don't have to take a pill any longer.

So, Gleevec was tremendously valuable, and the price increases we took were—we certainly took them over those years, Madam Chairwoman, but we were always the lowest-priced product in the class. The product has been generic now since 2015. We haven't taken a price increase since 2015, and today 55 percent of what we manufacture of Gleevec is given away to patients who can't afford it and given away for free.

Chairwoman MALONEY. Well, the bottom line is that Novartis went with the pricing strategy that would maximize net sales, raising Gleevec's price five times in three years.

The point here is that all the claims by drug companies about why they need to increase prices to pay for research and development and for innovation, they are simply not true. These documents show that they are increasing prices simply to make more money, plain and simple. That is why we need to finally allow the government to negotiate directly for lower prices, like all other countries.

Again, these drug companies make more off the United States than all the other countries in the world combined, buying their products.

There will be further questioning on the rebates and how they are really not working, or not getting to people, but I am over my time as I am, and I want to now recognize Mr. Massie for the same amount of time, for his questions. And thank you very much for allowing me to go through the slides. Thank you.

Mr. MASSIE. Thank you, Madam Chairwoman. Mr. Trudeau, you mentioned that Mallinckrodt was a manufacturer of generic drugs, and that was a big part of your market in the beginning. In general, what percent of prescriptions in the United States are generics?

Mr. TRUDEAU. I believe it is approximately 90 percent at this point.

Mr. MASSIE. So, 90 percent of the prescriptions that are written and filled in the United States, roughly, are for generic drugs. I think that is fantastic. But is the cost of generics in the United States significantly higher than in other countries? How do we compare when you go on a generic label?

Mr. TRUDEAU. Well, typically the United States generic market has been amongst the most efficient, meaning that prices drop most rapidly in the U.S. We have a very efficient market. And generic prices typically, in a relatively short amount of time, many times within a year, drop to about 10 percent of the branded price. So, we have a system that works from a generic perspective, certainly relative to other countries.

Mr. MASSIE. And what are some of the challenges you face when you want to make a generic drug, say after a brand name drug goes off patent? What are some of the hurdles that you have to overcome to get a generic drug to market?

Mr. TRUDEAU. Well, the primary thing that you have to do is generate bioequivalent status. You have to demonstrate that your product is bioequivalent to the branded product. That requires some clinical work. Sometimes it requires other investment, research and development investment. Then, of course, you need to be very efficient, from a manufacturing and distribution standpoint, because you are competing in a very aggressive, competitive marketplace.

Mr. MASSIE. Is there something that we can do in Congress to make it easier to get to a generic label from a brand name label after a drug goes off the patent?

Mr. TRUDEAU. I believe the generic environment today is actually quite good. I think there has been significant improvements on the regulatory side in improving the throughput of generic approvals. I think the statistics show that the FDA has generated significantly more approvals of generic products over the last couple of years. That certainly adds to competition, and that is certainly likely to drive down prices.

Mr. MASSIE. In order to produce a generic without infringing on a patent, the patent has to expire, I suppose, but can you also license the patent or is that not typical in the drug industry?

Mr. TRUDEAU. Certainly, it could be done but that is not typical. Mostly generic products enter the market after the expiration of patents.

Mr. MASSIE. And what is the lifetime of a patent?

Mr. TRUDEAU. Well, a patent can vary, but the lifetime is typically going to be on the order of 20 years. But recognize that is from the actual discovery itself, and much of that timeframe is actually taken up by research and development. Many times, when you launch a branded product you may only have a couple of years

left on the patent, because most of that time has been eroded because it has taken time to develop the product.

So, you know, typically it is 20 years. It can vary a little bit. But that is typically the timeframe.

Mr. MASSIE. That is 20 years from when the invention occurs, and like you said sometimes you are only left with a few years to try and recoup the investment. How many of the drugs that you develop actually result in a profit?

Mr. TRUDEAU. Well, on the generic side, typically you are likely to be reasonably successful because again you are not driving innovation necessary. But what you are doing is you are driving down cost because you are able to bring competitive products to the market.

On the branded side it is a little bit different. On the branded side I think, you know, the likelihood of success while you are actually driving innovation is dramatically lower. We have heard some statistics that 1 in 100 or so drugs ever makes it to market. That is probably in the range. It is a high-failure, high-risk environment when you are developing any kind of new innovation, as we all know.

Mr. MASSIE. Thank you. I have got a few questions for Mr. Bradway. Mr. Bradway, you talked about the sort of, I don't know if you used the word "convoluted" but it seems convoluted to those of us who aren't in the industry and trying to understand the drug pricing schemes and how it involves pharmacy benefit managers and rebates.

Can you tell us roughly what percent of the money that my constituents spend on drugs, or the government spends on drugs for my constituents, goes to pharmacy benefit managers, Mr. Bradway?

Mr. BRADWAY. Yes, I can tell you that the intermediaries, in general, which include the PBMs, have about 46 cents on every dollar in the pharmaceutical industry. So, 46 percent of what you see in the U.S. drug industry reflects revenues that go to the intermediaries, including the PBMs.

Mr. MASSIE. So, that is almost half of the drug price that the consumers pay or the government pays goes to an intermediary instead of the drug company?

Mr. BRADWAY. Or instead of directly to the patient. That is correct.

Mr. MASSIE. And when my constituents pay their copay on a drug, you mentioned that there are rebates that are paid. Do the rebates go to my constituents? Who do they go to?

Mr. BRADWAY. Thank you for raising this question, Congressman. I think this is important for you and your constituents to appreciate.

The copay is a function of list price and the rebates are also a function of list price. So, as list price rises, the rebates to the intermediaries rise as well. However, the other consequence of raising list price is that the patient at the pharmacy counter is having to pay a copay of now a higher list price, and the discounts that have been given to the intermediaries are not provided at the pharmacy counter to the patient.

So, we have wound up with a situation where the intermediaries are getting the rebates and not directly transferring that benefit to the patients. So, the intermediaries are seeing their share of the pie increase while asking the patients to reach into their pocket and pay more in the form of copay.

Again, that copay is not collected by the innovative industry. That copay is collected by the intermediaries in the system.

Mr. MASSIE. So the copay, because of the way the pharmacy benefit managers work and the other intermediaries, the copay that my constituents see, or the check that they have to write out, or sometimes they have to borrow the money for that copay, that copay isn't based on the actual price that goes to the drug company or the final price that the drug company receives for that drug. It is not even based on the real price of the drug once you count the rebates. It is based on a higher effective price. Is that correct?

Mr. BRADWAY. That is correct. You are absolutely right. Your constituents are paying a copay, again, which is a fraction of the list price, and the innovative company is receiving what is known as the net price, which is the list price minus the rebate returned to the intermediaries. And in the United States, the estimate of the rebates is approximately $150 million, but as I said earlier, 46 percent is in the hands of the intermediaries.

Mr. MASSIE. Madam Chairwoman, do I have time for one more question? OK.

So, can you explain to us, Mr. Bradway, what the intent was when we came up the pharmacy benefit manager system, what the intent was and how it was designed to make drugs more accessible or a lower price, and how that mission has possible wandered over the years?

Mr. BRADWAY. Sure, Congressman. I perhaps might point out two things. First, the structure of the rebate system that I am referring to is one that was created by legislation that enables us to interact with the intermediaries in a way that includes paying them rebates in order to secure formulary placement for our medicines.

But, you know, again, I don't want to just point the fingers at the PBMs. I think we heard in Mr. Trudeau's testimony one of the useful functions that the PBMs have played in our system through the years, which is helping convert patients to generic drugs when they are available. It is one of the reasons that we have 90 percent of the prescriptions actually being written for generic drugs.

I think the question, however, is whether they are playing an appropriate role when it comes to innovative, brand-protected innovations and design formularies that separate physician and the patient from one another at the pharmacy counter, where patients can't be sure that they are going to be able to walk away from the pharmacy with the medicine that their doctor intended them to have because of the structure of the rebate system that is in place in our industry.

Mr. MASSIE. It feels like to me, just in closing, we need some kind of truth in pricing here. If people bought cars this way and the actual price of the car wasn't what the consumer paid, and financing was based on a price that wasn't the real price, I think we would be outraged. So, maybe that is something we could look into.

I thank the chairwoman for her indulgence, and I yield back.

Chairwoman MALONEY. Thank you. I now recognize Representative Norton. Representative Norton, you are now recognized.

Ms. NORTON. Thank you very much, Madam Chair. I hope you can hear me.

Chairwoman MALONEY. Yes, we can hear you.

Ms. NORTON. I want to thank you for this very important hearing. In fact, the subject matter, drug pricing, is so important that you have scheduled two days, one after the other, on this subject, so we can clear this matter up.

I want to say to Mr. Bradway, Mr. Trudeau, and Mr. Kendris that we very much appreciate your joining us. Your testimony has been very helpful. We recognize, though, that you produce drugs that are crucial lifelines to patients and to their families. And you heard from the two witnesses who opened these hearings that far too many families lose access with each price increase, and that is before we get to the generic state of a drug.

Mr. Bradway, your company has raised the price of Enbrel 27 times since 2002. Amgen's profits from Enbrel has grown from $1.25 billion in 2003 to more than $5 billion today.

Now to turn to the other Amgen drug under investigation, Sensipar. Since launching the drug in 2004, Amgen has raised the price more than 20 times. Amgen's U.S. sales price for Sensipar also rose from $36 million in 2004 to $1.4 billion in 2018.

Mr. Trudeau, since acquiring Questcor, and, by extension, Acthar, in 2014, Mallinckrodt has raised Acthar's already high price by more than $8,200 per vial. That is a 26 percent increase. From 2014 to 2019, your company generated nearly $6 billion in net sales of Acthar.

Mr. Kendris, since launching Gleevec in 2003, your company has raised the price 22 times. Due to these price increases, your profits have grown from $1 billion in 2009 to more than $2.5 billion today.

Now nearly one in four Americans taking prescription drugs, against this backdrop, report difficulty affording their medicine. We began the hearing today with testimoneys from these two patients, who are on these medications for their lives but are struggling to make ends meet. Like many other families, they have to make heart-wrenching decisions to afford these vital drugs.

Mr. Bradway, yes or no. Will you commit to lowering the list price of Enbrel and Sensipar in the United States?

Mr. BRADWAY. Sensipar is now off patent in the United States and the price of Sensipar has fallen by some 95 percent. And as I said in my opening remarks, we have lowered our net prices across our portfolio in the U.S. over the past two years, and we are on track to repeat that again in 2020.

Ms. NORTON. Mr. Trudeau, yes or no, and I am afraid Mr. Bradway did not give me a yes-or-no answer. Will you commit to lowering the list price—and the reason I asked for a yes or no because my time up—will you commit to lowering the list price of Acthar in the United States? Yes or no.

Mr. TRUDEAU. I will commit to lowering the net price of Acthar in 2020 down to levels that it was in 2015.

Ms. NORTON. Thank you. Mr. Kendris, yes or no. Will you commit to lowering the list price of Gleevec in the United States?

Mr. KENDRIS. Congresswoman Norton, we have—the product went generic five years ago and we have lowered the price by giving discounts on the branded product, huge discounts, 40 or 50 percent discounts.

Ms. NORTON. But I mean the list price. I mean the list price, sir.

Mr. KENDRIS. Yes, we have given discounts on the list price post-generics, and we haven't raised the price. So we have, in effect, lowered the price and we are giving away 55 percent of what we manufacture now for free to patients who cannot afford their medicine. So, we are doing everything we can, Congresswoman, to make sure that every patient who needs Gleevec can get Gleevec.

Ms. NORTON. Thank you. Madam Chair, the problem is that they are not doing everything they can, and that is why this hearing is so important. I yield back.

Chairwoman MALONEY. Thank you.

Mr. Gosar, you are now recognized for questions. Mr. Gosar.

Mr. GOSAR. Thank you, Madam Chairwoman, and I am certainly happy that I follow my good friend, Thomas Massie, because he set the stage for me perfectly.

It seems to me that this hearing and yesterday's hearing are a little tone-deaf. We have countless states that have shut down with businesses crumbling due to the overreactions to COVID–19, yet we are here talking about how certain drugs need to have government-controlled prices. Yet there are millions who are thrust into unemployment because of these harsh restrictions. And this hearing isn't even focused on the drugs or therapeutics that most people have on their mind—a vaccine to COVID–19. But since we are here, I plan to get a little substance out of this hearing.

Today we have CEOs of some of the biggest pharmaceutical companies here with us. The way my colleagues on the other side of the aisle view prescription drugs and price tags are very top line. They see a drug that helps people but since it is not cheap, therefore we need the government to negotiate these prices. In typical fashion, you identify the problem properly but butcher the solution with more government. Ronald Reagan once said, "It isn't the government that is the solution. It is part of the problem."

As a doctor in a past life, the first step when diagnosing an ailment is look to the source and keep it as simple as possible. If there is something preventative that can be done to stop the problem from reoccurring, why not try?

Let's put this theory into practice. Why are drug prices so high? Many point to PBMs, greedy executives, a flawed patent system. Does anyone want to point a finger at the Federal Government? I know I do. In any prescription drug chain you have health insurers, PBMs, drug makers, pharmaceutical wholesalers, pharmacies themselves. What do they all have in common? Government influence and control. Right off the bat, health insurance companies are exempt from antitrust laws. That means they literally do not have to compete.

Many of my colleagues have been mentioning an infusion of competition to help lower prices, but how do you suppose we do this when a link in the chain can legally monopolize? I have been fighting my entire political career and before that to repeal this 75-year-old statute, because you can't even imagine a world where health

insurers have to compete for your businesses instead of leaving most Americans with little to no options.

As for other entities involved in the drug process like PBMs, these companies became a main focus of Obamacare and actually fueled the creation of new rules by CMS under the Obama Administration to come down on PBMs. And how about pharmacies and how they must deal with 340B contracts that set strict price controls on various drugs? No market force there.

And what about the drug makers we have here today? I am sure they could go on all day about how the government is involved in their day-to-day business. Just the FDA regulations alone could keep you guys talking for days, but unfortunately I only have so much time.

My colleagues on the other side of the aisle want to point to our current system and say that this is the free market. Well, if this is the free market and this is competition, it is failing America. What we now have is nowhere near a free market. It is crony capitalism at best, and it is just the excuse my colleague are using to push us closer to socialized medicine, where folks like these testifying today will be decimated and those created therapeutics for those who need it will be lost.

So, I say to you folks here today with us, join the side that is simplifying the prescription drug process. Be for the side of free market competition, because soon you may look like those drug companies in other countries where your profits are kept, your innovation is stifled, and your impact on making this world a better place will be completely evaporated.

Now last—hold your breath—I want to thank the majority for taking the first step in passing Congressman DeFazio's and my bill, the Competitive Health Care Insurance Reform Act, unanimously out of the House last week. This is the first step in which we create a solution where it is market driven. Now let's get the Senate to pass it, and what we see is patients, doctors, and the system all benefiting.

Thank you very much, Madam Chairwoman, and I yield back.

Chairwoman MALONEY. Thank you very much.

Representative Clay, you are now recognized for questions.

Mr. CLAY. Thank you so much, Madam Chair. Let me also thank you for mentioning our late colleague, Elijah Cummings. We knew that this was one of his signature issues and thank you for keeping his memory alive and keeping this effort.

Let me start off by thanking all three witnesses for being here, and let me say hello to a former constituent, Mark Trudeau, who has headed up Mallinckrodt, which has been a part of the St. Louis community for almost 150 years.

And, Mr. Trudeau, let me start with you. You know, part of the concern about Acthar is that it is a pretty old drug with a relatively high price and yet you have said Mallinckrodt is modernizing it. I think you said you have invested more than $600 million in it. Tell us why it is important to modernize this drug, and aren't there other, more modern therapies that can take the place of Acthar?

Mr. TRUDEAU. Thank you for the question, Congressman Clay, and good to see you as well.

So, like many opportunities, there are old drugs that have been repurposed for new indications and new purposes, for example, looking at some of the antivirals that are being developed to treat COVID–19, for example. In the case of Acthar, we believe that it is quite important to create new information, new evidence, things that have led actually to changing our label to provide patients and prescribers, as well as those responsible for reimbursement, the appropriate scientific-based information to make good economic and clinical decisions for their patients.

We are most focused on doing the best that we can for patients that are suffering from severe and critical illnesses who have relatively few options, and Acthar can make a difference in the lives of those patients.

Mr. CLAY. And, you know, I believe in the importance of medical innovation, and you have indicated that R&D is a major focus of your company and imply that Acthar is funding part of that R&D. How much does Mallinckrodt invest in R&D annually, and does your pipeline offer any promising options for patients?

Mr. TRUDEAU. We invest approximately $350 million a year in research and development, which is a large number for a company of our size. We believe that our pipeline is very promising and we have specifically focused on these underserved patients with severe and critical conditions that have relatively few options. So, we are developing two products for patients with severe liver disease, a product for adolescents and children that have a high mortality rate, called Niemann-Pick Type C. We are also developing a novel biotherapy to treat burns, severe burns, to reduce the need for autografting. So, our pipeline is really focused on driving innovation for these particular underserved patients.

Mr. CLAY. So, in my home state of Missouri COVID–19 has been a major concern. It is my view that during a national public health crisis like we are facing today pharmaceutical and health care companies should be focused on finding solutions.

Perhaps all three witnesses can tell us what your companies are doing in response to this national pandemic. Mr. Bradway, we can start with you.

Mr. BRADWAY. Thank you. We are very active in addressing the pandemic. I share your belief that all of the innovative biopharmaceutical industry needs to be working together, to find ways to develop vaccines, to develop therapies that can help prevent the infection from becoming serious, can help develop therapies to prevent the immune overreaction, which we see for many who are infected with the virus, and to be finding other ways to try to diminish the burden of this disease on our society.

But I am impressed by the speed and scale of the efforts underway, both at our company and across the industry, and I am optimistic that we will have solutions.

Mr. CLAY. Thank you. Madam Chair, can the other witnesses respond, or has my time expired?

Chairwoman MALONEY. Time has expired but the witnesses may respond.

Mr. CLAY. Thank you.

Mr. TRUDEAU. Madam Chairwoman, I am happy to comment on that. We agree with the Congressman that it is very important

that we do everything that we can to combat this challenging health crisis that we have created by COVID–19. We have done at least four things. One is that we have invested and partnered on clinical trials around one of our innovative therapies called INOmax, that can potentially help with patients that are ventilated as a result of COVID–19. It is being used at physician discretion today as an experimental therapy in over 250 hospitals.

We have donated PPE, ventilators, hand sanitizer around the country, and we have also made available some of our health care professionals, at company cost, to be treating patients on the front line. We believe it is that important to do everything that we can to combat this challenge.

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

Mr. PALMER. Thank you, Madam Chairman. I would like to start off by saying that obviously we are all interested in lowering drug prices, but at the same time we don't want to overreach and implement policies that stifle research and innovation that has literally brought us lifesaving miracle drugs. In fact, we want to encourage the discovery of new drugs, but at the same time, you know, discovering these new drugs doesn't do a lot of good if people who need the drugs can't afford them.

So, I want to followup on Mr. Massie's points on patents, and I brought this up yesterday. I support extending the length of patents if an extension will lower drug prices. And what I would like to know from each of you, and if you can answer concisely so that I can get in a couple of other things I would appreciate it, would extending the patent protections reduce drug prices? And we will start with Mr. Trudeau.

Mr. TRUDEAU. I believe that anything that we can do to incent innovation, and extending patent life could be one of those things, is likely to give the health care system an opportunity to get drugs to patients more efficiently and more effectively and potentially at lower prices.

Mr. PALMER. And Mr. Kendris and Mr. Bradway, if you agree with that, or do you have anything to add to that? I want to ask a couple of other questions.

Mr. BRADWAY. I think innovative biopharmaceuticals are an important way to control health care costs. We advocate for maintaining the 12 years of data exclusivity, in particular, for biologic drugs. So, we think that is an appropriate standard, and we see innovation as a way to bring down health care costs overall in the United States.

Mr. PALMER. OK.

Mr. KENDRIS. Congressman Palmer, I would agree with what the other two witnesses just said and would say that patents are essential to incentivize innovative companies to invest in high-risk research. And the patent system as it stands right now does that, and we support it.

Mr. PALMER. See, the reason, I think Mr. Massie and I both are asking these questions is because it should be obvious to everyone that a drug company needs to be able to recover their cost. My understanding of the private drug research industry is that it has led the way in the development of some incredible drugs, but there are

also a number of drugs that never made it to market. And you have to deal with that stranded cost that goes into your decisions on pricing of other drugs.

So, my question would be what would happen if the development of drugs—to the development of these life-changing, lifesaving drugs, if companies couldn't recover their cost? That should be a fairly simple question to answer. Mr. Trudeau?

Mr. TRUDEAU. Again, I believe my colleagues have agreed with this as well. Incentives are important if you are undertaking innovation, which inherently has risk. So, any additional incentives that can be provided to, you know, provide the potential to reduce that risk or increase the reward certainly are likely to lead to even more innovation, more inventions, and in the case of drugs, probably more potential cures or treatments down the line.

Mr. PALMER. If you guys have some ideas on incentives, whether it is write-offs for losses or other incentives that the government could provide, I would like for you to provide that to me and to this committee in writing.

But I do want to go back to something else that was discussed earlier, and that is the issue of rebates. Some of the information that I have gathered over the years—and this is not the first time I have looked at this; I started looking at this my first term in Congress—seems that there is some substantial abuse in the rebates and how this is handled. That might be an example of something that the Federal Government thought was a good idea at the time that is not working out quite so well.

That said, I would appreciate getting some feedback from each of you on incentives that you think would help the companies bring these prices down yet not compromise, in any way, the ability of companies to develop these drugs that, like I say, are not only lifesaving but life-improving.

Madam Chairman, I yield back.

Chairwoman MALONEY. Thank you. I now recognize Mr. Rouda. You are now recognized for questions.

Mr. ROUDA. Thank you, Madam Chairwoman. First, I would like to recognize the critical importance of the drugs that all of your companies manufacture——

[Pause.]

Mr. ROUDA. I apologize. The mic was not on.

Thank you, Madam Chairwoman. First, I would like to recognize the critical importance of the drugs that all of your companies manufacture to the health and well-being of many Americans. The essential nature of the prescription drugs and treatments you manufacture make it all the more vital for us to ensure their continued availability and affordability for all.

Mr. Trudeau, Mallinckrodt drug Acthar has proven effective and received FDA approval for numerous conditions that you outlined in your opening testimony. Acthar was first approved by the FDA in 1952, and it was actually priced at below $100 for 50 years. However, over the past two decades we have seen an astronomical price increase at the expense of American patients and taxpayers.

In 2001, Questcor, now a subsidiary of Mallinckrodt, acquired the rights to Acthar for $100,000, when the price per vial was still at or below $100—a vial, just like this, for $100, just 20 years ago.

Almost immediately, the price of the drug started to increase, and then, in August 2007, the price skyrocketed from $1,600 a vial to $23,000 per vial, literally overnight. When Mallinckrodt acquired Questcor in 2014 for $5.6 billion, the price of a vial already exceed $30,000.

So, today that same vial, from 50 years ago, that cost only $100, now costs $39,000, a 40,000 percent increase. Let me repeat, a 40,000 percent increase from this to this, in a matter of two decades. It is clear, American taxpayers are increasingly footing the bill for this drug.

While the number of Medicare Part D beneficiaries receiving Acthar increased by around 25 percent from 2013 to 2018, the cost to the Federal Government nearly tripled over that same time.

Mr. Trudeau, do you know how much your company has collected from Medicare Part D in recent years?

Mr. TRUDEAU. I don't know the exact amount. Certainly, it has been many millions of dollars.

Mr. ROUDA. It has. It has actually been approximately $2.5 billion between 2015 and 2018.

Mr. Trudeau, when Mallinckrodt acquired Acthar, how much of Acthar sales came from Medicare?

Mr. TRUDEAU. At the time of acquisition, the Medicare sales were approximately 25 to 30 percent.

Mr. ROUDA. That is correct, and that number has grown quickly. Do you know what percent is Medicare sales now?

Mr. TRUDEAU. I do. It is approximately 55 percent.

Mr. ROUDA. That is what the committee's information shows as well. We have gone from 25 percent to actually more than 60 percent of Mallinckrodt's net sales are from Acthar.

So, not only is Medicare your largest purchaser but internal data obtained by the committee shows that you also charge Medicare more than any other payer. Medicare's average net price, per vial, right here, is more than $4,300 more than what commercial payers pay. Do you know how much the Federal Government would have saved if Medicare had received the same discount—the same discount—as commercial payers between 2015 and 2018?

Mr. TRUDEAU. I don't know the exact amount, but the number would have been significant. In fact, Acthar is not on Medicare formularies, which actually prevents access to Medicare patients who could actually benefit from the drug. We would be very happy to consider similar discounts in Medicare if we had formulary positions and could get the same access that we get with commercial payers.

Mr. ROUDA. That would be helpful, and I am sure the American taxpayer would like to see it since the committee's estimate is that it would save American taxpayers $150 million a year.

Unfortunately, Mallinckrodt's 2013 tax inversion to Ireland has also burned American taxpayers. Is it safe to say you moved your headquarters over there to dodge corporate taxes here in the United States by having a lower corporate tax rate in Ireland?

Mr. TRUDEAU. No. That is, in fact, completely untrue. We spun out from a parent company that was Irish, and so this spun company, Mallinckrodt, became Irish as well.

Mr. ROUDA. Madam Speaker, I see that my time has expired so I shall yield back.

Chairwoman MALONEY. Thank you very, very much for your questions.

Mr. Cloud, you are now recognized for questions. Mr. Cloud.

Mr. CLOUD. Thank you, Chairwoman. It seems to me that oftentimes in Congress we go about trying to fix a problem before really stopping to ask what is broken about it. And, you know, we are talking about drug pricing, which we all agree we want to fix. It is definitely out of control. But I think it is important we stop to ask what brings costs down in an economy, and that is competition and customer accountability through price transparency.

Yesterday I had a chart up here that showed just how complicated that pricing system is, which makes it extremely hard for a customer to hold the manufacturers accountable or the system accountable when it comes to price transparency. In any other industry that is really how it work. You have a manufacturer that produces a product, the customer is able to look at pricing and market keeps prices low.

Now to foster innovation we have a U.S. patent system, of course, that protects research, incentivizes new cures. It has led to the U.S. being the undisputed leader in innovation, and to that extent the system is working. But what is broken is the customer accountability aspect and the price transparency that keeps prices in check.

Even if you think about the American people, they think that they go to their doctor, the doctor prescribes the best medicine, but that is not really what is happening, Mr. Bradway, is it? You talked about PBMs and what you are having to do to compete. Can you speak to that?

Mr. BRADWAY. Well, yes, so the physician hopefully is prescribing the most appropriate medicine for the patient. The challenge is, at that moment the physician and the patient may not know whether they are actually going to be able to walk away from the pharmacy counter with their medicine in hand or whether their insurance company is going to try to direct them to select something else.

Mr. CLOUD. Right. Manufacturers, basically, you have to pay rebates, or some would call it kickbacks even, to get a higher placing on the formulary, right?

Mr. BRADWAY. Correct. The structure that you have created for our industry involves us paying a rebate to the intermediaries in order to secure, amongst other things, formulary placement.

Mr. CLOUD. So, that is one mechanism in which the market is being manipulated, in a sense, breaking that customer accountability mechanism.

Americans also understand, you know, that companies do need to make a profit to exist and to create new cures. I don't think Americans have a problem with that. We understand that the profits today lead to new cures tomorrow. What they do have a problem with is abuse of the patent system, namely product hopping, adding on patents to extend introduction of generics, patent evergreening, you know, small changes to dosages and such that have little change but you gain an extension to your patent, and

then pay for delay. And these are issues, I think, that manufacturers do have to take seriously.

Now while I wish we had PBMs and pharmacies here—and I would encourage the chair and the committee to consider that if we are going to have a real discussion on pricing—we need to have all the players here, because the system is complex and it is broken in a number of different areas.

But my understanding is that Amgen has—you talked about Sensipar and you mentioned that the patent is—time has expired on that. Are you saying that generics are now available?

Mr. BRADWAY. Yes. That is correct. Generics now supply approximately 95 percent of the market, and the product transacts at about 95 percent less than what was prevailing before patent expiration.

Mr. CLOUD. OK. Now we had Teva here yesterday, and my understanding is that you had an agreement with them, Amgen did, to keep Sensipar—them from producing generics for Sensipar for a couple of years. Is that correct?

Mr. BRADWAY. No, that is incorrect. We sued Teva for infringing on our intellectual property, and they ended up settling with us after having launched at risk, settling with us for having, again, launched against the uncertainty of their patent position.

Mr. CLOUD. OK. But the timing, I guess, is interesting, that that lawsuit was dropped at the same time you all ended up purchasing some of their properties, I guess.

The thing that I think is important to note here is that we have a couple of bills that we are looking at. One is H.R. 19, which actually goes to address these different issues, where the system is broken, versus H.R. 3, which is a takeover of the system. And, you know, as we look at this I think it is important for us to keep in mind, let's not throw out the system that has brought the best innovation and has led to new cures that have helped so many people here and around the world. And I would really caution against a government takeover that H.R. 3 subscribes. Thank you.

Chairwoman MALONEY. Representative Welch, you are now recognized for questions.

Mr. WELCH. Thank you very much. Mr. Palmer said it well, that these drugs are a tremendous health benefit, extending lives and alleviating pain, but if we can't afford it, it does no one any good. And the question here is about the pricing practices of big pharma and how that is putting the cost of health care out of reach for individuals, for taxpayers, and for employers who are trying to provide health care for their employees.

I want to ask Mr. Bradway about the pricing strategy for a few of his drugs. What I understand, Mr. Bradway, Enbrel was originally approved by the FDA in 1998 for rheumatoid arthritis, and Amgen acquired the rights to sell Enbrel in 2002. Is that correct?

Mr. BRADWAY. That is correct.

Mr. WELCH. So, you bought a product—your company bought a product. It didn't create a product. Correct?

Mr. BRADWAY. Correct. We bought a product that was in short supply, a product for which there were tens of thousands of patients on a wait list, seeking therapy, and then——

Mr. WELCH. I get it. Fair and square, you bought the product. You didn't invent it. Correct?

Mr. BRADWAY. That is correct.

Mr. WELCH. And then you marketed it, and you produced it, and you raised the price of it. Correct?

Mr. BRADWAY. Yes, but I was trying to explain one of the important things that we did was invest in process improvements that enabled us to move literally tens of thousands of patients off the waiting list and be able——

Mr. WELCH. Well, I am going to the price, because the question here is not the legitimacy of what you did. It is legal to buy the product. You didn't invent it. One of the arguments that pharma makes is it costs so much to "invent." Well that didn't happen. What you did is you saw a market and you responded to it and you produced it.

But my understanding is that you have raised the price by 450 percent, to $5,500 for a monthly supply. It is about $70,000 a year. Is that correct?

Mr. BRADWAY. Yes, that sounds correct.

Mr. WELCH. All right. And in Canada that is $1,800 as opposed to $5,500. Is that true?

Mr. BRADWAY. That sounds correct.

Mr. WELCH. OK. Here is the question. Why can't people that are Americans get it for $1,800?

Mr. BRADWAY. There are a couple of things to observe. First, many of the medicines that are approved, the innovative medicines like Enbrel that are approved in the United States are not available in markets like Canada.

Mr. WELCH. Let's—let's—you know, we are throwing this word "innovative" around. This product was invented in 1998. I mean, this is not new. This is decades old. So, my question is why can't an American get the Canadian price?

Mr. BRADWAY. Yes. This is a product that we have continued to invest in. The product that patients use today is not the product that it was in 1998.

Mr. WELCH. So, a Canadian can buy this for $1,800, but you won't give the benefit of that price to the United States of America and our citizens.

Mr. BRADWAY. The product that you see today is not the product that it was in 1998.

Mr. WELCH. Let me ask you this. There is a lot of evidence in the record now that when your company, and other pharmaceutical companies, are making the decision on pricing, they have to meet revenue targets. You have got shareholders to take care of and you have got executive compensation to be mindful of. Correct?

Mr. BRADWAY. I don't think of it in that way, no.

Mr. WELCH. You don't think of it but you get the benefit of it.

Mr. BRADWAY. When we look at the pricing of——

Mr. WELCH. I mean, there are payouts of $100 million to executives, and it is really heartbreaking for a lot of folks who can't figure out how in the world they are going to get the medication for a person in their family that they love.

Let me ask you this. What is the problem of a company that is selling a product in bulk to a buyer, having a discussion with that

buyer about a bulk price discount? Do you have some philosophical objection to that?

Mr. BRADWAY. Congressman, that is what happens every day in our interaction——

Mr. WELCH. Except with Medicare. It is illegal. It is illegal.

Mr. BRADWAY. No, it is not——

Mr. WELCH. All right. Would you be agreeable to having a discussion with a bulk buyer, who happens to be Medicare, about a fair price when they make bulk purchases on behalf of U.S. citizens who are on Medicare?

Mr. BRADWAY. Congressman, if I may explain, we interact every day with——

Mr. WELCH. Well, that is a yes or no. No, that is a yes or no. You have got a big buyer, Medicare, and I am asking if you are willing to negotiate with them about a bulk price discount.

Mr. BRADWAY. The Medicare beneficiaries are represented by the insurance plans and the PBMs, with whom we negotiate every day for the inclusion of our products on the——

Mr. WELCH. So, that is a no to negotiating with Medicare directly.

Mr. BRADWAY. Well, Congressman, what I am trying to explain is what is happening already today. We do think there are some areas for improvement in Medicare, in particular, in Medicare Part D, and we have been advocating for a number of those——

Mr. WELCH. I am only asking about negotiating with the Medicare program. That is it. Yes or no?

Mr. BRADWAY. Yes, I am just trying to make sure, Congressman, that you and your constituents appreciate that that is already happening today. It is happening through the negotiations——

Mr. WELCH. So, why don't we change the law and make it legal to do that?

Mr. BRADWAY [continuing]. That we are having with your intermediaries. So, those discussions are already taking place today.

Mr. WELCH. I am asking about a law that makes it legal. Right now there is a law that makes it illegal, right? It is bizarre that a bulk purchase can't have a discussion and negotiate a bulk price discount. That is the law. Do you think that is a fair law?

Mr. BRADWAY. I don't know that I would agree with your construction of the question, Congressman. What I am saying is that we have a highly concentrated set of intermediaries in the United States health care system, the health care insurance companies and the pharmacy benefit manufacturers, and they are negotiating for the benefit of Medicare today, or across the landscape. Are there improvements that could be made? Absolutely. Do we advocate——

Mr. WELCH. Madam Chair, my time has expired, and I yield back.

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

OK, we can hear you.

Mr. GIBBS. Thank you, Madam Chair. First of all, I want to thank you for this hearing. I also want to make clear, I know Mr. Palmer and others talked about, you know, we want to make sure, we want to thank the drug companies for what they do, producing

these therapeutics and everything, curing cancer and making quality of life better, so we should never forget that.

But I do—you know, listening to all the discussion here about the pricing, it is enough to make your head spin. I guess, Mr. Kendris, you said that Gleevec is also used for six new cancers, OK. Now, has that price come down? I think it hasn't come down, has it? What is the status of that, Mr. Kendris?

Mr. KENDRIS. No, Congressman. We did raise the price over the years.

Mr. GIBBS. Yes, OK. Well, what I am trying to understand, in other sectors of our economy, when you have more utilization, and obviously you have more utilization of the product because you say it is now cleared by FDA to use in six types of cancer, so you have more utilization of the product, why does the product go up? Is it because it is the formulary process that we are having so much discussion and all the intermediaries and the complexity of this drug pricing and how it is broken? I mean, the price should come down.

Mr. KENDRIS. I think the answer to your question, Congressman, is that the value of Gleevec went up over those years, for a variety of reasons, including the patients survived longer, lived longer, it became a chronic disease instead of a fatal disease, and more patients were able to benefit because we got more indications from the FDA approved over those years.

Mr. GIBBS. I get that. So, more patients are buying it. You know, it is being utilized more. But that ought to drive the price down, because you can put your fixed costs over more customer base. In any other business, in any other industry that is how that works. If you are selling a product and you can sell more of that product to a bigger customer base, that drives down the cost because your fixed costs are more over the customer base. Do you see what I am trying to say? Does that make sense? But apparently it doesn't work that way with drugs.

Mr. KENDRIS. Congressman, in this case—I understand what you are saying, but in this case, for these rare cancers, the commercial opportunity is actually quite small. The patient populations are very small——

Mr. GIBBS. Let me ask the question——

Mr. KENDRIS [continuing]. But the research and development commitment is high.

Mr. GIBBS. That makes sense. That is the first comment I have heard today that makes some sense. You did say 65 percent of that drug, you give it away. Is that true?

Mr. KENDRIS. Today, 55 percent is given away for free, post generic approval, since 2016.

Mr. GIBBS. And I know Mr. Bradway said the same thing about Repatha, 60 percent discounts. So, there are a lot of things going on there. The drug companies are doing their best to help people that need the drug to get the drugs. So, I am kind of assuming—does anybody go without these drugs that need it, that they are getting it even if they can't afford to pay for it?

Mr. KENDRIS. We are doing everything we can. When we receive a patient complaint, we investigate each and every one, and we have a variety of ways of trying to ensure that that patient will get access to the product that they need.

Mr. GIBBS. And then, you know, the other area I think I see where the structure is broken is when you talk about 46 percent of a cost is going to the intermediaries, PBMs, and that seems like a problem. And I think it was you who made the comment, or one of the witnesses talked about the generics, and you go to the drugstore, the patient, to make sure they get the right generic, and the intermediary is doing that with the health insurer and everything. I always thought that is where the pharmacist fits in. The pharmacist, what role do they have now? Are they getting kind of pushed out by the intermediaries, or how does that function?

Mr. KENDRIS. Well, certainly the pharmacist at the drugstore is not responsible for the fact that the discounts that the manufacturers are giving to middlemen and intermediaries are not being passed on to the patient. That is not the responsibility of the pharmacist.

Mr. GIBBS. No, I understand that. But the pharmacist, if they say you can get another drug, a generic alternative, you know, and you are negotiating with the intermediaries, the PBMs, where does the pharmacist fit into that discussion, that the patient does get to make sure that the patient does get the right drug if there is a generic equivalent?

Mr. KENDRIS. I think the negotiation that you are referring to does not include the pharmacist in that case. Negotiating with the intermediary, with the middlemen, a contract, and that is how we sell it to the middlemen.

Mr. GIBBS. I am out of time, but I just want to followup on that. Do you think we should be looking into the role of the intermediaries and how it affects the patient and the doctor and the pharmacist, making sure they get the right drug, the right generic drug, a generic alternative, and——

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

Mr. KENDRIS. I do, Congressman. I think that we should do everything we can to make sure that the discounts are passed along to the patient.

Mr. GIBBS. Thank you. Thank you, Madam Chair.

Chairwoman MALONEY. Mr. Sarbanes, you are now recognized.

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

Chairwoman MALONEY. Yes, we can.

Mr. SARBANES. I appreciate the hearing, as a continuation of yesterday, and I want to thank the witnesses for being here.

I have heard a lot of you say that, you know, things are off patent now, the pricing over the last two years has gone down, et cetera. That doesn't excuse the price gouging that happens when things are still under patent, you have the exclusivity, and so forth. And I just don't buy that these price declines were part of your business plan. I think it is a response to the scrutiny that you are under, so it is nice to talk about that and kind of dance around the essence of the price gouging that has been going on for years and years.

But I don't trust the industry to do the right thing when we are not looking at you with these klieg lights, and so we need to put more guardrails in place, and this hearing is about that. This is why Elijah Cummings started this inquiry originally, and we are

going to keep following through. And there is going to have to be major restricting of how the industry operates going forward. I know you are trying to duck and cover here, but you better anticipate that that is coming, because the American public is fit to be tied about the high prices of prescription drugs.

Mr. Bradway, I want to talk about Medicare Part D. That is 45 million seniors that are served by that program, and we are all contributing as taxpayers to the strength of the Medicare program. Your company has collected more than $7 billion in gross sales from selling Enbrel to Medicare Part D between 2013 and 2018. Is that correct?

Mr. BRADWAY. Those numbers sound right.

Mr. SARBANES. OK. And in the same timeframe you collected, or Amgen collected about $4 billion from selling Sensipar to Medicare Part D beneficiaries. So, it is an understatement that Amgen gets a lot of business from the Medicare program.

Does Amgen offer Medicare Part D comparable discounts to other—to the discounts that you give to other government purchasers?

Mr. BRADWAY. For example, the Medicaid prices that we offer are lower than Medicare, as you know, because it is statutorily designed to be lower than the Medicare Part D program. So, it is not the case that all of our government——

Mr. SARBANES. What about the veterans? What about Veterans Health Administration?

Mr. BRADWAY. The veterans' health program is also different from the Medicare Part D program. It includes both statutory price allowances as well as formulary restrictions, which are not part of Medicare Part D, as you are aware.

Mr. SARBANES. Well, I think Amgen's discounts to the Veterans Health Administration are about twice what Medicare is currently receiving. But let's face it, that is because the VA is allowed to negotiate drug prices with the industry and Medicare Part D doesn't get those same opportunities, because we don't have that ability to negotiate. We proposed a bill last December, House Democrats did. This is common-sense legislation that would allow Medicare to negotiate directly with drug manufacturers for lower prices, just like the VA and the Department of Defense are able to do.

I am not going to ask you for your position on whether we should be negotiating. I think I can guess what it is. But it seems to me that if your industry—again, to get back to the broader sort of macro picture here—your industry has figured out a way to do business with governments overseas that negotiate and are much more aggressive on behalf of their consumers and their taxpayers in dealing with the industry, and your industry has found a way to be able to manage a relationship and conduct your affairs even though you are giving a better pricing to the VA and DoD because you are having to negotiate there.

So, you will figure out a way, I am confident, to survive as an industry, to make reasonable profits, even if we move forward and put negotiation in place with respect to the Medicare program, which is all we are trying to do. And Mitch McConnell and the Senate Republicans have stood in the way of this. They have blocked the door to better opportunity for consumers and patients for years

now, but we are not giving up. We are going to keep the heat on, we are going to keep pushing, and we are going to do it because every day we have constituents coming up to us, scratching their head, looking at us in disbelief, and saying, "Why is it, in a free market economy, in the United States of America, you can't negotiate on behalf of 45 million Medicare beneficiaries for better drug prices?" We are going to keep pushing on that because it is the only thing that makes sense.

And with that I will yield back, Madam Chair.

Chairwoman MALONEY. Thank you. The gentleman's time has expired.

Mr. Higgins, you are now recognized.

Mr. HIGGINS. Thank you, Madam Chair, and I appreciate the continuation of this hearing from yesterday. This is incredibly important subject matter. And I am finding that the arguments from both sides of the aisle are quite similar.

Mr. Bradway, I am going to address my questions to you, sir. Respectfully, I understand businesses across the United States have costs associated with opening their doors to the public, and in order to stay in business you have be able to cover those costs. We know that high costs associated with developing new drugs and

[Inaudible.] Please clarify for us...

[Inaudible.] ...Recoup development costs, and what would be the result of...

[Inaudible.]

[Pause.]

Chairwoman MALONEY. We have a technical problem here right now. We are going to try to fix it.

[Pause.]

Mr. HIGGINS [continuing]. This time.

Chairwoman MALONEY. There. He is back. Mr. Higgins. We lost you for a while. OK.

Mr. HIGGINS. Yes, ma'am. I have no receiving signal at this time. If we are back on, I don't know if my question was received by Mr. Bradway.

Mr. BRADWAY. I am afraid I didn't hear the full question, so if you wouldn't mind repeating it then I will do my best to answer it for you.

Mr. HIGGINS. Yes. Basically, sir, let me just quantify quickly, in the interest of time. I have a couple of hard questions for you, so I am going to begin with a soft one. We recognize it costs a lot of money to develop a new drug. We get that. We understand the basic business principles are recouping initial investment cost. What is the importance of maintaining that formula, and what would happen to the development of new drugs if there were legislative action out of Congress that would restrict research and development of new pharmaceuticals and restrict companies investing in that research from recouping their initial costs? What would happen to the development of new pharmaceuticals?

Mr. BRADWAY. I don't think we would see innovative new drugs being developed for diseases like Alzheimer's or the many forms of cancers that remain not cured today, or autoimmune disorders.

Mr. HIGGINS. OK.

Mr. BRADWAY. And if I may, Congressman——

Mr. HIGGINS. I want you to know, we all get that. We understand. We understand that there are legitimate expenses for the development of new 21st century, high-tech, very effective pharmaceuticals. We understand that there are investments in many formulas that never make it to market, and that becomes part of the expense that needs to be recouped. We get that. On both sides of the aisle I am hearing the same argument.

But I must say that I concur with many of my colleagues across the aisle here. I do not understand, my constituents do not get it, why the same formula drugs, from the same manufacturer, across the border in Canada, can be two, three times less than it is here in the United States.

My wife has M.S. The pharmaceuticals are a constant challenge. She receives a therapy that is equivalent to like chemotherapy for M.S. every six months, and every six months we have the same battle with the insurance companies due to restrictions from the pharmaceutical companies.

My constituents don't understand. I don't understand. We expect to fix it, and we are going to fix it out of Congress. There is a bill in the Senate right now, Madam Chair, that if it would be introduced in the House, if it passed in the Senate, it would pass in the Senate, it would be introduced in the House, it could be law in a couple of weeks. We could really move forward to fix this thing.

But I would like the gentleman to answer, just one more time, why are pharmaceuticals so much less in Canada than they are in the United States? Because I don't get it, and my constituents don't get it either. I give you the floor, good sir. You have a minute and five seconds. Explain the variance of prices between Canada and the United States.

Mr. BRADWAY. I share your frustration and empathize with those who are struggling to understand the difference between the two systems.

As I said previously, in the United States 46 cents of every dollar are in the hands of intermediaries in the pharmaceutical supply chain, not in the hands of the innovative companies. In Canada that is not the case. Canada does not have 46 cents of every dollar——

Mr. HIGGINS. But does your company not get to spend the Canadian earnings?

Mr. BRADWAY. I am trying to——

Mr. HIGGINS. You don't get to keep that money?

Mr. BRADWAY. No, of course we do. I am just trying to——

Mr. HIGGINS. OK. So, let's stop talking about the difference of expenses in the United States versus Canada, because you have a worldwide market. Do you have a board of directors for the United States and then one for Canada, two different companies?

Mr. BRADWAY. No. Certainly not.

Mr. HIGGINS. Thank you. So, your profits are your profits. Your expenses are your expenses. Why do the drugs cost so much less in Canada than here?

Madam Chair, my time has expired but I would like the gentleman to answer the question.

Mr. BRADWAY. Again, I would point out——

Chairwoman MALONEY. The gentleman may answer the question.

Mr. BRADWAY. Thank you, Madam Chairwoman. I would point out that in the United States many innovative drugs are available which are not available in Canada. If you look at drugs approved in the United States over the last decade——

Chairwoman MALONEY. Excuse me. That was not the question. The question from the gentleman was why does it cost two or three times, or upwards, four or five or six times more in the United States, where we produce the drug, why does it cost so much less in Canada, and I would say in Europe too? As I said earlier, we pay more for drugs in America than the entire world, combined.

So, that is his question. What is the answer?

Mr. BRADWAY. Thank you, Madam Chairwoman. The answer is that countries like Canada are prepared to ration and restrict the access to innovative new medicines in exchange for offering lower prices to the ones that they choose to grant access to.

Chairwoman MALONEY. Well, I respectfully disagree. The answer to that question is to allow Medicare to negotiate directly for drug prices with the drug companies, as they do in Canada and in Europe, and they are not allowed to do it in the United States. And that is one of the things many of us would like to do, to lower the price for the people that we work for.

I would like now to go to Wasserman Schultz. Congresswoman Schultz, you are now recognized.

Ms. WASSERMAN SCHULTZ. Thank you, Madam Chair. I want to pick up where I left off yesterday and ask about another nefarious tactic that drug companies use to maintain market exclusivity and sky-high prices.

This committee's investigation shines a spotlight on the ways that drug companies use litigation as a key part of their strategic plans to delay generic entry. Like yesterday, I again want to focus on how prices were inflated for lifesaving medication used to treat cancer.

Mr. Kendris, yes or no. Novartis engaged in patent litigation with the first manufacturer to apply to make a generic version of Gleevec. Correct?

Mr. KENDRIS. Yes, we did.

Ms. WASSERMAN SCHULTZ. OK. Some pharmaceuticals challenge the legitimacy of Novartis' patents, but rather than litigate, Novartis struck a deal with Sun, known as "pay for delay." Under the settlement, Sun agreed to delay generic entry into the U.S. for six months. Novartis made $1.3 billion in U.S. net revenue from Gleevec sales during that six-month delay.

As the first generic manufacturer, Sun Pharma was entitled to 180 days of exclusivity, meaning no other generics could enter the market during that period. Although Sun Pharma initially announced it would price its generic 30 percent below the price of Gleevec, it ultimately entered the market just 6.4 percent lower than the cost of Gleevec. In an internal email, Novartis executives hailed this high price as, quote, "good news."

Mr. Kendris, do you think delaying generic entry was indeed good news for patients?

Mr. KENDRIS. Congresswoman, when we settled that case we actually accelerated the introduction of a generic Sun product into the U.S. If we had litigated and further litigated, that litigation

could have gone through the length of the patent, which would have been another three years. So, our settlement actually meant that the Sun product was on the market faster, actually two and a half years, I believe, faster than it would have been had we done what you are saying other companies do, and I understand that happens. But in our case, we did not get paid for delay and there was no litigation that went on for years to delay the generic onto the market. It was actually accelerated.

Ms. WASSERMAN SCHULTZ. You are right. There was no litigation because you paid for delay. Published estimates suggest that this pay-for-delay settlement with Sun Pharmaceuticals created $700 million in excess costs for consumers. This is unacceptable.

Sun Pharma originally said they would price their generic, were they allowed to move forward through the normal process without being challenged by Novartis to do so, that they were going to price their generic 30 percent below Gleevec's price. After you paid for delay and after you negotiated the so-called better deal sooner for consumers, they only priced it 6.4 percent below, and delayed their entry into the market by six months.

It is patients that are left holding the bag when companies like Novartis exploit the patent system to keep their market share. Research shows that 42 percent of cancer patients deplete their entire net worth in the first two years after their diagnosis. And I will tell you, I am a cancer survivor. I know what it is like to go through the 15 months of hell that I went through, and the countless stories I have heard from constituents who battle cancer every day.

In total, Novartis sued at least five companies in order to prevent generic competition for Gleevec, leading to a class action lawsuit that alleged that Novartis was engaging in sham litigation.

And now you know that protection of intellectual property rights is important for any company. But when you have proactive prices that become anti-competitive, used to delay generic entry and drive sales, both patients and the U.S. health care system suffer.

So, if companies don't behave responsibly, Congress must act to rein in this unconscionable behavior. No one should be unable to afford the medication they need to survive, and brand-name companies, every single day try to delay as long as possible competition in the market, which drives up costs for patients who need this vital access to drugs.

The annual cost of your drug went as high as $123,000 a year for cancer patients. That is insanity. It is robbery, and it kills people, as a result of them not being able to afford your drug. I don't know how you sleep at night.

Thank you. I yield back the balance of my time.

Chairwoman MALONEY. Thank you. Thank you for your statement.

Mr. KENDRIS. Chairwoman?

Chairwoman MALONEY. Mrs. Miller, you are now recognized.

Mrs. MILLER. Thank you, Chairwoman Maloney and Ranking Member Comer, and thank you to all the witnesses for being here today. I am pleased that we are able to continue with this conversation, because as we all know, the United States is the leading global innovator for groundbreaking medicine.

However, now more than ever, during the COVID–19 pandemic, it is extremely important that research and innovation is at the forefront of pharmaceutical development. While we look toward our future we need to ensure that the public and private innovators are utilized to address situations such as a pandemic and improve access to everyday lifesaving medications.

Mr. Kendris, how has the COVID–19 pandemic—there you are, good—how has the COVID–19 pandemic highlighted the need for innovation as we are all racing to develop better therapeutics and vaccines?

Mr. KENDRIS. In so many ways, Congresswoman. Thank you for the question. Many companies, including Novartis, are working on therapeutics. We have two of our products in clinical trials now to see if they will work for the cytokine storm that COVID–19 patients suffer. We do not have a vaccines business, but we are helping other companies who do. Our company, AveXis, formerly AveXis, has agreed to manufacture a vaccine for one particular vaccine maker, and we are also making available our Sandoz products that would be used to treat—our generics products, that would be used to treat COVID–19 patients. We are making them available at cost, no profit, or for free. We are making them available. We announced that a while ago, toward the beginning of COVID–19 pandemic.

So, we are doing all we can to find therapeutics. We have research candidates in the lab, I think about 20 research candidates in the lab, so not yet in clinical development, that are being investigated for possible use against COVID–19.

Mrs. MILLER. OK.

Mr. KENDRIS. We have also—yes, please.

Mrs. MILLER. OK. Well, I was just going to say, I also want to know, since Gleevec is classified as a specialty medication could you please discuss how this impacts the price and the market?

Mr. KENDRIS. Gleevec is a very specific medication. It is the first targeted drug, the first smart drug, as people call it, the very first one, in 2001. As a specialty medication, as I mentioned in some earlier questions, the cancers that it treats are actually rare diseases with small patient populations. CML may be the largest patient population but GIST, stomach cancer, that came second, and then five other rare cancers that came after that, very rare, small patient populations. But Gleevec, because it is a targeted cancer therapy, works very, very well, very efficaciously, for those cancers. So, it is a specialty product in that it targets these specific cancers and helps turn these cancers from fatal to chronic, or even, with our follow-on product, to a disease where treatment can be—or remission can be obtained treatment-free. The patient can stop taking Tasigna.

Mrs. MILLER. But that——

Mr. KENDRIS. They can't stop taking Gleevec.

Mrs. MILLER. OK.

Mr. KENDRIS. So, yes, please. I am sorry.

Mrs. MILLER. Well, I was going to, but you didn't answer how it impacted the price, being specialty.

Mr. KENDRIS. That is something——

Mrs. MILLER. I will move on, because I do have other questions.

Mr. KENDRIS. Thank you.

Mrs. MILLER. Many of my colleagues across the aisle continue to advocate for single-payer health care that would discourage and stifle innovation. If it were to become a reality, what would the innovation space then look like for a drug like H.P. Acthar Gel and multiple sclerosis?

Mr. Bradway, could you discuss the importance of preserving the Bayh-Dole?

Mr. BRADWAY. Well, I think you were asking a question about a Mallinckrodt drug, so I don't know whether you wanted to direct it to Mr. Trudeau or whether you had a more general question that you wanted me to address.

Mrs. MILLER. Well, more generally, because I do want to get into moving from this into how would the march-in rights affect innovation. So, that is just an example.

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

Mr. BRADWAY. Sorry, Madam Chairwoman. I didn't hear your statement.

Chairwoman MALONEY. Her time has expired but you may answer her question.

Mr. BRADWAY. Thank you. Thank you, Congresswoman. I think the effect would be chilling on innovation. I think the size of the so-called march-in rights for intellectual property would have a very deleterious effect on those who commit resources to risky research and development.

Chairwoman MALONEY.—yields back. Mr. Khanna, you are now recognized for questions.

Mr. Khanna? Representative Khanna? Is he there?

Mr. KHANNA. Yes, I think I was muted.

Chairwoman MALONEY. OK.

Mr. KHANNA. Thank you, Madam Chair.

Chairwoman MALONEY. We hear you now.

Mr. KHANNA. Can you hear me?

Chairwoman MALONEY. Yes, we can.

Mr. KHANNA. Great. I want to focus my line of questioning concerning the Amgen Enbrel drug, and if you could first explain, sir, the Enbrel drug—and this is for Mr. Bradway—it is an anti-inflammatory drug? Am I understanding that it was introduced in 1998?

Mr. BRADWAY. That is correct.

Mr. KHANNA. And it is one of the best-selling drugs in the world. Is that correct? It is largely for arthritis?

Mr. BRADWAY. Yes. It is for a form of arthritis known as rheumatoid arthritis and other autoimmune disorders.

Mr. KHANNA. And the primary patent on this expired in 2010. Correct?

Mr. BRADWAY. No. When you say the primary patent what are you referring to? Are you referring to the patent on the molecule itself that is Enbrel?

Mr. KHANNA. Yes.

Mr. BRADWAY. No, the patent on the molecule that is Enbrel has not expired. It was granted in——

Mr. KHANNA. What expired in 2010?

Mr. BRADWAY. A different patent but not a patent on the molecule.

Mr. KHANNA. What was that patent on?

Mr. BRADWAY. That was a use patent.

Mr. KHANNA. So, that expired. Correct?

Mr. BRADWAY. Correct.

Mr. KHANNA. How many patent applications have you filed since then to try to extend the monopoly on Enbrel?

Mr. BRADWAY. I don't know how many patent applications we have filed but I would guess several——

Mr. KHANNA. You don't know how many patent applications you have filed on one of your most important drugs?

Mr. BRADWAY. I wouldn't know that off the top of my head.

Mr. KHANNA. A thousand?

Mr. BRADWAY. No. I would guess it's——

Mr. KHANNA. Is it five?

Mr. BRADWAY. Excuse me, Congressman. I would guess that it is several dozen patents.

Mr. KHANNA. Sixty-eight patents. Doesn't that strike you—I mean if you were just talking to your neighbor or some person you were growing up with, you know, go back to when you were in high school, and they say, OK, you come up with a new drug. Let's say, OK, you file a patent. Do you think any person would say, yes, we should file 68 patents on a certain drug and extend that patent protection until 2037? I mean, just step back from your role as CEO. Do you think most Americans would think that makes common sense?

Mr. BRADWAY. Congressman, I think what is appropriate is the question of whether we are investing in innovation that deserves to be protected by patents, and fortunately——

Mr. KHANNA. No, I get all that. I get the debate, innovation. I understand we need patents. But just from a common-sense perspective, there is a drug, people take that drug. If you were talking to an ordinary person and you said, "We are going to file 68 different patents on this drug to protect our rights on it until 2037," do you think they would think that that was logical?

Mr. BRADWAY. Well again, Congressman, I think it would require a discussion about what those patents are being issued for, what innovation we are claiming in the patents, and we are fortunate to have the patent rights in this country protected by——

Mr. KHANNA. How much does the drug cost in Europe compared to in the United States?

Mr. BRADWAY. I don't have the answer to that question, Congressman.

Mr. KHANNA. You don't know how much the drug is priced in Europe? Would it surprise you if you know that the drug was 50 percent cheaper for Europeans than Americans?

Mr. BRADWAY. No, it wouldn't surprise me, but I remind you, Congressman, that we don't and have never sold or marketed the drug in Europe.

Mr. KHANNA. But you are selling the drug in Europe where you face actually competition. Isn't that correct?

Mr. BRADWAY. No, sorry, Congressman. We don't sell the drug in Europe. We don't own the product in Europe.

Mr. KHANNA. But my understanding is in Europe the price is 50 percent—it has similar bio, similar competition, and that has caused the price to drop by nearly 50 percent since 2018. Is that not accurate?

Mr. BRADWAY. Congressman, I wouldn't know the answer to that. We don't own the rights to Enbrel in Europe, so you would need——

Mr. KHANNA. No, I understand you don't, but Enbrel is being sold in Europe for 50 percent less, and you have competition there. Correct?

Mr. BRADWAY. Again, Congressman, I don't have the facts about Enbrel pricing in Europe. We have——

Mr. KHANNA. Can you make a commitment to the American people today that no American should pay more than people in Europe are paying for Enbrel? I mean, it is a simple thing. Are you an American, sir?

Mr. BRADWAY. Yes, I am. Proudly.

Mr. KHANNA. OK. So, can you tell your fellow citizens that no American should pay more for Enbrel than someone in Europe?

Mr. BRADWAY. Well, Congressman, the patent in Europe has expired, so the European situation is different from what we have in the United States.

Mr. KHANNA. So, the European patent has expired, so you think the Europeans don't want innovation for their drugs? I mean, so the Europeans don't think they need innovation, yet you think you need patents until 2037. I am asking you a very simple question. Make a commitment today, to the American people, that no one will pay a dime more for Enbrel than people pay in Europe. If you love this country, if you love America, you should be willing to tell Americans that they shouldn't be paying more than the French and the Germans and Europeans. Are you willing to make that commitment today, to the American people?

Mr. BRADWAY. Congressman, I would just repeat that in Europe the intellectual property for that product has expired.

Mr. KHANNA. I am just asking you a simple question. You can say no. If it were me and someone said will you make a commitment——

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

Mr. KHANNA [continuing]. Paying more than Europeans, I would say absolutely. Are you willing to make that commitment?

Mr. BRADWAY. We don't sell Enbrel in Europe, Congressman.

Chairwoman MALONEY. I take that as a no.

Moving along, Mr. Steube, you are now recognized for questions.

Mr. STEUBE. Thank you, Madam Chair.

Over 3.5 million Floridians are enrolled in some form of Medicare prescription drug coverage. With so many of my fellow Floridians and constituents dependent on lifesaving prescriptions, I understand the need for affordable drug prices.

Despite the efforts of Republicans to make bipartisan progress to reform the prescription drug standards, our Democratic colleagues refuse to collaborate. They will try to suggest that H.R. 3, which is a key example of partisan government overreach, would solve some of the problems that we are discussing today. This is not the case, and the Trump administration decisively acted to approve a

record number of generic drugs and bring down overall prescription prices down 13 percent. Obviously, there is still a lot of work left to do and I am glad we are taking steps to discuss this situation and hope we can move toward establishing solutions.

Mr. Bradway, my first question is to you. What is Amgen currently doing to assist in this mutual goal of providing Americans with lower drug prices?

Mr. BRADWAY. Congressman, thank you for the question. As I mentioned in my opening statement, our net prices in the United States have decreased in 2018 and 2019, and we are on track to have further decreases in 2020.

In addition, Congressman, we have made a significant investment in biosimilars and we are making available to patients and prescribers biosimilar medicines for some of the biggest-selling drugs in the United States, at more affordable prices than the innovator products that they are designed to replicate.

In addition, Congressman, we are working with a variety of different patient assistance programs through which we give away free drugs to those who are uninsured and can't afford their drugs or underinsured. We try to provide copay assistance for those who are struggling, who have insurance plans but are struggling with making payments for their deductibles and seeking to make contributions to other charitable foundations that can assist patients with their medicines as well.

So, across the board, sir, we are trying to do quite a lot to help make sure that patients who need medicines can afford them.

Mr. STEUBE. I was interested that in your testimony you stated that Amgen voluntarily lowered the list price of one of your medicines by 60 percent. However, you described a situation where even after lowering the list price some patients did not see a meaningful difference in what they had to pay out of pocket at the pharmacy. Some of my colleagues believe that forcing you to lower your prices will solve all of our problems, but it doesn't seem like that happened in that instance. Can you explain why?

Mr. BRADWAY. Thank you, Congressman. Yes. You are referring to a drug called Repatha, which is our product designed to lower cholesterol and prevent heart attacks and strokes. It is one of our most important innovative new medicines. We lowered the list price for that medicine by 60 percent in order to try to make it more affordable at the pharmacy counter. Remember, that patients pay a copay as a function of list price, so by lowering the list price we were lowering their out-of-pocket expenses.

However, we found that it took more than a year for the insurance plans to move patients, to direct patients from the high list price product to the low list price product. So, we ran the experiment and found that it didn't work in the way that we thought it would. We see this as an example of how the system is not working today for patients, and that is one of the reasons why we think we need to reform the rebate system that exists in the United States today.

Mr. STEUBE. Thank you. I understand there are certain payment programs in place which can help patients afford drugs like Enbrel and Sensipar. Would you be able to discuss their effectiveness in any other similar initiatives that you are discussing?

Mr. BRADWAY. Thank you. Yes, we have a number of programs designed to help patients pay for expensive medicines. So, for example, in the case of Enbrel we have copay assistance in place so that more than three-quarters of the patients who use Enbrel today have a copay of less than $50 a month for their medicine.

When it comes to Medicaid, 93 percent of patients are able to receive their medicine at less than $10 a month in copay. And when it comes to Medicare, we have 77 percent of the patients being able to receive their medicine at less than $50 a month.

So, there are examples across our portfolio of the ways that patients are benefiting from the support provided to them in order to be able to access these innovative, life-changing medicines.

Mr. STEUBE. Does Amgen utilize rebates for PBMs and how does that impact patient price?

Mr. BRADWAY. Yes, we do use rebates. Again, rebates are a function of list price, so if we increase the list price we increase the rebate. You might ask why are we increasing the rebates? Why do we feel pressured to increase the rebate, and the answer is to secure competitive formulary position for our molecules. So, we increase the list price to be able to increase the rebate to the intermediaries. The unfortunate effect of that is it also increases the out-of-pocket cost for patients at the pharmacy counter. And again, that is why we advocate for changes that would include passing through the rebate at the pharmacy counter.

Mr. STEUBE. Thank you. My time has expired. Thank you for being here.

Mr. BRADWAY. Thank you.

Chairwoman MALONEY. Thank you.

Congresswoman Speier, you are now recognized for questions.

Ms. SPEIER. Thank you, Madam Chair, and thank you all for participating today. I appreciate it. I think all of us appreciate it. Many others declined the invitation.

I want to start with Mr. Kendris and Gleevec. Gleevec is a miracle drug. My former chief of staff's wife died of CML. Had she lived another couple of years Gleevec would have been discovered as this miracle drug and her condition would have been chronic and she would be alive today. So, we truly appreciate the miracle that Gleevec has become for leukemia patients.

I would like to educate the public on what LOE is. It is called loss of exclusivity. And I would like for the staff, if they would, to put a slide that the committee got that was part of a presentation that was, I guess, provided to some of the staff of the company, and shows a dramatic increase in the price of Gleevec toward the end of its exclusivity.

[Slide.]

Ms. SPEIER. In fact, between 2013 and 2015, Novartis' price increase accelerated. It raised the price of Gleevec five times in two years. It turned out to be a 20 percent increase in that drug.

Now company executives knew that Gleevec sales would decrease once it lost its exclusivity so they tried to get as much profit out of the drug for as long as they could. This plan was explicitly stated in internal documents by Novartis executives who wanted to, quote, "maximize value of brand prior to loss of exclusivity." Is that not the case, Mr. Kendris?

Mr. KENDRIS. Congresswoman, can you identify the document that you have in front of you? I don't have it in front of me right now.

Ms. SPEIER. Well, the staff would be able to provide you that, but they are evidently documents you provided to the committee.

Mr. KENDRIS. Yes.

Ms. SPEIER. So, it is a fact. In the last two years of exclusivity you raised the price almost 20 percent. There is a chart we can put up that shows your net revenues going from $1.9 billion to $2.53 billion, and I don't know if the committee staff can put that on.

Mr. KENDRIS. Congresswoman—I am sorry. Please.

Ms. SPEIER. So, I mean, the question is, did you not increase the price of Gleevec some 20 percent in the last two years because you saw that there was going to be loss of exclusivity?

Mr. KENDRIS. Congresswoman, I don't know specifically why the increases in that period were taken. I was not there in the oncology——

Ms. SPEIER. All right. We will move on.

Mr. KENDRIS. But I can tell you that, as I was saying earlier, it is indisputable that Gleevec, that its value increased over the time it was on the market, and it was always the lowest product in its class, the lowest-priced product in his class.

Ms. SPEIER. OK. Mr. Kendris, I am reclaiming my time——

Mr. KENDRIS. Yes, please.

Ms. SPEIER [continuing]. Because I want to go to another line of questioning. I just want to point out that Medicare—this is the Federal Government—paid $5.6 billion to your company between 2011 and 2018, and that one-third of all the money you made in the United States came from the taxpayers through Medicare. And Medicare right now is two years from basically falling off a cliff.

I want to go to each of you now and ask you this question. How much money do you spend on marketing? Mr. Kendris?

Mr. KENDRIS. Our marketing spend, Congresswoman, is approximately 400 million U.S. dollars in direct-to-consumer advertising.

Ms. SPEIER. OK. $400 million. How much do you spend in Europe?

Mr. KENDRIS. I am not sure I know the answer to that off the top right now but I can get you that.

Ms. SPEIER. All right. Thank you. If you would get that to the committee.

Mr. KENDRIS. Thank you. I will.

Ms. SPEIER. Mr. Bradway, how much do you spend in direct-to-consumer marketing?

Mr. BRADWAY. Direct-to-consumer TV advertisement in the U.S., less than $200 million.

Ms. SPEIER. $200 million. How much do you spend in Europe?

Mr. BRADWAY. A fraction of that. Not on TV but in other forms of——

Ms. SPEIER. In fact, there is no TV allowed in Europe. Is that correct?

Mr. BRADWAY. I believe that is correct. Maybe

[Inaudible.]

Ms. SPEIER. And then, Mr. Mallinckrodt, how much do you spend?

Mr. TRUDEAU. We don't spend any money on direct-to-consumer advertising, Congresswoman.

Ms. SPEIER. All right. Mr. Trudeau?

Mr. TRUDEAU. Yes, that was me, Mr. Trudeau. We don't spend any money on direct-to-consumer advertising.

Ms. SPEIER. All right. My final question is this. Do you all commit—and I just need a yes-or-no answer—do each of you commit to not increase the cost of your drug, moving forward, beyond the inflation each year?

Mr. Bradway?

Mr. BRADWAY. I would point out that we have decreased our prices——

Ms. SPEIER. So, yes or no, sir.

Mr. BRADWAY [continuing]. We have decreased our prices over the last three years and increase of list prices have been below inflation. So, you know——

Ms. SPEIER. Your answer is yes, you would commit to doing that.

Mr. BRADWAY. My answer is that is how we have been operating the business the last couple of years.

Ms. SPEIER. OK. Mr. Trudeau?

Mr. TRUDEAU. As I said earlier, we are committing to reducing the net price of Acthar to 2015 levels by the end of 2020, which is the first year—2015 was the first year, actually full year, we acquired Acthar.

Ms. SPEIER. And Mr. Kendris?

Mr. KENDRIS. As to net prices, Congresswoman, yes.

Ms. SPEIER. All right. Thank you. I yield back.

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

Mr. KELLER. Thank you, Madam Chair. We all need to ensure patients access to affordable drugs, particularly those in rural areas that rely on essential safety net programs. Contract pharmacies are essential to the rural areas of Pennsylvania that I have the privilege to represent. About 80 percent of rural hospitals are 340B. They use pharmacies to provide access to outpatient drugs for those who need them, many of whom are seniors and/or have chronic conditions.

Mr. Kendris, thank you for being here. I wanted to ask you about your new, quote, "integrity initiative to address duplicate discounts requiring covered entities to register and upload 340B claims data originating from contract pharmacies onto a new web-based platform."

Your announcement from August expresses support for a sustainable 340B program. I do have concerns about this threatening hospitals in Pennsylvania, and their ability to offer home infusion services, telemedicine, and expand their outpatient facilities, stretching scarce resources to patients in need.

So, Mr. Kendris, what kind of collaboration have you had with 340B hospitals about his integrity initiative?

Mr. KENDRIS. Thank you, Congressman Keller, for the question. I appreciate it.

So, Congressman Keller, we support the intent and the design of the 340B program to help lower outpatient drug prices for the uninsured and the net profit safety net providers that you were just

describing to your constituencies. They serve underserved populations in those communities and the 340B program helps them. We support the 340B program.

However, we also believe that over many years there have been some abuses that have grown into the system, and we are trying to resolve those abuses. We have raised the problem over the years—many companies have—with HRSA, and we are committed to ensure that our medicines are accessible to as many patients as possible, and through 340B as well. But we believe that the current state of the program is somewhat distorted from its original intent——

Mr. KELLER. I understand that. If I could just jump in.

Mr. KENDRIS. Thank you.

Mr. KELLER. I have a letter dated August 17, explaining your integrity initiative. My question was, prior to the letter have you talked to hospitals about this program and how it might be implemented?

Mr. KENDRIS. I believe that our staff is in contact with hospitals. We are collecting responses to that letter, and we are going to continue to work with them.

Mr. KELLER. So, if I can just jump in, I have got a limited amount of time. So, if you are in consultation with the hospitals, when were you planning on making this in effect and stopping some of the discounts to the 340B hospitals? It is my understanding that were to begin at the beginning of this month.

Mr. KENDRIS. We had asked for the data by October 1st. We are still evaluating the responses. We have not heard from all the hospitals, and we are evaluating the data that we have received, and we are going to continue to evaluate that data. And as we move forward, it is going to be based on what we see in the data we receive.

Mr. KELLER. So, if a hospital hasn't registered that data by October 1st, are they still going to be able to participate in the discounts?

Mr. KENDRIS. Yes. We still intend to honor valid, legitimate 340B discounts, and what we will do is we will see the responses, we will look at the data, and then we will talk to the hospitals and move on from there.

Mr. KELLER. OK. And a question on the web-based portal. Is this a secure platform or should we be concerned about data security?

Mr. KENDRIS. I believe it is a secure platform. I can check with our team on that, but I believe it is.

Mr. KELLER. OK. Do you expect there to be any administrative burden on hospitals, or what would that be?

Mr. KENDRIS. No. Actually, we believe that it is easy to pull this data. It is not burdensome. It is actually the same claims data that they have been sharing with the intermediaries that we talked about earlier in the hearing. So, the data should be available—I think it takes about five minutes every two weeks to pull this data.

Mr. KELLER. So, you know that the intermediaries have this data already. So, have you asked them for the data, rather than make the hospitals do it if it is already available? Have you looked at another way to get it?

Mr. KENDRIS. I think that relationship is between the hospitals and the intermediary, and I think we have to ask the hospitals for it. I can check into that, Congressman, but I believe that is what we have.

Mr. KELLER. OK. I just would like to end by saying that 340B discounts are crucial for my constituents, and we should be thoughtful about how any changes to the program would affect this going forward. We need to ensure that the changes to the program are manageable and in the best interest of health providers and the patients they serve.

Thank you, and I yield back.

Mr. KENDRIS. We agree, Congressman. Thank you.

Chairwoman MALONEY. Thank you.

Mr. Connolly, you are now recognized.

Mr. CONNOLLY. Thank you, Madam Chairwoman.

Mr. Trudeau, when you acquired Questcor, one of the very lucrative drugs in their command was Acthar. Is that correct?

Mr. TRUDEAU. That was virtually the only product that they had.

Mr. CONNOLLY. And it is my understanding that when Acthar first came on the market a vial, one vial, cost $40. By the time you acquired Questcor that price had gone up to almost $31,000. Is that correct?

Mr. TRUDEAU. That is correct.

Mr. CONNOLLY. Forty dollars to $31,000 for the same vial. And my understanding is the only difference wasn't the composition of the drug. It was the status, the legal status of the drug, that Questcor was able to get Acthar granted orphan drug status before you purchased it. Is that correct?

Mr. TRUDEAU. That is not necessarily the only thing but certainly that was something that did occur, that Acthar was granted orphan drug status.

Mr. CONNOLLY. Well, should we not correlate the two events, with respect to the value put on a vial of the drug? I mean, how do we explain going from $40 to $31,000 for the same vial, with the same efficacy and impact on a patient, other than it got reclassified as an orphan drug, which gave it a seven-year market monopoly for that designated use. Isn't that correct?

Mr. TRUDEAU. It did get an orphan drug designation. That is correct. In addition, the label was actually updated in 2010 to reflect the current set of 19 indications.

Mr. CONNOLLY. Right. So, the skyrocketing inflation in this particular drug had nothing to do with PBMs, for example. It had to do with the positioning of the drug as an orphan drug and the protection that provided, which allowed it to have highly enhanced value, which made it an attractive acquisition for your company. Is that not correct?

Mr. TRUDEAU. Based on FCC filings that Questcor filed at the time, the company was actually in an existential situation. They had a very essential drug for infantile spasms, and they were potentially looking at going out of business and not being able to provide that drug anymore to the marketplace.

Mr. CONNOLLY. So, you kind of came in and saved the day.

Mr. TRUDEAU. When we acquired Questcor and we acquired Acthar we did three things: one, we invested in clinical trials and

manufacturing; two, we started engaging with our customers to provide discounts and rebates; and three, we provided extensive patient assistance programs to minimize patient out-of-pocket expense and ensure that patients that could benefit from Acthar had good access to the drug.

Mr. CONNOLLY. And when you provide this drug through Medicare, for example, what is the discount?

Mr. TRUDEAU. We provide all allowable discounts under statute, and as I discussed earlier, Acthar is not on any Medicare formularies, and certainly if there were an opportunity for Acthar to get a formulary position in Medicare there might be the opportunity to provide additional discount, similar to what we do in the commercial sector.

Mr. CONNOLLY. Would the discount in this case, with respect to, say, Medicare, be about one percent?

Mr. TRUDEAU. I believe most recent data is on the order of one to two percent. That is correct.

Mr. CONNOLLY. Yes. So, a $31,000 drug that once cost $40, you are giving rebates to Medicare of less than one percent between 2015 and 2018.

Is it also true that your company is looking to use this drug for other treatments, other than the original infant seizure treatment it was developed for?

Mr. TRUDEAU. The company has been developing evidence to support the 19 FDA-approved indications that are currently on the label.

Mr. CONNOLLY. And if you do that, do you do that under the auspices of your protective status as an orphan drug or do you have to redefine that, because it is no longer being used exclusively for that original purpose?

Mr. TRUDEAU. The orphan drug exclusivity actually expired a number of years ago. Acthar is not affected. It does not have any exclusivity under any of the traditional patents or other exclusivities such as orphan drug. It is a drug that is designed primarily for underserved patients that have very few alternatives, a relatively very small population that is very sick.

Mr. CONNOLLY. I appreciate that, although I would add when you charge $31,000, or now $33,000 a vial, in today's price, I think that is not much of an alternative for a lot of patients either.

I yield back, Madam Chairwoman.

Chairwoman MALONEY. Thank you.

Ms. Foxx, you are now recognized for questions.

Ms. FOXX. Thank you very much, Madam Chairman. I want to thank our witnesses for being here today, for being where you are today.

My first question is for Mr. Kendris. Mr. Kendris, it has been said that Gleevec is a magic bullet for people fighting chronic myeloid leukemia. Can you discuss why this drug was such a game-changer?

Mr. KENDRIS. Thank you, Congresswoman, for the question. Yes, it was a game-changer. It was the first targeted therapy. So, you may have heard the term "smart drug." It was the first smart drug. It turned off a particular gene and it was able to be extremely efficacious, first in chronic myeloid leukemia and then in gastro-

intestinal stomal tumors, and then in five rare cancers, and that is because it was a smart drug. It worked very specifically on these very specific cancers, and by its mechanism of action the efficacy was so high that, as I said earlier, diseases, these six cancers, or seven cancers, were turned from fatal conditions for a patient who had died before Gleevec, into conditions where they lived and they were able to lead normal lives. And now we have developed a follow-in product, Tasigna, which allows patients to go treatment-free. If they get remission for a long enough time they no longer have to take any drug.

Ms. FOXX. OK. So, what is the current list price of Gleevec?

Mr. KENDRIS. The current list price of Gleevec is $120,000, and the net price is $85,000.

Ms. FOXX. OK.

Mr. KENDRIS. The price of a generic is $4,200.

Ms. FOXX. OK. So, how much does the average patient pay for it?

Mr. KENDRIS. Well, the average out-of-pocket cost for a Part D patient, Congresswoman, is $856 a year.

Ms. FOXX. OK. So, how does the patient get such a discount price?

Mr. KENDRIS. I think it depends on who the patient is and what their insurance coverage is.

Ms. FOXX. OK.

Mr. KENDRIS. The price I just gave you was for a Medicare Part D patient, for out-of-pocket cost, $856 average annual out-of-pocket cost.

Ms. FOXX. OK. So, a drug considered a magic bullet, and basically it is not quite a cure but it puts people in remission, has gone down from $120,000 to $856 for Part D. Thank you very much for that.

So, I would like to ask Mr. Trudeau, how does your company decide the right price to set for a new drug that may truly save someone's life?

Mr. TRUDEAU. Thank you, Congresswoman. What we try to do is we try to match the value that we believe that our products are going to bring to patients and kind of compare those two. And the value is in two ways. One is the benefit that it provides to patients themselves and their families, and again, we are typically developing drugs for some very devastating diseases where there are relatively few alternatives. And then we are also looking and creating data, actually, to see what value it may bring to the overall health care system.

So, for example, using the drug might increase the drug cost but it might have the impact of reducing overall health care costs for a particular disease.

Ms. FOXX. So, Mr. Bradway, the Congressional Budget Office estimates that Democrats' H.R. 3 would result in 38 fewer cures being developed over the next decade. What would be the impact on patients and innovation if there were 38 fewer cures created over the next decade?

Mr. BRADWAY. Well, I think that is potentially devastating. So, not only devastating to the patients and their families but I think also to the economy. I think our economy benefits from innovation

that enables us to treat serious illnesses. We are seeing the benefit of that every day now. So, anything that diminishes that opportunity I think would be tragic.

Ms. FOXX. OK. Very quick question for all three of you. On average, how often does your company, or even the whole pharmaceutical industry, bring to market a novel or game-changing treatment or cure? Each one of you answer fairly quickly, please.

Chairwoman MALONEY. The gentlelady's time has expired. The gentlemen may answer her question.

Ms. FOXX. Please answer. Mr. Bradway?

Mr. BRADWAY. Thank you for the question. We have 22 different novel, game-changing medicines that have been approved throughout our history. We have three, for example, this year. We are waiting for registration-worthy data. So, from one year to the next is different but 22 through our history, three more that we are waiting for this year.

Mr. KENDRIS. Congresswoman, it is Tom Kendris. For Novartis, I believe it could be more, but I believe last year we had at least four. This year I believe we have already had two, and we may have more to come this year. So, it is three to five almost every year, as an average, I would say.

Ms. FOXX. Mr. Trudeau?

Mr. TRUDEAU. Congresswoman, I think from an industry perspective we are trying to get as many novel, lifesaving medicines to the market as we can. For our company specifically, we are hoping to have two or three in the next two to three years.

Ms. FOXX. Thank you. I am sorry for going over, Madam Chairman.

Chairwoman MALONEY. Mrs. Plaskett, you are now recognized for questions.

Ms. PLASKETT. Thank you so much, Madam Chair, and thank you to the witnesses for being with us this day to answer these questions and to provide more information about drug pricing.

Mr. Bradway, when we talk about high drug prices, many times we talk about the list price. And large discounts are provided off the list price and then, as part of the insurance design patients are charged a percentage as a co-insurance. But my understanding is that this is always a percentage of the list price and not the discounted price. Is that correct? Do I have that correct?

Mr. BRADWAY. Yes, you have that generally correct.

Ms. PLASKETT. OK. I know my answer is probably simplistic. So, what are some of the ways in which to bring down what a patient pays? Your thoughts on that.

Mr. BRADWAY. Well, we have advocated for changes to the system that would include, for example, passing the rebates that have been negotiated between the intermediaries and the innovatives comes through to the patients at the pharmacy counter. That would have the immediate effect of reducing the out-of-pocket costs for the patient in the picking up the innovative medicine.

Second, we have advocated for placing an out-of-pocket cap on patients so that after they have paid a certain amount for their medicines during the course of the year they reach a cap and no longer have to have a copay.

So, those are two examples of things that we are advocating for. And as you may be aware, we have also taken the unusual step of even lowering list prices for our medicines by 60 percent in the case of our game-changing medicine known as Repatha, which lower the risk of heart attack and stroke.

Ms. PLASKETT. Great. Thank you. But in some instances the list price, they may go up, and there are reasons for that. But my understanding, as well, and I hope this is not too simplistic, but has the net price, what is actually made off the drug, gone down in recent years for any of the products that you make?

Mr. BRADWAY. Yes, Congresswoman. In 2018 and 2019, and again we expect in 2020, that the net prices for our portfolio in the United States will have decreased. So, across our portfolio net prices have fallen.

Ms. PLASKETT. And then can you explain to us how the net prices go down but yet the list price may go up, in many instances?

Mr. BRADWAY. Yes, Congresswoman. That occurs when the rebates that we are giving to the intermediaries exceed the increases in list price.

Ms. PLASKETT. Mm-hmm. OK. And can you explain how can biosimilars play a role in reducing health care costs and costs for patients?

Mr. BRADWAY. Yes, Congresswoman. Again, Amgen is a heavy investor in biosimilars. We have committed more than $2 billion to develop a portfolio of biosimilars. We make three of those available today in the U.S., with a plan to add more, to patients and prescribers. We provide them at a price that is a discount to what the innovative products are charging, and commit to having a reliable, safe supply of that lower-cost alternative available to patients.

Ms. PLASKETT. Thank you. Thanks so much for that.

I want to ask any of the witnesses, how have your companies, if you are, in fact, involved in the fight against COVID–19, what are the steps any of your companies are taking to improve diversity in clinical trials?

Mr. KENDRIS. Congresswoman, it is Tom Kendris from Novartis.

Ms. PLASKETT. Thank you.

Mr. KENDRIS. Thank you for the question. So, before COVID–19 hit our global drug development group was focused on this issue for our own clinical trials. It is a crucial step that must be taken, because I think the basis of your question, I am sure you realize, if a product is studied in a limited patient population, after it is approved doctors are comfortable prescribing it only in that limited patient population. So, if it is not studied in a minority population, whatever minority population that is, doctors will be more hesitant to prescribe it there because they don't have data.

So, we recognized before COVID broke that we needed to change that in our own clinical trials. Since the COVID–19 pandemic began, what we have done through our Novartis U.S. Foundation is to begin the process of convening other companies, and some groups like the NAACP and other groups focused on racial equity, to have a conversation about this very issue across the industry, so that we can improve diversity in clinical trials, in all clinical trials of all types, and to address the underlying problems, which have to do with many things, but trust for patients who are in clin-

ical trials would be one of those things. And that is going to take a broader conversation that we are going to try and convene.

Ms. PLASKETT. Yes. Thank you.

Chairwoman MALONEY. The gentlelady's time has expired.

Ms. PLASKETT. Thank you, Madam Chair. I would love to be part of that conversation, and I know the congressional Black Caucus is very concerned about this, and we would love to offer any thoughts and discussions on this.

And thank you, Madam Chair, for holding this hearing. I wanted to, at some point, ask these gentlemen, in another form, about how do we move manufacturing back to U.S. flags and what we can do to support bringing that infrastructure and those jobs back to our country.

But thank you for the hearing.

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

Mr. GROTHMAN. First I have a question for Mr. Kendris, and this is kind of a followup on a previous question. I also am concerned about the 340B program. Right now there are companies out there like Eli Lilly—I am aware they are not here today. They have refused to continue to offer the 340B prescription drug discounts to contract pharmacies that our kind of safety net hospitals, critical access hospitals, and community health centers rely upon.

To my knowledge, Novartis, at this point, has not refused to provide new discounts. However, you have been requesting claims data in order to prevent potential duplicative discounts.

Are you willing to give us assurances today that Novartis will be a good steward of the 340B program moving forward and will not do what Eli Lilly has done?

Mr. KENDRIS. Our intent, Congressman, is to be a good steward of the program. As you said, we have asked for data from the hospitals that will help us to avoid paying multiple duplicate discounts. So, we support the program, and allowing hospitals to use our discounts to provide the patient care that was originally intended by 340B. But what we don't support is allowing intermediaries, middlemen, to profit from the program.

Mr. GROTHMAN. OK. The next question, I guess, is really for any one of you. I guess maybe I should pick somebody else. Maybe we will pick Mr. Trudeau.

Specialty biologics are some of the major drivers of prescription drug costs because they often treat very particular diseases with limited patient populations. Evidence has shown that introduction of biosimilars in the market reduces that cost for patients. Since all your companies do have biologics on the market, how has the introduction of biosimilars impacted the price of your medications, and have any of you tried to prevent biosimilars from coming to market in an effort to stifle competition? And a followup question, how can Congress incentivize companies to break more biosimilars to market?

Mr. TRUDEAU. Congressman, thank you for the question. We are focused on what is in the best interest of patients, meaning that patients have access to the best possible medications they have for their condition at the lowest possible cost. We also support competition. Biosimilars, in some markets, have been shown to enhance

competition. Our company does not produce biosimilars, so that might be a question better directed to one of the other individuals.

Mr. GROTHMAN. OK.

Mr. BRADWAY. Congressman, this is Bob Bradway from Amgen. We are active in the biosimilar market. We have invested a couple billion dollars to develop our capabilities here in the U.S. We think this will provide an appropriate alternative choice for patients and providers.

So, far we have launched three medicines, the first two in the cancer field, where we have had very strong receptivity to our product offerings. So, we are providing those at a discount to the originator products and see a significant market already, after a short time being on the market. So, we think that the industry as created by the legislation known as BPCIA is working effectively, and the U.S. is nearly——

Mr. GROTHMAN. OK.

Mr. BRADWAY [continuing]. Biosimilars, and expect us, again, to be an important opportunity for patients and providers.

Mr. GROTHMAN. Let me just give you a quick yes-or-no question on this. President Trump's FDA released a biosimilar action plan which streamlined the process to approve biosimilars. We believe this is resulting in significantly more approvals of biosimilars than under the Obama Administration, which was not as aggressive in this area.

Would you agree the President's plan is saving patients money?

[No response.]

Mr. GROTHMAN. OK. I will give you a different question. Do you agree, you know, in trying to get more biosimilars to market under the President's plan, is that saving patients money?

Mr. KENDRIS. Congressman, it is Tom Kendris from Novartis. I am not sure that I am familiar with the President's plan, but we have Sandoz, as I mentioned earlier, a generics company and a biosimilars company. We brought the first biosimilar to market, Zarxio, in 2015. So, we certainly support biosimilars, and Zarxio itself——

Mr. GROTHMAN. Let me give you a quick followup question because I am on my final minute here.

Mr. KENDRIS. Sorry.

Mr. GROTHMAN. I am going to be introducing a bill, or have introduced, H.R. 8190, a Biosimilar Insulin Access Act, which will expand on what President Trump has done. Will you guys pledge not to get in the way of any expansion of biosimilars? Is that something you are going to fight, or do you—will you agree that we should be getting more biosimilars to market?

Mr. KENDRIS. Congressman, it is Tom Kendris. I think generally speaking we support more biosimilars coming to the market. Sandoz has biosimilars in its pipeline and is actively trying to get them onto the U.S. market, and that will help patients and reduce health care costs in the U.S.

Mr. GROTHMAN. Thank you.

Chairwoman MALONEY. The gentleman's time has expired. Representative Raskin, you are now recognized.

Mr. RASKIN. Thank you, Madam Chair.

Mr. Kendris, our investigation found that drug companies use anticompetitive tactics to prevent generic competition in order to prop up profits. Novartis engaged in pay for delay, where companies pay off generic competitors to delay their entry into the market. Novartis struck a deal with the first generic competitor to postpone its entry by six months. This is on Gleevec. The generic originally announced it would price its product 30 percent below Gleevec, but then they ultimately set the price at only six percent below Gleevec.

Experts say that these various maneuvers employing a six-month delay and then a six-month duopoly, resulted in $700 million in excess costs to payers alone, in a single year, in 1915-'16. And you collected your highest net revenue from Gleevec during that two-year period when more than 100 Novartis employees collected more than $1 million a year, and the CEO, I understand, earned a total of $72 million that year.

One strategy of anticompetitive exclusion is to engage in restrictive contracts with health plans and pharmacies to ensure that those health plans and pharmacies only cover or dispense the branded, or non-generic, form of the drug. These contracts are called National Drug Code locks on generics, or NDC blocks, for National Drug Code.

Internal records showed that Novartis developed and implemented an NDC block strategy. Novartis offered higher Gleevec rebates or discounts to health plans in exchange for their plans blocking generics from the covered drug list. This meant that Gleevec would automatically be substituted instead of a generic version.

Mr. Kendris, do you agree that NDC blocks are fundamentally anticompetitive?

Mr. KENDRIS. Congressman Raskin, no, I don't agree with that. I think payer contracting actually saves the health plans and the brand is cheaper than the generics in that case. What we did was we lowered the price of the branded product with steep discounting, and we competed with generics on price with our brand.

Mr. RASKIN. Well, but why did you need to institute a formal block to keep the generics from being in competition at that point?

Mr. KENDRIS. It wasn't to prevent generics to be in competition. There were physicians and patients who wanted branded Gleevec, and in order not to be automatically substituted at the pharmacy counter those patients wanted Gleevec, and these payers, who we contracted, wanted to get Gleevec brand to them.

Mr. RASKIN. Well, you actually promoted to consumers the idea that they should only order Gleevec. Tell us about your dispense-as-written campaign for doctors to write "dispense as written" or "DAW" on prescriptions.

Mr. KENDRIS. That is a campaign to make sure that doctors and patients know that if they want Gleevec, the branded product, and many patients who are stable, in remission from cancer, want to stay on the branded product and not go to a generic, if they want that they need to write—they need the doctor to write the prescription for Gleevec, the brand, or they will be automatically substituted at the pharmacy. So, that is what "dispense as written" means, and it is for the patients and the doctors who would like

to keep the patient on Gleevec as opposed to being switched to a generic automatically at the pharmacy.

Mr. RASKIN. But don't you actually try to influence consumers or patients in that choice? You say, "It is your right to ask your pharmacist for branded Gleevec. Tell them to dispense as written. The power is in your hands. Demand the brand. Multiple generics can lead to patient confusion. If you get generic your medication may change shape, color, size, from month to month." Aren't you actually out there campaigning against generics and making the patient believe that they need to get the branded pill?

Mr. KENDRIS. Look, Congressman, we have our own generic company that sells thousands and thousands of generics every year. In fact, they are the second-largest seller of generics in the United States. So, we don't do what you just described. What we are doing is we are reaching out to patients and doctors who already want to stay on the brand, and we are educating them how they have to do it. They will not be able to stay on the brand if they want to unless they write a prescription for Gleevec.

Mr. RASKIN. Did you pursue the NDC blocks in order to try to keep Novartis' market share up, even with generics in the market? Is that why you went for the NDC block strategy?

Mr. KENDRIS. No. That is part of the negotiation with the payer in the contracting process.

Mr. RASKIN. OK. Well, Madam Chair, I just think that these NDC blocks were tremendously profitable for Novartis, as they have been for other companies, and the cost is not paid by the company. It is paid by the patients, it is paid by Medicare, and all of us through increased prices.

But thank you for your testimony. I yield back to you, Madam Chair.

Chairwoman MALONEY. Thank you.

Mr. Comer, you are now recognized.

Mr. COMER. Thank you, Madam Chair. My first few questions will be addressed to Mr. Bradway with Amgen.

Sir, you explained in your opener that net prices are not the same as list prices. You said that part of the list price calculation includes benefits to patients. Can you quickly explain how you are able to calculate that?

Mr. BRADWAY. Yes. The list price is the price that we establish. The rebates are the price that we pay to the intermediaries, creating a net price. It is the net price that we receive. And the patient then pays a copay as a function of the stated list price.

Mr. COMER. While patients no doubt benefit from these lifesaving drugs, I think you can understand that patients have a hard time understanding that cost benefit calculation. How can patients be sure they are getting the best price available for their medicine?

Mr. BRADWAY. Thank you, Congressman. I think that is an important issue, the issue of transparency, and it is very difficult in the system that is in place today. It is difficult, for example, because patients don't get the benefit of the rebate at the pharmacy counter. In fact, it is very hard for a patient to have any idea what rebate has been negotiated between their plan sponsor, their PBM, and the innovative drug company. So, it is a challenging problem,

even for the initiated patient who wants to try to get the answer to your question.

But we and others publish our list prices, for example, on the website, for our individual medicines. We provide an indication of the range of rebates and, therefore, give a sense for what the net price is. But our net price is different for individual payers, based on the contracts that we have negotiated with each of them individually.

Mr. COMER. I spent a lot of time in the hearing yesterday talking about my dissatisfaction with the PBMs and that process, so I am going to shift gears and mention that for a second.

Mr. Kendris with Novartis, this is an incredibly complicated process. It seems to me that the savings are not always being passed on to the consumer. President Trump, in one of his recent Executive orders, mandated that PBMs pass these rebates onto Medicare Part D patients, but this covers only a small percentage of the patient population.

Mr. Kendris, what can we, in Congress, do to ensure patients are benefiting from these discounts rather than middlemen like PBMs?

Mr. KENDRIS. Ranking Member Comer, thank you for the question. I think one answer to your question, quickly, would be transparency, and I think that we need to encourage patient access and affordability. And I think there are three ways.

We can give access to value-based products, value-priced products with low cost-sharing so we encourage their use and we don't restrict their access to formularies. We can cap what patients have to pay in out-of-pocket costs for drugs in Medicare Part D. And we can require plans to share some of the discounts they negotiate for drugs with patients. Those savings should be passed along to patients at the pharmacy counter. Those three things would encourage patient access and affordability.

Mr. COMER. And I agree 100 percent with your statement about transparency. Who is the agency or bureaucracy in charge with overseeing the PBMs and their transparency? Who holds the PBMs accountable? Educate me on that.

Mr. KENDRIS. That is a very good question, Ranking Member Comer, and I think perhaps HHS is the answer. Perhaps HHS should be overseeing the PBMs, and to some extent they probably do. But I think the oversight and the changes in terms of passing on discounts at the pharmacy counter is something that needs to happen. Maybe it is HHS. Maybe it is a different approach. I am not sure.

Mr. COMER. And I think that is something, Madam Chair, I mentioned to you after the hearing yesterday, that is something that we should certainly look into more when we are going to continue our efforts to investigate the out-of-control costs of drugs for Americans.

One other thing, and my time is running out, but just to touch on what Representative Keller mentioned with the price difference between Europe and the United States, I don't think any of like that but I am curious, how much do you spend on litigation in Europe versus the United States? Is there a big difference in your litigation costs?

Mr. KENDRIS. I believe there probably is. I would have to get back to you with specifics, Ranking Member Comer, but there is a probably a difference.

Mr. COMER. If both of you all could get that back to me I would just love to know, out of curiosity.

Madam Chair, I yield back.

Chairwoman MALONEY. Mr. Gomez, you are now recognized, and Mr. Gomez is the vice chair of this committee.

Mr. GOMEZ. Thank you so much. Mr. Trudeau, I want to followup on something you said to Chairwoman Maloney when she asked you about the cash cow slide. Can we put up Exhibit 68 again, please?

[Slide.]

Mr. GOMEZ. So, now let's just review this slide. It refers to Acthar as, and I am quoting from the title here, "a cash cow." Now Mr. Trudeau when Chairwoman Maloney asked you about this you downplayed it. You said, "Oh, it is just a draft and it was never sent to the board." You were pretty much implying that your companies doesn't view this drug as a cash cow. Do you still stick with the assertion that your company does not view Acthar as a cash cow? Yes or no.

Mr. TRUDEAU. Yes, I do.

Mr. GOMEZ. OK. Thank you. Are you familiar with the term "synonym." Synonym?

Mr. TRUDEAU. Cinnamon?

Mr. GOMEZ. Syn-o-nym. Yes, the term that basically refers to one word means the same thing as another word, right, or nearly the same thing. Are you familiar with that concept?

Mr. TRUDEAU. I am, sir, yes.

Mr. GOMEZ. OK. So, we obtained some emails that I want you to take a look at, and it is from your company's execs.

In fact, one of these email chains, your corporate executives have a discussion about this exact term, and I quote, "Do we really want to say 'cash cow' to the board?" He obviously recognized how bad this sounds. So, then your company's chief commercial officer responds. In his own email he wrote, and I quote, "Instead of 'cash cow' I will replace it with 'profit maximizer'." So, replacing one term with another term, "cash cow" with "profit maximizer," doesn't change the intent of your company, which is to make as much money as possible, right?

So, Mr. Trudeau, you were under oath when you answered Chairwoman Maloney's question. You swore to tell the truth and the whole truth. Were you trying to mislead the committee?

Mr. TRUDEAU. Not at all. We don't think about Acthar in any——

Mr. GOMEZ. OK. So, let me reclaim my time. Can we put up the next slide?

[Slide.]

Mr. GOMEZ. This is the actual slide that was sent and was included in the final presentation that was prepared for the board, and it includes the term "profit maximizer." Do you deny that, Mr. Trudeau?

Mr. TRUDEAU. No, I don't.

Mr. GOMEZ. OK. So, that was the whole point that Ms. Maloney was trying to make, that your company is trying to maximize prof-

its. Then you denied it, and then you downplayed this document. You said you removed the word "cash cow," but there was no question that you were trying to maximize profits, right? "Cash cow" and "profit maximizer," you just replaced one term with another, but the intent was the same, to make the most money.

I think you owe the chairwoman and this committee an apology. How do you respond?

Mr. TRUDEAU. Very clearly, sir, these were options that were being considered, but I think the actions are what you need to focus on——

Mr. GOMEZ. No. I am going to reclaim my time.

Mr. TRUDEAU [continuing]. And that is that we——

Mr. GOMEZ. Do you—what—do you agree that the main purpose—your team replaced one term with another, right, one term with another, and it was the same intent, to maximize profit, right?

I would like to put up—and your team, your company, has brought in nearly $6 billion in net sales from Acthar. I would like to put up Exhibit 76 on the screen, please.

[Slide.]

Mr. GOMEZ. The presentation emphasizes that the merge was a, quote, "unique opportunity that should be pursued urgently" because this deal would, quote, "provide rapid revenue and earnings growth." In fact, soon after the acquisition your executives boasted about how well this strategy worked, highlighting to shareholders that Acthar had already contributed $123 million toward net sales in only six weeks. In an investor briefing in October 2014, Mr. Trudeau, you personally explained that your company's primary goal was to deliver, quote, "top-level shareholder returns by focusing on highly profitable specialty drugs like Acthar." Do you recall saying that?

Mr. TRUDEAU. I don't recall that specifically but it wouldn't surprise me that I did say that.

Ms. SCANLON. Yes. And the reason why is that, you know, just changing the term from "cash cow" to "profit maximizer" doesn't change your intent. The intent of your company is not to help the bottom line of the health outcomes for the American people or for the public in general. It is to maximize your profits.

Your company then proceeded—you already had this drug and it was already highly profitable, and then you proceeded to increase the drug by more than $82,000 per vial, an additional 26 percent increase. So, I believe that you misled this committee, I believe that you owe the chairwoman an apology, and I believe that you owe the American people an apology as well.

With that, Madam Chair, I yield back.

Chairwoman MALONEY. The gentleman yields back.

Mrs. Tlaib, you are now recognized for questions.

Ms. TLAIB. Thank you so much, Chairwoman. Let's talk about the sham patient assistance programs, which we hear a lot from companies like yours. I know because, you know, many of the big pharma companies use many of these programs in some ways to hike up prices so that they are completely unaffordable, and then they offer these charitable programs so that patients can afford the very drug you have made unreasonably expensive.

So, these so-called fake assistance programs do not get into the underlying problem, and as many constituents tell us, which is that these drugs simply do not have to be expensive, that it is a choice, a choice that every CEO testifying today makes. And it is really a choice that is killing people, in my district and across the Nation.

So, I know you all there are a lot of documents this committee has obtained. These are not things that are coming and falling out and these are not theories. They are all documentation that proves what we are trying to explain to all of you, is that these schemes, again, are hurting people. So, the internal documents obtained by this committee through the investigation show that these so-called sham—you know, they are sham charitable programs—are really just money-making schemes.

So, let's start with Novartis' copay assistance program. In one of your response letters to the committee you stated that Novartis used its copay programs to, quote, "ensure that every patient who needs Gleevec has access to it." Mr. Kendris, would you consider Novartis' copay and other patients assistance programs a financial investment or charity?

Mr. KENDRIS. Congresswoman Tlaib, we are trying to make sure that patients can get access to Gleevec, so when they can't afford it, for whatever reason, we try and make it available——

Ms. TLAIB. Sure. Sure.

Mr. KENDRIS [continuing]. In a variety of different ways, and that is one of them.

Ms. TLAIB. Yes. Well, let me—so the documents don't kind of match up what you are trying to say here. So, documents again obtained by the committee also show that Novartis viewed its copay programs as investment, and strategically—this is a scheme here—you all used it, the copay program, to drive demand for Gleevec, particularly after it began competing with generic versions of the drug.

I would like to put up Exhibit 15 upon on the screen.

[Slide.]

Ms. TLAIB. So, it appears to be an analysis of when to launch the so-called enhanced copay program in anticipation of the generic competition. Can you see that, Mr. Kendris? I want to direct your attention to the table.

Mr. KENDRIS. Yes. Hold on one second, Congresswoman. I am getting a paper copy of it because I don't see it very well on the screen. But I have it now. So, it says, I think on the top, I don't see it on the screen but is the one that you are referring to, does it say "the optimal scenario is a six-month pre-LOE start"?

Ms. TLAIB. That is right.

Mr. KENDRIS. OK.

Ms. TLAIB. So, Novartis expected that every dollar it put into the enhanced copay program—you know, the scheme—that it would get back a return or investment of between 5.1 and 8.9 dollars. That means for every $1,000 put into this copay program, you would expect upwards of nearly $9,000 in profit. Am I reading that correct?

Mr. KENDRIS. I am not sure, Congresswoman.

Ms. TLAIB. Mr. Kendris, you are under—listen, you took an oath——

Mr. KENDRIS. I am sorry.

Ms. TLAIB [continuing]. To be very specific, you are seeing this as investment. In your own charts, from your own company, to this committee you are literally making $9,000 in profit when you insert $1,000 into these sham charitable programs.

Mr. KENDRIS. Congresswoman, I am not sure I understand this chart the way you are describing it.

Ms. TLAIB. OK. So, according to the slide——

Mr. KENDRIS. Sorry.

Ms. TLAIB [continuing]. According to the slide——

Mr. KENDRIS. Yes.

Ms. TLAIB [continuing]. The optimal scenario was to launch the copay programs six months before your company lost exclusive rights to the drug, and then a generic version would become available. That is because launching six months prior would result in the greatest return on investment by keeping patients on Gleevec before lower-cost generics entered the market. Does that sound right to you?

Mr. KENDRIS. Congresswoman, I am looking at the chart, and I see what you are saying——

Ms. TLAIB. OK.

Mr. KENDRIS [continuing]. And I would like the opportunity to take this back and talk to——

Ms. TLAIB. OK. Well, let's look at another document.

Mr. KENDRIS [continuing]. At my oncology business unit. Yes. Sure. Thank you.

Ms. TLAIB. In 2013, Novartis executives appeared to have conducted a literature review to consider enhancing its patient assistance programs, the scam. Let me put this document on the screen. It is Exhibit 14.

[Slide.]

Ms. TLAIB. I hope you can see that. As you can see, executives noted—it is highlighted there—that for patients that have higher copays there is a risk that they may not adhere to the drugs. But then the review reached this conclusion, quote, "Because cancer drugs are a necessity for patients, there is less sensitivity to price increases." What this document is saying, basically, is that cancer patients will keep taking drugs, no matter the price, because they simply have no choice. Am I reading that correct, Mr. Kendris?

Mr. KENDRIS. Congresswoman, the next sentence says something that I also think is a fact——

Ms. TLAIB. Mm-hmm.

Mr. KENDRIS [continuing]. That research shows that there is an upper limit of OOP costs at which patient adherence begins to decline. So——

Ms. TLAIB. Well, you can try to mislead the public, but when it comes down to——

Mr. KENDRIS. I am not trying to mislead. It is——

Ms. TLAIB. Mr. Kendris, your own documents are basically saying, which is really sickening, that it doesn't matter because these are lifesaving drugs. Let's go ahead and increase the prices, even though you don't have to. You have increased the prices to make more of a profit off of people that are suffering from cancer. And all these scams and these, you know, so-called patient assistance programs that you mislead everybody into trying to look like good

citizens, they are not. They are money-making schemes. And it is, again, verified over and over again in documentation provided to this committee.

I yield.

Chairwoman MALONEY. The gentlelady yields. Thank you.

Mrs. Porter, you are now recognized for questions.

Ms. PORTER. Thank you for being here. I want to hear today about innovation. As you know, this is our second day of hearings with the CEOs of big pharma companies, and we have heard so much important information about the very real costs of research and development, R&D.

Mr. Bradway, what was Amgen's total revenue in 2017?

Mr. BRADWAY. Oh gosh. Approximately $22 billion.

Ms. PORTER. OK. So, it was $23.7 billion. How about 2018?

Mr. BRADWAY. I don't have that at hand but it again it would be 24——

Ms. PORTER. That is OK. I have it handy. $22.8 billion. 2019, $23.4 billion. This totals up, because I know it is hard to do math on the fly, to $69.9 billion.

Mr. BRADWAY. Thank you.

Ms. PORTER. Mr. Bradway, over those three years that we are talking about, 2017 to 2018, how much of its own revenue did Amgen invest in that really important research and development work?

Mr. BRADWAY. Approximately $10 billion.

Ms. PORTER. OK. So R&D, taking you at your word here, was about $10 billion. Great. That is a big number. Investing in R&D dwarfs some of your other expenses. Is that right? It is one of your largest expenses.

Mr. BRADWAY. That is correct.

Ms. PORTER. How much did Amgen spend on lobbying over that same three-year period?

Mr. BRADWAY. I don't have the exact number but it is approximately $10 million a year.

Ms. PORTER. That is correct, $32.52 million on lobbying. How much did Amgen pay for the salaries of the top five, the top five executives over this two-year period?

Mr. BRADWAY. Oh goodness. It is about, I would guess, $6.5 million per year, so $13 million would be my guess.

Ms. PORTER. Thirteen million? Would you like to revise? Take a look right here, sir.

Mr. BRADWAY. Sorry. You asked salary. I gave you an answer to the question about salary.

Ms. PORTER. Oh, I am sorry. Let me rephrase. How much did Amgen spend on compensation for the top five executives?

Mr. BRADWAY. That is the number you have written on the board. Thank you.

Ms. PORTER. Could you say that number please, for the committee?

Mr. BRADWAY. Yes. I will assume that your number is correct. It is $124 million.

Ms. PORTER. OK. Wonderful. And then my final question is how much did Amgen spend on stock buybacks in that same two-year period?

Mr. BRADWAY. Sorry. Two-year or three-year period?

Ms. PORTER. Right here. Three-year period. Sorry.

Mr. BRADWAY. Three-year period. I don't know the number off the top of my head, but that includes the period where tax reform was implemented, so I would guess it on the order of $30 billion.

Ms. PORTER. Right around this number. Can you say it for the committee? I am not a witness, sir, so I can't testify as to your profits. I need you to state the number.

Mr. BRADWAY. The number that you have written is $28.6 billion.

Ms. PORTER. Thank you. So, you spent double, more than double, almost triple on stock buybacks over the three-years as you did on R&D. Is my math correct? $10 billion is roughly one-third of $28.6 billion.

Mr. BRADWAY. Yes, but what you haven't included there is the capital that we allocated to acquire research and development externally, which would be about $19 billion in that period.

Ms. PORTER. OK. You make an anti-inflammatory drug called Enbrel, which is used to treat conditions like arthritis. Mr. Bradway, did Amgen do the research that led to the creation of Enbrel?

Mr. BRADWAY. No, not the originally discovery, but we have done millions of dollars of work on——

Ms. PORTER. It is just a yes or no. Did you do the research that led to the creation of Enbrel?

Mr. BRADWAY. Congressman, I stand by my answer. The Enbrel that you use, that patients use today, did we do the research and development work associated with it? Absolutely. Quite a bit of it.

Ms. PORTER. Did you yourself oversee the trials of the drug? Did any executive at Amgen help invent this breakthrough drug?

Mr. BRADWAY. No, I did not. I was not involved in breakthrough development of the drug or the discovery of the drug.

Ms. PORTER. In fact, Enbrel was invented in an academic medical center, and its discovery was funded largely by taxpayers. Amgen later acquired the biotech company who manufactured Enbrel. Amgen did not directly pay for the discovery of Enbrel. Correct?

Mr. BRADWAY. No, that is incorrect. Your statement is wrong. Enbrel was discovered by scientists at a biotechnology company called Genentech.

Ms. PORTER. OK. What I would like to do now, Mr. Bradway, is I would like for you to please explain to the American public why you and four other executives deserve to pay yourselves tens of millions of dollars each year. I have got an empty whiteboard ready to take down your justifications.

Mr. BRADWAY. I recognize that that is a considerable sum of money. I would, of course, point out that I don't have any direct input to my compensation. That is derived by the board and it is forwarded to a vote of the shareholders, who overwhelmingly supported the compensation package for me and the other main executive officers.

Ms. PORTER. Reclaiming my time, sir. Do you not know why you are getting hundreds of millions of dollars, tens of millions of dollars a year? What is the justification? I would like to show the American people.

Mr. BRADWAY. Our compensation is consistent with competitive positions at other companies like ours.

Ms. PORTER. Mr. Bradway, reclaiming my time. The other guy gets paid too much too isn't a justification. I would like to hear what you do to deserve $124 million in salary, you and your top five executives, over a three-year period.

Mr. BRADWAY. Well, more than——

Chairwoman MALONEY. The gentlelady's time has expired. The gentleman may respond to her question.

Mr. BRADWAY. OK. More than 90 percent of my compensation is based on performance measures that include how our shares perform relative to the market, and our compensation program is aligned with that of our owners, our share owners. So, a large part of my compensation reflects the fact that we have been creating value for our share owners by advancing innovative medicines like those that we have in the marketplace today.

Ms. PORTER. I wish you would focus on creating value for sick patients, Mr. Bradway, not just your shareholders. I yield back.

Chairwoman MALONEY. The gentlelady yields back.

Mrs. Kelly, you are now recognized for questions. Mrs. Kelly?

Ms. KELLY. Thank you, Madam Chair. I want to take a moment to address an argument we have heard a lot about today, that pharmacy benefit managers are responsible for rising drug prices. Mr. Trudeau, I would like to start with you first.

The average net price per unit of Acthar, which is the price of the drug after subtracting all rebates and discounts has increased every single year since—I am not going to pronounce this right, but Mallinckrodt purchased Acthar. I would like to put on the screen a graph of the average net price per vial of Acthar between 2015 and 2018.

[Slide.]

Ms. KELLY. This graph was created using data your company provided to the committee. You can see on the chart that in 2015, the average price was around $30,000, and in 2018 it was around $33,000, basically increasing by nearly $3,000 in three years, and that is after factoring in rebates and cost.

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

Mr. TRUDEAU. I don't believe that is true. We have actually increased discounting significantly to our customers well beyond the rate of increase that is shown there.

Ms. KELLY. OK. In addition, data your company provided to the committee revealed that the rebates that paid Medicare for Acthar are practically nonexistent, in stark contrast to Mallinckrodt's documented efforts to perpetuate this misleading narrative. Excuse me. Between 2015 and 2018, the rebates that you paid to Medicare averaged less than one percent. By comparison, rebates paid to TRICARE for Acthar averaged more than 26 percent.

So, turning to you, Mr. Bradway, U.S. net price of Enbrel, again, the price of the drug after subtracting all rebates and discounts, has also increased since 2014. The same is true for Amgen's drug,

Sensipar. Even though rebates were stable, Amgen increased the price of Sensipar by 34 percent between 2015 and 2018.

And finally to you, Mr. Kendris, data provided to the committee reveals that between 2011 and 2015, the net price of your cancer drug, Gleevec, increased by double digits annually. At the same time, your data suggests that the rebates Novartis paid for Gleevec remained lower than big pharma would lead the public to believe. Between 2009 and 2015, before Gleevec lost exclusivity, the average of all discounts and rebates provided by Novartis related to Gleevec sale was just 15 percent of total gross sales.

Let's be clear. PBMs certainly play a role in our current pricing system. We won't deny that. But based on the data we have received it is equally clear that pointing the finger at PBMs is a convenient way for drug companies to deflect blame for their own actions. So, it simply cannot be that it is just PBMs are responsible for all of these price increases.

I don't know if anyone wants to comment on that.

[No response.]

Ms. KELLY. If not I will yield back my time.

Chairwoman MALONEY. The gentlelady yields back, and the chair now recognizes Mr. Comer for his closing comments.

Mr. COMER. Thank you, Madam Chair, and I will be very brief. We have had two long days of hearings. Hopefully in the future we can come together, instead of identifying all the problems we can try to work toward some solutions to those problems.

I want to mention that many of the problems that my friends on the other side of the aisle mentioned today can be solved in H.R. 19, our bill, the Republican bill. For example, Representative Wasserman Schultz mentioned several times the pay-for-delay settlement. You know, we don't like that. I don't think anybody likes that. That is bipartisan, and that is in our bill, H.R. 19. So, I think that there is an opportunity to work together on this issue moving forward, and I certainly hope that we can do that.

With that, again, I appreciate the hearings that we had. I appreciate all the witnesses that came before us over the last two days, and hopefully we can work together moving forward, because this is an issue the American people are demanding Congress address. And I think that we can do that and I hope that moving forward we work in a bipartisan way to have solutions to the problems.

I yield back.

Chairwoman MALONEY. The gentleman yields back, and I thank the gentleman, and I can assure you that my colleagues and I are open to working with you for solutions and solving this problem.

But before I close I would like to enter into the record a letter to the committee received from the mayor of Rockford, Illinois, Thomas McNamara. The mayor's letter explains the various essential services that the city would have funded with the $500,000 that it spent on Acthar. He mentions installing 350 streetlights, planting 2,000 trees, or replacing two miles of sidewalk.

I ask unanimous consent to place this letter into the record. Without objection, so ordered.

Chairwoman MALONEY. With that let me close by thanking the six, all six of the CEOs who agreed to participate in these two days

of landmark hearings. And I would like to thank the staff for all the work that they did in preparing these hearings.

To me, the single most remarkable revelation coming out of these hearings is the claim by drug companies that they need to raise their prices for research and development or to promote innovation. This is completely and utterly false, it is baseless, and I think Ms. Porter underscored this is in her comments.

The internal documents that we obtained show that the pricing discussions going on inside these companies have nothing to do with research and development or promoting new innovation. They show a meticulous, even ruthless focus on squeezing every possible dollar out of the pockets of the American people and the American taxpayers. Whether you call it a "cash cow" or a "profit maximizer," it shows that these companies view these drugs as a profit basis, in profit-based terms, and that was clear in the documents we saw.

I want to make clear also that these drugs are lifesaving and life-changing in many, many ways, and we are grateful for that. But we cannot let these drug companies continue to target our country, the United States of America, for the biggest and deepest price increases anywhere in the world.

Not everyone knows this but we have a law on the books in this country that bars our country from negotiating directly with drug companies to lower prices for Medicare, one of the biggest drug purchasers in the world. Of course, the companies know this and they exploit it to the tune of hundreds of billions of dollars, and that is what these new documents showed.

These companies make profits in Europe where they negotiate, in Canada, where they negotiate, and in all sorts of other countries that negotiate. But we, in America, we have our arms tied behind our back and we are not allowed to negotiate, to help our people, and that is not a free market. A free market is when two people or two parties come to a table and agree to a price one is willing to pay and the other is willing to accept. Our system is the opposite of a free market. It lets the drug companies increase their prices over and over and over again, dozens of times, by thousands and thousands of dollars, as we heard today and saw in the documents.

This is absolutely unsustainable. We need to pass the legislation that Elijah Cummings championed and that President Trump used to support before he broke his campaign pledges. We finally need to let our government negotiate, just remove this block that does not allow us to be treated fairly. We are exploited in this system.

Now I want to let members know that these two days of hearings will not be our last. We have heard testimony from six CEOs, but we have been investigating several other companies as well. So, I will keep members appraised of the additional hearings, potentially when we return in November and in December.

And finally, I want to thank the members of our committee on both sides of the aisle. This is a critical issue for all of our constituents, and I believe all members demonstrated your command of the material and your desire and drive to help your constituents and to help the American people.

I sincerely hope we can take these findings and move forward on real legislative changes to help American families together. And

with these two days of hearings I again thank the staff that has worked incredibly hard on this, and this hearing is adjourned.

[Whereupon, at 1:36 p.m., the committee was adjourned.]