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LOWERING PRESCRIPTION DRUG PRICES:

DECONSTRUCTING THE DRUG SUPPLY CHAIN

THURSDAY, MAY 9, 2019

House of Representatives

Subcommittee on Health

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 10:02 a.m., in Room 2322 Rayburn House Office Building, Hon. Anna G. Eshoo [chairwoman of the subcommittee] presiding.

Members present: Representatives Eshoo, Engel, Butterfield, Matsui, Castor, Sarbanes, Lujan, Schrader, Kennedy, Welch, Ruiz, Dingell, Kuster, Kelly, Barragan, Blunt Rochester, Pallone (ex officio), Burgess, Shimkus, Guthrie, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Carter,

Gianforte, and Walden (ex officio).

Staff present: Jacquelyn Bolen, Professional Staff; Jeff Carroll, Staff Director; Waverly Gordon, Deputy Chief Counsel; Tiffany Guarascio, Deputy Staff Director; Josh Krantz, Policy Analyst; Aisling McDonough, Policy Coordinator; Joe Orlando, Staff Assistant; Alivia Roberts, Press Assistant; Kimberlee Trzeciak, Senior Health Policy Advisor; C.J. Young, Press Secretary; Jennifer Barblan, Minority Chief Counsel, O&I; Mike Bloomquist, Minority Staff Director; Margaret Tucker Fogarty, Minority Staff Assistant; Caleb Graff, Minority Professional Staff Member, Health; Peter Kielty, Minority General Counsel; Ryan Long, Minority Deputy Staff Director; James Paluskiewicz, Minority Chief Counsel, Health; Brannon Rains, Minority Staff Assistant; Zach Roday, Minority Communications Director; Kristen Shatynski, Minority Professional Staff Member, Health.

Ms. Eshoo. The Subcommittee on Health will now come to order. Good morning, everyone. The chair now recognizes herself for 5 minutes for an opening statement.

I want to begin today by acknowledging that Robert Pear, the New York Times health reporter, died on Tuesday. For 40 years -- 40 years -- for 4 decades, his meticulous straightforward reporting helped the American people make sense of the Washington health care debate. He was a giant in his field and he is going to be missed.

I want to welcome the witnesses that are here today and I want to thank you for being willing to testify. I understand that some of the witnesses preferred not to be formally sworn in and I want to reiterate that each witness, so that the public knows as they are listening in, that each witness has signed a statement certifying that, quote, knowingly providing material false information to this subcommittee is knowingly concealing material information from this subcommittee and is a crime.

So thank you again to the witnesses. My staff did reach out to nearly a dozen drug companies to testify and there were few that were willing to do so. Express Scripts was the only major PBM willing to testify. CVS Health and OptumRx both said no.

So, today's hearing focuses on a health crisis facing American families: the soaring costs of prescription drugs. At this hearing, we are going to ask each stakeholder in the drug supply chain about the role that they play, the impact they have, each one has on drug prices, and the value each one brings to patients.

We are going to follow the money. We are examining the system from beginning to end because in order to fix it, we need to understand it and then be able to act. We have already taken some first steps. The House passed two drug bills yesterday and we are pleased about that but we have a lot of work ahead of us.

So instead of a lengthy opening statement, I want to summarize my questions from the top for the first panel now.

First, we have the drug makers. Pfizer has done well, earned $53.6 billion in revenue last year and Amgen earned $23.7 billion. We will also hear from a small cancer company, Exelixis, which has only two products.

To the drug makers: How do you price your drugs? We know there are costs -- research and development, salaries, advertising, whatever the investment to bring the drugs to market. After the costs are calculated, how do you set the price? Who in the drug supply chain do you exchange money

with and how?

The next link in the chain are the pharmacy benefit managers or the PBMs. They use their buying power to get the best deal on drugs for the clients they represent, which are commercial health insurers, self-insured employers, Medicare Part D Plans. This is a highly profitable business and, in 2017, Express Scripts, who is here today and we are grateful that they are, earned $100 billion in revenue.

So my question for the PBMs is: What value do you add? You don't invent. You don't manufacture. You don't conduct research and development. Explain to us how you earn your money and who in the drug supply chain do you exchange money with and how?

So on this first panel, we can conservatively estimate that our witnesses represent nearly $200 billion in revenue. That is a very important part of our national economy. And my question for each is: Where do those billions come from? Where can we cut so that Americans can afford their drugs?

During the second panel, we will examine the second half of the drug supply chain and we will hear from a health insurer, a health system, a pharmacy, a physician, and a patient representative.

So, the chair now is pleased to recognize Dr. Burgess,

the ranking member of the subcommittee for 5 minutes of his opening statement.

Mr. Burgess. Thank you, Madam Chair.

And too, it is with some sadness that I look over in the corner of the room, where the press occupies the press gallery, and some great deal of sadness with Robert Pear not being with us today. And through many of these arguments, Troubled Asset Relief Program, the Stimulus Bill, all of the Affordable Care Act debates, Robert was always there, faithfully writing. I didn't always like what he wrote but I could always count on him to be fair and do a very reasonable job of imparting the information to his readers. We will miss Robert Pear.

So I appreciate this hearing today. And Madam Chair, when we sat down at the beginning of this Congress to sort of discuss some of the bipartisan goals, we agreed that the drug supply chain hearing that was held in December of 2017 was immensely helpful. So today's hearing is a continuation of that, this hearing being more company-specific rather than industry-wide. Both perspectives are important.

I am hopeful that the witnesses here today will impart their firsthand experience and knowledge of the supply chain so that members of the subcommittee can build on the

foundation of information that we began in the last Congress.

I can't possibly be out of time. It is going up. Oh, good, I have got the rest of the week.

The nature of the current drug supply chain is complex and has multiple stakeholders involved in each step. There are actors who are essential to the supply chain but do not affect the price of the medication. Bringing all of these stakeholders to the table today can give us an opportunity.

It is my hope our discussion is substantive and focused on the patients who are prescribed these medications because, at the end of the day, it is the patient who matters most in this conversation. They are bearing the cost of these medications. They are the ones who stand to benefit from the cures or the maintenance of their good health.

Prescription drugs continue to play a vital role in the United States health care system, not just improving patients' lives but producing healthcare savings through fewer hospitalizations and medical procedures. You know I do just have to note Pfizer is here today. Pfizer didn't discover penicillin; Sir Alexander Fleming did and we all are familiar with thee statue that~~of~~ the bullfighters erected to Sir Alexander Fleming. But it is Pfizer that democratized penicillin and brought it available to the rank and file

regular American citizen and, most importantly, brought its availability forward to be used right before the D-Day invasion in 1944. So in some ways, we owe our success in World War II to the United States pharmaceutical industry and I always feel obligated to mention that fact because people do forget.

Improving access to life-saving treatments for consumers is a bipartisan priority. I would like to see us continue to build upon the successes that we have seen from 21st Century Cures and to spur biomedical innovation. That being said, it is imperative that we ensure that our system is ready to understand and pay for the treatments and cures in today's development when they reach the hospitals tomorrow and the doctors' offices in the future. It does no good if the patient is not able to afford them. And maybe at some point we can talk about perhaps not depending upon last century's model of paying for things, , but think of this century's model, where the cost of some of these novel treatments can be amortized over a longer period of time, even though they may be a single treatment. With some gene therapies and cell therapies, it will be a single episode of treatment but the benefit will accrue over a long period of time.

I hope this hearing will shed some light on the

interworkings of price negotiations between the stakeholders. This subcommittee has done good work on the issue of drug pricing this Congress, especially with the Purple Book and the Orange Book bills passed yesterday, but we need to find a bipartisan way to move forward with additional legislation.

The hearing in the last Congress involved a fair amount of finger pointing among witnesses and that is okay. That is the reason it was constructed the way it was. I expect we will see some of that today, but I do want to remind our witnesses that our goal is to solve a problem, not assign blame. And to that end, we have invited you here and, if you will remember my admonition at the end of the last supply chain hearing was, you all have the knowledge and expertise to solve these problems. We lack that knowledge and expertise. But if you don't solve it, we will and you probably won't like the expertise that we have in how it is solved.

So I really call upon you to, not necessarily even during this hearing but in the days, and weeks, and months to come, please interact with us and share with us your ideas because they are critically important. There are legitimate differences of opinion. I recognize that every participant here this morning does aspire to the common goal of saving

lives and alleviating human suffering. But out of these areas of disagreement, I hope to identify areas of consensus so that we can begin delivering solutions to the problems identified this morning.

I know I took some extra time. I would be happy to yield back.

Ms. Eshoo. Thank you, Dr. Burgess. The gentleman yields back.

The chair is now pleased to recognize the chairman of the full committee, Mr. Pallone, for 5 minutes for his opening statement.

The Chairman. Thank you, Madam Chair.

Today we continue to focus our attention on reducing the price of prescription drugs by closely evaluating the pharmaceutical supply chain. It is critical that we have a full understanding of how drugs are developed, priced, delivered, purchased, and dispensed so we can consider policies that will best improve the system to drive down costs and save consumers money.

Drug prices continue to dramatically increase, while consumers pay more and more out of pocket for the medications they need. In fact, nearly one in four Americans who take prescription drugs say it is difficult to afford their

medications. And I want to stress that this is simply not acceptable. I follow-up on what Dr. Burgess said. You know our constituents are just tired. They have had enough with the pharmaceutical industry. They think that the excuses are lame and they just want prices to come down and they want us to do something about it.

Fortunately, this committee is already taking bipartisan action to make prescription drugs more affordable. Last month, we favorably reported out of committee bills that would help bring generic drugs to market faster. Yesterday on the House floor, we passed two of those bills that will increase the accuracy and transparency of the food and drug administration's databases that generic and biosimilar manufacturers depend on to bring more affordable prescription drugs to market. And next week, the House will consider legislation that has been reported out of our committee that will further these goals as well, including the CREATES Act and legislation to address pay-for-delay agreements.

Now, I am proud of the bipartisan work but it is critical that we recognize that the work cannot and will not stop there. Solving this drug-pricing crisis will require a multifaceted approach that addresses the misaligned incentives throughout the supply chain that often encourage

gaming and lead to higher costs.

The pharmaceutical supply chain is an intricate and complicated network made up of drug manufacturers, wholesalers, providers, insurers, pharmacy benefit managers, pharmacists, and patients. It is critical that Congress, as well as the American people, have a clear understanding of how these entities operate, how they work in relation to one another, and what impact they have on the drug prices consumers ultimately pay.

Now we know that innovation has paved the way for a new generation of life-saving and life-changing therapies for patients who otherwise may have faced more difficult outcomes. However, as newer and more specialized medicines come to market, these drugs typically have much higher prices that are too often just simply unaffordable.

And I am interested in hearing from our witnesses today how much manufacturers set prices for newly launched drugs and why some drugs that are already on the market have continually increased in price. I also want to know how pharmacy benefit managers work with health insurance plans to decide how to cover these medications and under what conditions. It is also important to discuss how healthcare providers, hospitals, and pharmacies deliver medications to

patients. But ultimately, I am most interested in how these decisions impact consumers, our constituents, and what they pay when they reach the pharmacy counter or receive a bill for drugs administered in a hospital.

And it is our hope that the witnesses will discuss specific policy solutions that Congress should keep in mind as we move forward with legislative proposals to bring down costs. I would like to hear our witnesses' thoughts on providing for an out-of-pocket cap in Part D, increasing transparency about -- around drug mechanisms and price increases, and further incentivizing competition in the marketplace.

So today's hearing is an important step in our efforts to fulfill the promise we made to the American people to reduce their healthcare costs and I look forward to hearing form our witnesses and I hope that we can continue to work in a bipartisan manner to reduce prescription drug prices and consider real solutions that will lower costs.

This is the number one issue that I hear when I go home. People want to know what we are going to do to lower prices. And you have heard both Democrats and Republicans and, certainly, the President of the United States prioritize this.

And so as Dr. Burgess said, I don't want to put words in his mouth, you know you give us some ideas, obviously, we are going to take action because we have no choice.

Lastly, if I could, I did want to say that I wanted to mention the passing of New York Times reporter Robert Pear, who spent a lot of time in this room and downstairs covering our hearings and markups. You knew it was a big health hearing when Robert was here. And yesterday, I was really saddened to hear about his passing. He was a gentleman in every sense of the word, a phenomenal reporter. I am going to miss seeing him here at our hearings discussing healthcare policy with him and reading his stories. I always would wait to see what he was going to write the next day after he was here.

So it is a huge loss and I know that a lot of people in this room today are feeling that loss.

So, thank you, Madam Chair. Ms. Eshoo. I thank the chairman. The gentleman yields back.

The chair now is pleased to recognize the ranking member of the full committee, Mr. Walden, for 5 minutes for his opening statement.

Mr. Walden. Thank you very much, Madam Chair, and I want to join my colleagues in recognizing the loss of Robert

Pear and expressing our condolences to his family and friends. He was fair. He was fierce. And he was factual. And you knew when he approached you with questions, he had done his homework and you better be ready.

And he came out to my district in the winter of '17, traveled around, went to a Rotary Club meeting, a town hall, and a few things. And so he got on the ground, too, and I was always impressed with his writing. And sometimes, like Former Chairman Burgess said you agreed and sometimes you didn't but you knew he had done his homework and he is a real role model for journalists.

So I want to thank you, Madam Chair, for the hearing. As you know, last Congress we did a similar hearing when I was chairman and I think really we got a lot of positive feedback from members and so I think this really builds on that to educate us about the whole pharmaceutical supply chain, the players involved, many of whom will be represented on the two panels today. We appreciate your~~our~~ participation because we are all trying to figure out how do we make sure the medical miracles that are discovered here or elsewhere get to our patients, our constituents in a way they can afford to take them and save their lives.

And this is a very difficult issue. I have never seen a

President more engaged on this issue than President Trump is and his Secretary of HHS. They have some innovative and creative ideas, some of which may work better than others, but there is no doubt this administration is very committed to this cause of getting prices down.

So as we all seek to continue to improve our understanding of the drug supply chain and how each step in the process impacts consumers, we can further deconstruct how the supply chain affects drug prices by hearing from our witnesses from each step of this process, manufacturers, payers, pharmacists, providers, patients. So I would like to welcome each of you here today.

Our committee has done a lot to help get life-saving treatments to patients. This includes championing the landmark 21st Century Cures bill, which I think everybody on the committee participated in but it was led really by then-Chairman Fred Upton and Congresswoman Diana DeGette. It sought to modernize the nation's biomedical innovation infrastructure, streamline the process for how drugs and medical devices are approved, and get new treatments to patients faster.

However, the impact of cutting-edge life-saving cures cannot be fully realized if they remain largely unaffordable

to most patients. So while innovation and market competition are the key drivers of priced reduction, we must also acknowledge that the complexity of the supply chain does have an impact on access. It does have an impact ~~access~~ on delivery and on the cost of drugs.

Meanwhile, in the last Congress, in a bipartisan, I think unanimous, way we reauthorized the Food and Drug Administration. It gave the agency some new tools and resources to get generic drugs into the market faster. We have already seen the positive effects of that legislation play out. We have seen last year the FDA approved a record number of generic drugs, driving competition and giving consumers more choices. Just last month, this committee unanimously approved a number of FDA policies designed to increase transparency in the supply chain and bring down prescription drug prices.

So I hope we can continue to work across the aisle on common sense policies to address the rising drug costs and, in doing so, we will rely on the testimony and insight of witnesses like those before us today.

And again I would say, having been involved in these efforts for years, we need to look from one end to the other of everything related to health care, Madam Chair, not just

drugs, not just PBMs, not just insurers but we need to get this right for our constituents, for our country. I don't think there is a country on the face of the planet that does more in innovation, in health care than the United States. So that is important but even with all the changes from various players in how insurance works and all, again, we are seeing people priced out of markets with enormous deductibles, enormous copays, premiums going up, drugs that get left on the counter because they can't afford them. And so our work must continue.

So I appreciate your leadership on this and I look forward to hearing from our witnesses. I would admit up front we have a concurrent hearing on energy with the Secretary downstairs so, I will be popping back and forth.

And with that, Madam Chair, I yield back.

Ms. Eshoo. I thank the gentleman. The gentleman yields back. And thank you for your statement.

I now would like to introduce the first panel of our witnesses for today's hearing and thank you again for your willingness to be here with us today to testify.

Mr. Justin McCarthy, Senior Vice President of Patient and Health Impact Group at Pfizer, thank you; Mr. Kave Niksefat -- am I pronouncing your name correctly -- he is the

Vice President of Value and Access at Amgen; Mr. Jeffrey -- is it Hessekiel -- Hessekiel -- good. I don't have an easy last name to pronounce so I don't like it when it is mispronounced and I don't want to mispronounce yours -- is the Executive Vice President and General Counsel at Exelixis; Amy Bricker, Senior Vice President for Supply Chain at Express Scripts; Mr. Brent Eberle, who is the Chief Pharmacy Officer at Navitus Health Solutions.

So thank you again for joining us today and we really look forward to your testimony.

I don't know whether I need to explain the lighting system. I think you are all familiar. Probably the most important one is red and you need to stop then. All right? And you don't have to read your entire statement into the record; that will be placed in the record. If you want to summarize that, simplify it, however you wish to approach it, I think the simplifying it is most welcome by members.

So we will start with Mr. McCarthy. You are recognized for 5 minutes.

STATEMENTS OF JUSTIN MCCARTHY, SENIOR VICE PRESIDENT, PATIENT AND HEALTH IMPACT GROUP, PFIZER; KAVE NIKSEFAT, VICE PRESIDENT, VALUE AND ACCESS, AMGEN; MR. JEFFREY HESSEKIEL, EXECUTIVE VICE PRESIDENT AND GENERAL COUNSEL, EXELIXIS; AMY BRICKER, SENIOR VICE PRESIDENT, SUPPLY CHAIN, EXPRESS SCRIPTS; AND BRENT EBERLE, CHIEF PHARMACY OFFICER, NAVITUS HEALTH SOLUTIONS

STATEMENT OF JUSTIN MCCARTHY

Mr. McCarthy. Chairwoman Eshoo, Ranking Member Burgess, and members of the subcommittee, thank you for inviting to testify today. It is an honor to be a part of this panel. My name is Justin McCarthy and I lead the Pfizer team responsible for reimbursement and market access for medicines and vaccines.

At Pfizer, more than 90,000 colleagues come to work each day aligned around a singular purpose -- breakthroughs that change patients' lives. In 2018, we estimate that more than 784 million people around the world use the Pfizer medicine or vaccine to improve their health and we want to help even more.

With approximately 100 programs in our pipeline, we hope

to bring a wave of innovative new medicines to the market that address the most challenging and conditions. Just this week, we received approval for a breakthrough medicine with the potential to change the lives of patients battling cardiomyopathy, a rare life-threatening disease for which there were no previous options for patients. Unfortunately, these scientific innovations will not change patients' lives unless patients can get access to them and can afford them.

Medicine should not be out of reach for patients but three trends have evolved since the Part D benefit was enacted that are contributing to the affordability challenge. First, patient out-of-pocket costs are rising due to increased coinsurance and high deductibles. And while the original intent of out-of-pocket costs was to turn patients into smart consumers of health care, in reality, it is just causing patients to delay or defer care.

Second, the growth in rebates are depriving patients of negotiated discounts.

And third, we have seen tremendous advances in biomedical innovation that were not envisioned when the Part D benefit was enacted.

All of us on this panel share a responsibility to help find solutions that address the affordability challenges that

I know this committee cares deeply about.

I have outlined four solutions in my written testimony that address both health system and patient affordability and this morning, I would like to focus on two of them: relieving patient cost-sharing burden and supporting the uptake of biosimilars.

First, to relieve patient affordability, we should impose a cap on out-of-pocket costs and pass through negotiated discounts to the patients. Abandonment of medicines is a growing problem. Nearly a third of all Part D prescriptions are abandoned at the pharmacy counter if seniors are asked to pay $250 or more. This number can approach 75 percent for new prescriptions and this trend is made worse because patients pay an average of 14 percent in out-of-pocket costs for medicines and only two percent for other healthcare costs.

Abandoning prescriptions is bad for both patients and overall health system costs. That is why we are advocating for capping seniors' out-of-pocket costs in Part D and offering solutions to help fund that cap.

In addition, the current system of rebates has increasingly led to perverse market incentives, where patients do not receive the direct benefit of negotiated

rebates for the medicines they are taking. These patients are paying their deductible and coinsurance based off the full list price, not the negotiated price. If rebates are passed to Medicare beneficiaries at the point-of-sale, we estimate that seniors taking Pfizer medicines could save hundreds of dollars per year. The resulting improved adherence could also reduce total healthcare spending.

To be clear, the rebate reform is not a windfall to Pfizer or the pharmaceutical industry. We are committed to converting all our rebates to point-of-sale discounts. We also fully expect that enhanced transparency will enable PBMs and plans to negotiate even greater discounts.

Second, incentivizing the use of low-cost biosimilars. Medicines are the only segment of the healthcare system with built-in cost containment. When a medicine's patent expires, low-cost generics are made available, often at just five percent the cost of original branded products. The system works well for generic drugs; however, the system is not yet working for biologics, where the adoption of biosimilars is facing resistance.

Biosimilars have the potential to save billions in healthcare costs. That is why we must incentivize the use of biosimilars which, today, can be as much as 40 percent less

expensive than the branded biologic.

In closing, medicines are our best hope for preventing, curing, and treating disease. They can also help significantly reduce overall healthcare costs by mitigating the need for more expensive treatments. We all want America to remain the leader in biomedical innovation and to ensure that people have access to medicines when they need them most.

Again, thank you for the opportunity to testify today. I look forward to answering your questions.

[The prepared statement of Mr. McCarthy follows:]

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

Ms. Eshoo. Thank you, Mr. McCarthy. Excellent testimony.

Next, I would like to call on Mr. Niksefat. You are recognized for 5 minutes.

STATEMENT OF KAVE NIKSEFAT

Mr. Niksefat. Chairwoman Eshoo and Ranking Member Burgess, and members of the subcommittee, thank you for inviting me to be here today.

My name is Kave Niksefat and I am Vice President and head of U.S. Value and Access at Amgen, one of the world's leading biotechnology companies. For nearly 40 years, Amgen has been providing innovative biologic medicines to patients suffering from some of the world's most serious, prevalent, and costly diseases, including cancer, osteoporosis, and heart disease. I believe we have a helpful perspective on the drug supply chain and the important role it plays in determining what patients pay for their medicines.

Amgen is part of the drug supply chain, of course, and we understand the role that we play in proactively taking steps to ensure that patients have access to the medicines they need. Amgen is a leader, for example, in value-based partnerships and in developing high-quality biosimilars, and we support policy solutions in these two areas and others that will improve affordability to patients.

Perhaps the most significant way Amgen addresses affordability issues for patients is through the responsible

pricing of our medicines, which is also where the complexities and inefficiencies of the drug supply chain begin to show themselves more clearly.

Let me start by noting that the overall net selling price of Amgen medicines in the U.S. actually declined in 2018 and is expected to further decline in 2019. Why then are there so many Americans still struggling to afford the medicines they need from Amgen and others?

The examples of one of Amgen flagship and growing medicines, Repatha is illustrative. Repatha is approved by the FDA to prevent heart attacks and strokes by substantially lowering cholesterol in a wide range of high-risk heart patients. Last year, Amgen took the unprecedented step of making Repatha available at a 60 percent reduced list price, with the hope of improving affordability for patients and supporting the growth of this product in a competitive marketplace.

To allow for a smooth transition to the lower list priced Repatha by the supply chain, we have temporarily continued to offer Repatha at its original list price. In a well-functioning system, that transition would happen quickly, especially at a time when the U.S. spends $600 billion every year on heart disease.

Unfortunately, this transition has been much slower than you might expect. Why? We believe it is due to the embedded issues in today's rebate-driven supply chain. For example, only about half of commercially insured patients currently access the lower list price Repatha. While Amgen has offered equivalent or lower net prices on the lower list price option of Repatha, Amgen pays fewer rebate dollars to achieve the same net price. We believe this lower rebate makes the lower list price Repatha less attractive to portions of the supply chain, especially in a marketplace where the competition can offer a higher overall rebate and achieve the same net price.

Amgen intends to discontinue the original list price option of Repatha, once we see sufficient adoption in the market of the low list price option, which we hope will occur by the beginning of 2020.

To be clear, I am neither putting all the blame for high drug prices on any one actor in the supply chain, nor am I calling for the elimination of PBMs, which play an essential role in our supply chain. We are supportive, however, of market and policy changes to ensure that the more than $150 billion in rebates and price concessions that the biopharmaceutical industry provides each year to the supply chain actually make their way to patients in the form of

lower out-of-pocket costs at the pharmacy counter. Until these changes are made, we feel the rebate dollar will continue to be the single largest economic driver in the drug supply chain.

In closing, all of us on both of these panels have a role to play in ensuring that the U.S. drug supply chain works better. I commend this committee for seeking bipartisan solutions that will benefit patients. Amgen remains committed to working with Congress and the administration to advance market-based reforms that will promote competition and improve access to new therapies without stifling innovation.

Thank you again.

[The prepared statement of Mr. Niksefat follows:]

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

Ms. Eshoo. Thank you, Mr. Niksefat. You certainly delivered that with great clarity and we appreciate it.

I now would like to recognize Mr. Hessekiel. You are recognized for 5 minutes for your testimony.

STATEMENT OF JEFFREY HESSEKIEL

Mr. Hessekiel. Chairwoman Eshoo, Ranking Member Burgess, and members of the subcommittee, thank you for the opportunity to appear here today.

I am Jeff Hessekiel, Executive Vice President and General Counsel at Exelixis, a 500-employee biotech company based in Alameda, California. We are on a mission to discover, develop, and commercialize new medicines for difficult to treat cancers.

I am here to give voice to small- and medium-sized biopharmaceutical companies whose voices are rarely heard in Washington, even though we drive the lion's share of drug discovery in the United States. In fact, in 2018, these companies patented almost two-thirds of new drugs approved by the FDA.

I am also here to describe the tremendous risks and costs that businesses like ours assume. Overall drug pricing is certainly a cause for concern in the cancer space, which is my employer's focus. The more immediate concern, however, is patient access and affordability. To address that problem, we ask Congress to let us provide support to Medicare Part D patients diagnosed with cancer in the same

way that we do for commercial patients.

Exelixis' flagship product is cabozantinib, a Part D drug currently approved for forms of liver, kidney, and thyroid cancers. For kidney cancer, it has quickly become the number one prescribed therapy of its kind.

At this point, I would like to acknowledge Dena Battle, founder of a patient advocacy organization known as KCCure. Formerly a congressional aide, Dena is in the room with us today. Her late husband, Chris, was diagnosed with stage 4 kidney cancer. After fighting by his side, Dena is now a full-time advocate helping to increase kidney cancer research funding.

After he had exhausted all other treatment options, Chris was one of the first patients to benefit from cabozantinib when it was FDA approved. We are thankful that our medicine gave him 9 additional months with Dena and their daughters before, sadly, he passed away.

It was Exelixis' great privilege to help Chris Battle, as it is our privilege to help every patient that we serve. That is why we exist. However, it may come as a surprise to you that 2 years after we were able to help Chris with our FDA-approved product, Exelixis almost went out of business. We had spent $2.3 billion in research and development and the

revenues from sales of cabozantinib were meager, due to the very small patient population for which the drug was approved at the time.

Our hopes for long-term financial security rested on four pivotal trials. In 2014, when the first two of these trials read out negatively, as often happens in cancer research, Exelixis went into a tailspin. Our stock plummeted. We had dwindling cash reserves, considerable debt, and had to lay off nearly 75 percent of our employees.

Despite these setbacks, Exelixis persevered. Our trials in kidney and liver cancer showed strong results and later, FDA approvals in these indications offered the opportunity to serve larger patient populations. We now offer cabozantinib at the price necessary to recoup a portion of our past R&D investments, fund our extensive development programs in over 20 forms of cancer, and undertake new drug discovery efforts. The resulting revenues have enabled us to steady our financial ship.

Exelixis' ups and downs illustrate the risks frequently faced by emerging biopharma companies and it bears repeating that despite such huge challenges that these companies face, we are the overwhelming source of medical innovation, especially for critical and catastrophic diseases. For this

reason, we caution Congress not to undermine, disrupt, or even destroy the biopharma innovation cycle that drives the discovery of life-saving new medicines for Americans.

Some countries have implemented price controls to keep drug prices artificially low. Others have weakened intellectual property protection. However, it is the United States that has been the driving source of humanity's most critical medicines and Americans have benefitted immeasurably from that innovation.

In closing, we believe Congress' foremost health care concern should be to help facilitate patient access to critical medicines. Cancer patients too often face crippling out of pocket costs and are forced to delay or even abandon their therapy. For these patients, we do not accept the policy argument that patients must have financial skin in the game in order to obtain their therapy.

At Exelixis, we have a deeply held commitment: no patient who requires one of our therapies should go without because of an inability to pay and we do everything that we can under law to fulfill that commitment. We strongly urge you to allow Exelixis to do more. Let us provide Part D patients the same cost-sharing assistance that we provide commercial patients.

Thank you for the opportunity to appear here today to speak for emerging biopharma companies. I look forward to responding to your questions.

[The prepared statement of Mr. Hessekiel follows:]

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

Ms. Eshoo. Thank you very much for your highly instructive testimony.

I now would like to recognize Ms. Bricker. You are recognized for 5 minutes and thank you, again, for saying yes to us.

STATEMENT OF AMY BRICKER

Ms. Bricker. Absolutely.

Chairwoman Eshoo, Ranking Member Burgess, and members of the subcommittee, thank you for inviting me to testify at this hearing. My name is Amy Bricker, Senior Vice President of Supply Chain for Express Scripts.

I am a pharmacist by training and I began my career in the community pharmacy setting. In my current role at Express Scripts, I oversee key relationships and strategic initiatives across the pharmaceutical supply chain. I work directly with drug manufacturers and retail pharmacies with the mission of helping more than 80 million Americans achieve better health with greater choice, affordability, and predictability. I appreciate the opportunity to testify on the challenge presented by high drug prices.

Prescription drug affordability affects patient health and I am pleased that the subcommittee is examining the entire supply chain. Express Scripts' role in the supply chain serves to drive down prices and deliver savings to consumers. We are part of the solution but every part of the supply chain needs to be part of the solution and this isn't always the case.

Innovation can yield life-changing new therapies and treatments that improve or extend life but the increasingly high price tag that accompanies these medications is putting them out of reach for patients. At Express Scripts, we are focused on solutions that support both innovation and affordability so that patients can access the care they need.

Health plans, unions, government plans, and employers, including many pharmaceutical companies, trust us to manage pharmacy and medical benefits for millions of Americans. Our clients work with us because high drug prices present an enormous challenge and we deliver value and innovation for them every single day. The savings are real.

In 2018 alone, Express Scripts returned $45 billion in savings to our clients. Because of our innovative solutions, our clients achieve the lowest drug trend in decades, just 0.4 percent across employer-sponsored plans. Despite rising list prices, the average 30-day prescription costs only six cents more. In Medicare, we delivered an unprecedented 0.3 percent decline in drug spending across the plans we serve. Without the work we do, cost to patients and taxpayers would be higher.

More must be done to lower costs for patients and that starts with more competition, consumer choice, and

responsible drug pricing. Our ability to direct patients towards lower cost more effective medications yields most patients from high out-of-pocket cost. However, those with high deductible health plans, those who pay a portion of the drug's cost based on coinsurance, and those that are uninsured are too often subject to high prices at the pharmacy counter because they are paying based off the list price. Too many drugs, often without rebates, are coming to market with little or no regard for affordability. Manufacturers continue to bring drugs to market with eye-popping list prices that are not rebated. Let's be clear. The problem starts with list prices, not rebates but we owe it to our fellow Americans to find solutions.

Our combination with Cigna will enhance our ability to design targeted solutions to address these disparities and improve choice, affordability, and predictability for our consumers and clients. For example, within the first 100 days of our merger, we were able to launch a Patient Assurance Program, which will cap insulin costs. While this committee knows the price of insulin has more than doubled since 2012, the cost for our patients will be limited to just $25 a month. This is one early example of the accelerated change our combined company is driving.

Similar to the construct of our Patient Assurance Program, we believe there are more direct and effective ways to deliver relief to patients through expanded benefit designs without disrupting coverage for millions. Solutions include allowing more preventative services to be covered in the deductible phase and assuring biosimilars have a clear pathway to the market.

We commend this committee on its recent efforts to approve legislation creating more competition in the generic and biosimilar markets. We are proud of the role we play to lower prescription drug costs and we look forward to working with the committee on targeted solutions to improve the affordability of prescription drugs for all Americans.

Thank you.

[The prepared statement of Ms. Bricker follows:]

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Ms. Eshoo. Thank you for your testimony.

I now would like to call on Mr. Eberle. And you are recognized for 5 minutes and thank you for being here today.

STATEMENT OF BRENT EBERLE

Mr. Eberle. Thank you. Chairwoman Eshoo, Ranking Member Burgess, and members of this Health Subcommittee, thank you for the opportunity to come before you today. My name is Brent Eberle and I am the Senior Vice President and Chief Pharmacy Officer at Navitus.

Navitus was formed in 2003 in response to a market need for a PBM model with enhanced focus on transparency and aligned incentives. Today, we are owned by SSM Health Care, a not-for-profit integrated health system headquartered in St. Louis. Navitus administers pharmacy benefits for over 6 million members across the country, across multiple lines of business.

As a full pass-through transparent PBM, Navitus has a different business model that remains unique in the industry. The term pass-through means that we pass through to our clients all of the payments that we receive from drug manufacturers, including rebates and any other discounts. We also pass through 100 percent of the discounts that we receive from pharmacies. We simply charge a flat known administrative fee for the services we provide. We believe that this approach ensures there is no conflict of interest

or confusion about who we are working for.

In spite of the negative attention that PBMs have been getting recently, PBMs perform several critical functions that are necessary for patients to access the medications they need. PBMs act as consolidators of market power for those who offer pharmacy benefits, acting as a counterbalance to the market power of drug manufacturers and large pharmacy chains. By representing their clients, PBMs are able to combine buying power of many individual plans and negotiate with manufacturers and pharmacies to obtain lower prices than any individual plan can attain on their own.

PBMs also perform numerous other important tasks, including multiple operational and clinical management functions. Operational activities include management of eligibility, standardization of claims processing, determining member and plan costs, and controls to prevent fraud, waste, and abuse. A typical pharmacy claim transacts in less than a second but involves hundreds of calculations and hundreds of data elements to ensure that claim processes correctly.

Part of my role at Navitus is to oversee the clinical activities of the organization. Since PBMs are in the unique position to impact pharmaceutical care at a macro level, our

teams design products and services that are targeted to improve population health in a number of different areas. These areas include helping ensure medications are used appropriately and according to current practice guidelines, increasing medication adherence through patient education and engagement, and preventing the overuse or misuse of medications through our opioid management efforts.

Our clinical teams are passionate about improving care and our business model based in operational and financial transparency helps to ensure the programs we develop provide value and optimize the dollars our clients have available for pharmacy. We play an active role in being stewards of the pharmacy benefit for our clients, who trust us to perform this service.

In 2018, our net drug spend was nearly flat and almost half of our clients actually saw their pharmacy spend decrease from the previous year. These positive results not only benefited our clients but their members as well, who saw a two percent decrease in their out-of-pocket pharmacy costs. Our current efforts are focused on further extending transparency to providers and our members through innovative technology that is focused in improving the provider and patient experience. We are accomplishing this in numerous

ways, including the expansion of electronic prior authorization, the use of real-time benefit checks, and mobile applications that let members see where their lowest cost pharmacy is in their area.

Additionally, the growth in the internet of things creates numerous opportunities for us to develop and collaborate on tools and services focused on improving drug treatment adherence. We know that adherence is key to ensuring patients have the best chance for their treatment plan to be successful. Our vision is that these investments will continue to enhance patient engagement, resulting in improved health and lower overall costs.

As with all parts of health care, transparency and aligned incentives can play a significant role in improving quality and reducing costs. We believe any effort to reform the PBM industry should start with increasing transparency so that decision-makers in benefit plans and in governmental entities for government-sponsored plans have all of the information that they need to make the decisions -- the best decisions they can.

In the current system, too often, decisions are made based on partial or incomplete information. By making the necessary information available to plan sponsors and by

continuing to root potential conflicts of interest, the entire system can be made more efficient and better decisions can be made, resulting in improved care and lower costs.

Thank you for the opportunity to share with you an overview of our pass-through PBM model and to highlight the vital role PBMs play in the drug supply chain. I look forward to your questions.

[The prepared statement of Mr. Eberle follows:]

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Ms. Eshoo. Thank you very much.

We have concluded the opening statements. We are going to move to member questions. Each member will have 5 minutes to ask questions of our witnesses and I will start by recognizing myself for 5 minutes.

Mr. McCarthy, Mr. Niksefat, and Mr. Hessekiel, you heard my questions in my opening statement. Can you briefly instruct the committee members? How do you price your drug?

We know that you have costs. So, we are not talking about costs. How do you price your drug?

Mr. McCarthy. Thank you. I will do my best to answer that important question.

So first of all we start -- our starting point is always to look at the burden of disease, the burden to patients and the burden to the cost to the system. And that is our starting point.

What we then do is look at what is the benefit that our medicine brings. Is it safer? Is it more effective? Does it avoid other downstream costs and hospitalizations? And that is our framework.

We also then look at the population that we are treating, affordability to the system and to patients, and we also look at our need to continue to sustain investment and

innovation.

And we take all of those factors and we put it together and come up with what we think is the value. What we do next is we go out and we talk to providers. We talk to patients. We talk to plans. And we test our assumptions, and we get their feedback, and then we refine our price.

That takes us to the next stage, which is where we go out and we negotiate with plans and PBMs for coverage. And sometimes we get coverage; sometimes we get restricted coverage; and sometimes we get excluded. And that is basically the process.

Ms. Eshoo. Mr. Niksefat.

Mr. Niksefat. Thank you, Madam Chair. A very similar answer to the gentleman from Pfizer.

When we look at setting a list price for a drug, it is not done in a vacuum. It is looked through and established at the pricing principles that we have that start with what is the value of the medicine to physicians, patients, and ultimately the healthcare system overall.

We then look at what is the economic benefit that that drug brings, in terms of additional offsets to costs that exist in other areas, and look at it as well to see how large is the patient population we believe it will impact, and

making sure that we can sustain continued investment and innovation.

We also look at how does this drug play within our existing pharmaceutical supply chain, especially when competition is present.

Ms. Eshoo. Thank you.

Mr. Hessekiel.

Mr. Hessekiel. Sure. To establish the launch price for cabozantinib, we conducted extensive market research to determine the opinion of potentially prescribing physicians, plans, and payers concerning the value of cabozantinib based on the data from our clinical trials and the drug's safety profile.

We also considered the market context into which we were launching the drug, such as the attributes and prices of competitor products.

Finally, we evaluated our own level of R&D spending which, as I had mentioned at the time, was $4.3 billion that we had spent to get to that point, and we figured what was necessary in order for us to discover and investigate cabozantinib, as well as the amount we are currently spending on that investigation, and how much more we would need to spend in the future.

Ms. Eshoo. I still don't quite get it but I want to move on to my next question.

To the manufacturers: In your negotiations with the PBMs, do you pay them anything?

Mr. McCarthy. We pay them in two respects. We have the rebates, which we have been talking about --

Ms. Eshoo. Discounts.

Mr. McCarthy. Discounts, rebates --

Ms. Eshoo. Yes, let's use discounts because rebate -- the connotation of a rebate, to me, is I associate that with consumers but I don't believe that that ultimately is reaching them. Some people think that but I don't.

So let's use the word discount, all right?

Mr. McCarthy. Okay, we agree. So we pay discounts that we agree to --

Ms. Eshoo. You negotiate discounts.

Mr. McCarthy. We negotiate discounts.

Ms. Eshoo. But do you pay any money to them for anything?

Mr. McCarthy. Well we negotiate discounts and then we also pay administrative fees which are not based off the list price but are administrative fees for administering the benefit. It is a general administration fee.

Ms. Eshoo. To the PBM?

Mr. McCarthy. to the PBMs, yes.

Ms. Eshoo. Why do you pay that?

Mr. McCarthy. It is an administrative fee for managing the formulary and other services.

Ms. Eshoo. To the manufacturers, again: Are there any other fees or monies that are associated with manufacturers and PBMs that I have missed?

You just pay administrative fees and you do the discounts.

Mr. McCarthy. Uh-huh.

Ms. Eshoo. To Ms. Bricker and Mr. Navitus, you have different business models, obviously. You are a small PBM. You are one of the giant of three in our country.

You are paid by your clients to negotiate with the drug manufacturers. Do they pay you money as part -- do they pay you anything for these negotiations?

Ms. Bricker. Thank you for the question, Congresswoman.

Yes, our clients do pay us for the services that we provide.

Ms. Eshoo. And is it a fee-based payment or is it based on the discount? What is it based on?

Ms. Bricker. The arrangements vary by client. They

choose how they elect to pay us. Some do --

Ms. Eshoo. They choose; you don't set it.

Ms. Bricker. Yes, ma'am, they choose.

Ms. Eshoo. Mr. Eberle?

Mr. Eberle. Yes, for our clients, we do everything on a fee-for-service basis. So it is a flat per member per month administrative fee or a fixed per claim charge. But that is what our clients charge us -- or what we charge our clients to provide that service.

Ms. Eshoo. So the $64,000 question is: Your business model -- well, you both view it this way but it seems to me that your business model, given what you have testified reaches the patient -- the savings.

Mr. Eberle. Yes, all of the savings that we receive from manufacturers and pharmacies get passed back to the plan sponsors. Those plan sponsors can then elect to share those savings with members, either through a point of rebate plan design, they can lower premiums, or lower overall copays and coinsurances.

Ms. Eshoo. So there is one more step in it. The insurers and others need to make that decision.

Mr. Eberle. Correct.

Ms. Eshoo. And we are going to have them on the second

panel.

Mr. Eberle. Correct.

Ms. Eshoo. To Express Scripts, tell me about the specialty pharmacy. Do you own specialty pharmacies?

Ms. Bricker. Yes, we do own a specialty pharmacy called --

Ms. Eshoo. And why? How does that work?

Ms. Bricker. So specialty pharmaceuticals are those that are really high-cost and require careful education around how to administer the product, ensuring that it is taken appropriately, ensuring that it is best managed. And so there are a team of specialty pharmacists and nurses that work very closely with physicians to ensure that patients are actually taking the medicine appropriately and correctly.

Ms. Eshoo. It is a business that you have set up.

Ms. Bricker. It is a pharmacy.

Ms. Eshoo. Well, I have gone way over my time.

I am going to recognize now the ranking member of the committee, Dr. Burgess for 5 minutes of questioning.

Mr. Burgess. Thank you. People who have heard me at this type of hearing before know that I sometimes say if we don't understand the difference between Sovaldi and Daraprim, we are going to get the wrong answer to this.

So bearing that in mind, Sovaldi being a breakthrough cure for hepatitis C and we are grateful. It is a gift that we are able to cure a disease that when I was in my residency training program it didn't even have a name and now is a cure; not a treatment, a cure.

But maybe our PBMs at the end of the table, if I could just ask a question. When I go online and look at the price for Daraprim, why is it still so expensive? Sovaldi has come way down with competition. Daraprim has been around a long time, it is no longer on patent, no one is trying to recoup a research cost. How come it costs so much?

Mr. Eberle. I am not sure that we can address the question of how that list price is established. We pay the list price that is set. It is a generic. There are not rebate/discounts available. So we are working to negotiate the best price we can but we are not setting the list price for that product.

Ms. Bricker. Yes, my answer would be similar. We, too, are outraged by the list price of Daraprim and Sovaldi when it launched. Your observation is accurate that with competition in hep C, pricing came down. We are really proud of the work that we were able to do in working with manufacturers to secure those deep discounts. But in

Daraprim, it is an outrage and, unfortunately, I am not able to shine any light on why they have set the price they have.

Mr. Burgess. Well, it is a single manufacturer. And I guess what I don't understand is why, with what they are charging for the drug, I would think someone would be saying hey, I will do that for half price. Because when I go on my app that I have for drug prices, it is -- I mean it is way up there. For a month's therapy, it is like $60,000. It is unbelievable.

Ms. Bricker, I was grateful to hear you bring up the issue of your Patient Assurance Program. We have another subcommittee on the Energy and Commerce Committee. We had a hearing on insulin prices. Heaven help me, I do not ever want to run an insurance company. I can't imagine how difficult that is but my observation that morning was that if I did run an insurance company and I had a patient who I was responsible for, and had some sort of longitudinal relationship with, and they were unfortunate enough to be diagnosed with diabetes, I would want to pay for their medicine. I wouldn't want them leaving the pharmacy without their script because untreated diabetes is a whale of a lot more expensive than treated diabetes.

Is that something that you all have found in your

business?

Ms. Bricker. Absolutely. We focus many of our programs on ensuring adherence or compliance with medications, not just in diabetes but in many chronic diseases.

But to your point, thank you for acknowledging the Patient Assurance Program. It did allow us to roll out a program that offers insulin, all insulin, at $25 a month and we did that in collaboration with the manufacturers.

Mr. Burgess. And is that $25 a month, is that still a barrier for some patients? Do you have a mechanism by which a patient can still get access to their medicine if that $25, although that is significantly better than other options, but do you have an option for that patient if the $25 is a barrier?

Ms. Bricker. As testified in the prior committee, the manufacturers often offer additional patient assurance or foundational dollars to support those that have a financial need. And so we do attempt to work with them as well.

Mr. Burgess. And Mr. Hessekiel, you brought up a point. You said that cost-sharing assistance is available to patients on commercial insurance but not to those on public insurance. Is that correct? Did I understand you right?

Mr. Hessekiel. That is correct. Legally, under current

law, we are not allowed to provide cost-sharing, coinsurance, copayment assistance to patients on public healthcare plans.

Mr. Burgess. But you would if you could. It is not because you are hard-hearted. It is because you are prevented by law?

Mr. Hessekiel. Absolutely. I have been making rounds on the Hill now, since we started our government affairs function, with one singular purpose which is to ask that something be done so that we can extend that so that patients who have cancer can get that assistance.

Mr. Burgess. And just so I am clear on that, that is a legislative fix, not an administrative fix. The good folks over at the department of Health and Human Services can't just promulgate a rule and fix that. We have to fix that?

Mr. Hessekiel. It actually could be addressed either way.

Mr. Burgess. Either way?

Mr. Hessekiel. Yes, there is a OIG rule that views that as a form of kickback and so it is seen as an inducement to try and get patients on drug.

I want to be very clear. We are not advocating for the--

Mr. Burgess. Correct.

Mr. Hessekiel. -- elimination of that restriction across public health plans. We are saying that for cancer patients and patients with catastrophic disease --

Mr. Burgess. It make sense.

Mr. Hessekiel. -- who have gotten a diagnosis of this devastating illness and the next thing they know, they are in financial distress in order to deal with it.

Mr. Burgess. Well, I will follow-up with you offline about that because that is bothersome to me as well and I share your concern about that.

And I have got a ton more questions but we are out of time. So I am going to be submitting significant questions for the record and would appreciate your prompt response to those.

Thank you very much.

Ms. Eshoo. The gentleman yields back.

It is a pleasure to recognize the gentlewoman from California, Ms. Matsui, for 5 minutes of questioning.

Ms. Matsui. Thank you very much Madam Chair. And I think we are really very happy to have this session here today to try to entangle the drug supply chain.

One of the things that struck me about this hearing and standing out about this is that the rising drug costs and

need for greater transparency in the whole chain. And I don't think anyone sitting here today or the Federal Government has really a complete picture into this and that is why we are here today.

Now this lack of transparency has really caused some States to take action. California, Vermont, Nevada, and Oregon have laws regarding transparency and it is my hope that we might consider Federal legislation regarding transparency. Certainly, it will benefit our federal health programs and so American families understand.

We have already seen good actors in the manufacturing space take meaningful steps to increase transparency. For example, both Sanofi and Janssen have agreed to disclose the drug price increases each year. Sanofi has also announced they will put limits on how much it will increase drug prices annually. This is a first great step but much more needs to be done.

I would like to ask all of our drug manufacture witnesses here today, Mr. McCarthy, Mr. Niksefat, Mr. Hessekiel, do you believe that greater transparency in our healthcare system would help to improve our understanding of what is driving up the cost of prescription drugs and care in this country? Just a yes or no.

Mr. McCarthy. Yes.

Mr. Niksefat. Yes, we support it across the entire system.

Ms. Matsui. Okay.

Mr. Hessekiel. Absolutely.

Ms. Matsui. Okay, if Congress were to pursue financial transparency in the drug supply chain, what would that look like? Are there lessons learned from some of the State actions?

Mr. McCarthy. So my view would be a federal transparency bill should look across all of health care because I believe it is not only important to inform consumers but we have talked a lot about value-based care and the shift to value-based care. I believe some sort of federal transparency bill will be essential for us to be able to compare value across different health care interventions and I believe that is one of the barriers that is preventing us from moving to value-based care now. It is very difficult to look across the spectrum of health care to assess which intervention is most valuable.

Mr. Niksefat. We believe the best way to increase transparency within the system is to allow and ensure that patients always receive the negotiated discounts at the

point-of-sale and that will shine a light across everything across the entire system.

Ms. Matsui. Okay, Ms. Bricker, in your testimony, you discuss increasing price transparency for patients and provider at the point of prescribing as one proposal to lower drug price costs for patients.

Can you explain how this proposal might work and what benefit could it bring to patients?

Ms. Bricker. Yes, thank you for the question.

So, we are highly supportive of tools that are at the fingertips of prescribers. This information is available today but connectivity between physicians, electronic medical record, and this information is a barrier. So we want to do more to ensure that every physician has this information.

It would explain what drug was on formulary. It would explain the out-of-pocket cost. It would explain if there was prior authorization required and all of that would be known real-time.

We are also supportive of tools for patients so that they can make informed decisions. We have those today at Express Scripts but they are not universally available across all drug plans.

Ms. Matsui. Okay. Now, I realize the formulary

management is a common strategy used by pharmacy plan sponsors to control the cost of prescription drugs. I am interested in better understanding of how this practice impacts patient access to behavioral health medications, including medication-assisted therapies and antipsychotics.

When building your national formulary, what factors do you consider when making initial coverage and tier placement decisions for FDA-approved treatments for behavioral health disorders?

Ms. Bricker. Yes, so it starts with an independent panel of physicians that review the clinical attributes of the product. Once they have determined that a product should or could be included on formulary, we work with the manufacturers to secure discounts.

From that, then we determine the best net cost products and put those on formulary as preferred status.

Ms. Matsui. Okay. Continuing on here, I am really concerned because I am looking at some of these costs we are talking about here and there are various aspects we talk here about Part D. But in Part B, we are looking at the fact that without rebates, the cost of prescription drugs could keep increasing. Is that correct?

Ms. Bricker. Yes, that is correct.

Ms. Matsui. And I guess I am going to ask the manufacturers why would that be so.

Mr. Niksefat. We believe that Part B is also a competitive marketplace and the competition can drive prices down.

Ms. Matsui. You all agree on that? Okay.

Mr. McCarthy. I would just add, Congresswoman, I think there is work to be done in terms of the uptake of biosimilars and we would be happy to talk about that.

Ms. Matsui. Well, I have run out of time. So, I yield back. Thank you.

Ms. Eshoo. The gentlewoman yields back.

Now I would like to recognize the gentleman from Illinois, Mr. Shimkus, for 5 minutes of questioning.

Mr. Shimkus. Thank you, Madam Chairman, and welcome.

As a Member of Congress, except for a few of us, we are expert generalists. We know a lot about a little bit and so that is why hearings like this are just very important as we are trying to figure out your business models and how it relates to our constituents and your customers and the like. That is why I really appreciated Dr. Burgess's questions on Sovaldi and Daraprim.

And I think in this debate for us, we know probably the

prescription drugs we are taking and then we get the -- hopefully, we do, and then we will get the anecdotal story of a constituent like I shared in our last health care hearing, who brought me a box of biosimilars that was 20 -- how much was it -- $310 over a year's use monthly dosage. And I went into this debate on Medicare D and the donut hole and trying to figure out how does that work.

So we get these smatterings but trying to put the value chain together is very challenging. So I want to thank the chairman for having this. And we had a similar one in the last Congress trying to work through this.

A point that I want to make, because on the two panels, I have a large rural area. I have 33 counties. So I know Walgreens is on the next panel. They are, obviously, a national chain. We still have a lot of local community pharmacists, standalone operations that they are the only one there. And so as we talk about the value chain, Madam Chairman, for me a lot of times in my debate on how this focuses is on that local community pharmacist because some of these pricing mechanisms really hurts these individual pharmacists.

So I have made statements to the like and I understand the big picture but when you have a county that only has

5,000 people in, you know we have to make sure that they still have the same access to life-saving drugs as anyone else does.

Having said that, I want to look at issues that were kind of addressed by Dr. Burgess also, is where are we getting in the way or what can we do through regulations or rules, like Dr. Burgess mentioned in the Medicare D space, on Mr. Hessekiel's comment. But where else might there need to be either a promotion of rule changes or legislative fixes?

So sometimes, for example, do we have any recommendations how reforms to existing laws like Stark or the Anti-Kickback statute could accelerate value-based contracting within Medicare and Medicare Advantage?

And that is really for everyone, if you could go by real quick. So we can start with Mr. McCarthy.

Mr. McCarthy. So yes, I agree. While those laws were well-intentioned, they didn't contemplate value-based agreements. Having exemptions for value-based agreements both in the Anti-Kickback statute and from the best price provisions would enable us to accelerate value-based agreements.

Mr. Niksefat. I agree with Mr. McCarthy.

Amgen is a leader in value-based care and we believe

that we could extend several of the programs that we offer in the commercial marketplace to the Medicare marketplace if reforms were put in place.

Mr. Hessekiel. I am going all in on my change to the rules concerning being able to provide coinsurance, cost-sharing assistance to Medicare Part D beneficiaries but I do, speaking on behalf of Exelixis, we do agree that changes should be made to facilitate value-based arrangements.

Ms. Bricker. Yes, at Express Scripts, we are also supportive of reform so that manufacturers can participate in value-based contracts and programs for Medicare and government programs.

Mr. Eberle. We agree as well. Value-based programs offer a unique way to impact the cost of prescription drugs and however we can do to expand that across all lines of business we would be in favor of.

Mr. Shimkus. So who wants to, in the last 40 seconds, define value-based for members who have been here for a long time and for the new members of the committee?

Mr. Niksefat?

Mr. Niksefat. Yes, certainly. We have defined value-based contracts as those available contracts that really take a look at the value of a medicine and potentially an outcome

of that medicine and either provided further discounts or a further cost, if the drug performs as it should.

So for example, in Repatha, we offer a so-called outcomes-based rebate. If a patient who is taking Repatha unfortunately has a heart attack or stroke, we will refund the entire value of that patient's medicine back to the health plan. Given that these events can take many years to develop, we are able to offer those in the commercial marketplace but we have a harder time offering them in the Medicare marketplace.

Mr. Shimkus. I appreciate that. Thank you very much.

Madam Chairman, I yield back.

Ms. Eshoo. I can't help but think that you said you set the value at the beginning when you are setting your price, though.

I would now like to recognize the gentleman from North Carolina, Mr. Butterfield, for 5 minutes of questions.

Mr. Butterfield. Thank you very much, Madam Chair, for convening this very important hearing. I think it is important to all of us and we can tell that by the attendance here today. The members, even though they have two or three hearings going on at the same time, members are trying their best to go in and out to hear from these witnesses. And so

thank you so very much for the hearing and certainly thank you to the witnesses.

You know I, some years ago, was taught that corporations -- I guess I was taught this in law school -- corporations exist to create a product and to make a profit. That is 101 in corporate law, to make a good product and to make a profit. And I assume that most, if not all of you, agree with that statement.

But in the world of drug manufacturing, how do you reconcile the corporate desire for profit against the fact that you make a drug that can save lives?

And I represent a low-income district in eastern North Carolina and so many of my constituents simply cannot afford drug prices. They cannot afford the out-of-pocket costs and they cannot afford the other costs associated with health care.

And so how do you reconcile, Mr. McCarthy, the appropriate goal of a company to make a profit against the need to create affordable medications?

Mr. McCarthy. Well for us, it is fairly simple. We feel like we will succeed through our innovation. If we are able to develop an innovative medicine and bring it to patients in need, we will do well, the health system will do

well, but, most importantly, our patients will do well.

Mr. Butterfield. What are some of the factors in price points that drug manufacturers consider in establishing prices?

Mr. McCarthy. So as I mentioned earlier in response to the chairwoman, we always start with what the burden of the disease is and what are available treatments to that patient. How are they managing that condition? What is the burden to the system? Does it result in hospitalization? Does it lead to death? That is always our starting point.

And then we look at what benefits does our medicine bring and it has to be either safer, more effective, deliver savings to the system, otherwise, we don't pursue it. Those are the main factors but we also look at the population. Some of the diseases we are looking at now have very, very tiny populations. They are very rare conditions.

So we look at that and we look at affordability but we also look at our ability to sustain investments and innovation.

Mr. Butterfield. So, affordability is a consideration.

Mr. McCarthy. It is absolutely a consideration.

Mr. Butterfield. What about with Amgen, same thing?

Do you consider affordability?

Mr. Niksefat. Yes, sir, we do.

Mr. Butterfield. That is a factor in drug pricing?

Mr. Niksefat. Yes, it is.

Mr. Butterfield. All right.

Someone mentioned earlier in their testimony that one legislative solution could be capping out-of-pocket costs for Part D, and I certainly agree with that, and I am trying to think that through. If an out-of-pocket cap is put in place under Part D, what are the corresponding changes on the other side of the ledger? Does the cost for the insurance company go up? I mean how do you compensate for the cap?

Mr. McCarthy. So I will offer to answer that, since I was the one who raised it.

I think there could be thoughtful to the Part D benefit. And what we would consider, what we would like to discuss more is possibly closing the coverage gap and then shifting the various responsibilities in the catastrophic phase so the cap would eliminate the five percent patient responsibility in the catastrophic phase. And then there would be shared responsibility between the manufacturers, the plans, and the government. That would be our recommendation.

Mr. Butterfield. Thank you for that.

Some people suggest that drug manufacturers are tone

deaf when it comes to the affordability of drugs and I think that may have been the case some years ago but I have discerned a change in attitude among all of you over the last 3 or 4 years and I want to thank you for it. And I look forward to working with each one of you as we, together, try to lower drug costs in this country.

Thank you so very much for coming. I yield back.

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

I now would like to recognize the gentleman from Virginia, Mr. Griffith, for 5 minutes of questioning.

Mr. Griffith. Thank you very much.

Ms. Bricker, thank you so much for being here. I have asked a lot of tough questions in other hearings to PBMs and I still have lots of questions but one of the things I noted in Mr. Eberle's testimony was he said that one of the problems that all of us could make is if we start making decisions that are based on partial information. And when folks don't show up, even if we are going to ask tough questions and maybe have a disagreement, if they don't show up and give us that information, then we are making decisions based on partial information and we will make even more mistakes than we might otherwise make as human beings.

And so we are just trying to get the info and I do appreciate you being here. I know some of the colleagues of yours chose not to be here today and I regret that for them but am very pleased that you are here. So thank you for doing that because we need full information.

Mr. Eberle, you know I like your model, from what I can tell. It is not going to solve all the problems in the chain but I would like for you to talk about that some because one of the concerns that I would have is you actually said in your written testimony that one of the values of PBMs, and you laid out some things that PBMs do that are valuable and that we shouldn't throw the baby out with the bath water, more or less.

One of the things you said was that PBMs act as a counterbalance to the massive market power of drug manufacturers and pharmacy chains. So what if the pharmacy chain and the PBM are owned by the same people?

Mr. Eberle. Well I don't know that I can comment on that specifically. We don't have that situation for the organization we work for.

How we do that, our negotiations with pharmacies and with manufacturers is, with pharmacies in particular, we are looking at gathering access discounts. Does the client want

a broader, limited network doing the Geo Access requirements so that we can make sure that there is a pharmacy available so that we never have a network where there isn't a pharmacy within range? And we have that as then a competitive negotiation with the pharmacies to determine our network.

Mr. Griffith. Now I do have to ask because I represent a very large rural district, what is within range?

Mr. Eberle. So there are a number of standards. Both state Medicaid and CMS developed Geo Access Standards that we apply both to those federal programs but also to any state or our commercial books of business.

So they set standards based on rural, urban, and suburban area, how many pharmacies within specific ranges of that. And that sets the Geo Access standard.

Mr. Griffith. Okay and I appreciate that.

I like the concept of charging a certain fee because one of the things that I pushed on in another hearing that we had on this issue because this is a bipartisan concern, the drug pricing across the board, and we are trying to get to the bottom of it. One of the things I pushed on was it looks like that the cost of the drug in many of the other cases, in the spread model that you mentioned in your testimony, the price of the drug can push the amount of money that the PBM

receives for processing that drug.

And you indicated that could create a conflict of interest for the PBM because if they then encourage the manufacturer to increase the price of the drug, even if they rebate it back down to the same price that it would have been before they increased the increase or asked for the increase, they are still receiving, even if it is only one or two percent, they are then receiving a larger amount of money for processing and that fee, ultimately, gets passed on to the consumer.

Is that pretty much what I understood you to say?

Mr. Eberle. Very similar, yes. We wanted to take any incentive out, either from the rebate spread or from the pharmacy network spread, and really just have our clients know exactly what we are charging for that service. So that is how we approach it.

Mr. Griffith. And so the folks back home understand, when you are talking about clients, you are not talking about the person who goes to the drug store to buy the drug. You are talking about the insurance companies and other plans. Isn't that correct?

Mr. Eberle. Yes, we represent anyone that provides pharmacy benefits. So that could be a health plan. It could

be a State and local municipality. It could be just a large or small employer but any provider of pharmacy benefits.

Mr. Griffith. And I believe you indicated, I think to Ms. Eshoo, earlier, that if you passed that on to those folks, those people who have the pharmacy benefits, the insurance company, et cetera, then it is between them and their consumers as to whether or not they pass that on to the individual patient. Isn't that correct?

Mr. Eberle. Correct. They can make the decision as to whether within their plan design if they offer a point-of-sale rebate as part of that plan design. Do they use those dollars just to offset their overall pharmacy costs and share that either through lower premiums or lower copays and coinsurances.

Mr. Griffith. Right and that is one of the reasons why we need to have transparency and you also advocated for transparency. But that is one of the reasons when you have transparency across the entire drug supply chain, because the manufacturers have a role, the PBMs have a role, the insurance companies have a role, and the pharmacies have a role. Isn't that correct?

Mr. Eberle. Correct, absolutely.

Mr. Griffith. I appreciate it and I yield back. Thank

you very much.

Ms. Eshoo. I thank the gentleman, again, for excellent questions.

I now would like to recognize the Chairman of the full committee, Mr. Pallone, for his 5 minutes of questioning.

The Chairman. Thank you, Madam Chair.

I want to discuss the pricing methodology that manufacturers consider when a novel therapy is about to launch onto the market and what, if any, constraints there are on price in those instances.

We know that first-in-class novel drugs can change lives, sometimes even with a single dose, and lead to improve health outcomes for patients who may not otherwise have options for treatment. However, I am concerned this also means that the market lacks the necessary tools to manage prices or restrain costs since there is no competition.

So let me start with Mr. Bricker. How does Express Scripts control the cost of these sole-source drugs when they lack competition?

I am going to go around. So, try to be brief.

Ms. Bricker. Without competition, it is very difficult to extract additional discounts from manufacturers. We rely heavily on that independent board of physicians to determine

whether or not the product must be included on formulary. But more and more, we just encourage competition, and biosimilars coming to market, and a faster pathway for generics and others.

The Chairman. So I was going to ask you and Mr. Eberle what are the options available to PBMs to constrain the cost of these drugs, short of keeping these new therapies off the formulary list but I think you already gave me your response.

So let me go to Mr. Eberle.

Mr. Eberle. A very similar answer. If there is no competition and there is only one therapy for a specific indication or disease state, PBMs are very limited in what we can do to control list price. We have no control over list price and very limited in terms of what we can negotiate in terms of discounts.

We do use an independent group of physicians and pharmacists to develop utilization use criteria to determine to make sure that the right patients are getting that product but beyond those clinical controls, our ability is somewhat limited.

The Chairman. Well let me go back to the two of you again. It is my understanding is that sole-source drugs often do not have any significant rebates. Is that true and

can you explain why, briefly?

I will go back to Ms. Bricker.

Ms. Bricker. Yes, so 90 percent of all prescriptions that are dispensed are generics. Of the ten percent that are branded products, about 25 percent offer a rebate or a discount. And so there is a very large percentage of branded products that do not offer discounts today.

The Chairman. Do you want to add to that or, if not, do you agree?

Mr. Eberle. I agree.

The Chairman. All right.

Mr. Eberle. I would just add one quick comment that generally there needs to be competition for a manufacturer to be willing to negotiate a discount.

The Chairman. Okay. So again, to both of you or maybe just one of you, given what you just said, would the Trump administration's proposed rule to eliminate rebates in Part D have any measurable impact on the issue of high prices for sole-source drugs?

You could just say yes or no, if you want.

Ms. Bricker. No.

Mr. Eberle. No.

The Chairman. Okay, so let me now go to Mr. McCarthy

and Mr. Niksefat.

Can you explain what additional considerations your companies take into account when pricing a novel therapy that lacks competition? How do you determine the price in those cases? And then I guess, do you have any solutions for how to control cost for these therapies?

Mr. McCarthy.

Mr. McCarthy. So I have explained the considerations we go through when pricing a medicine. And I will point out when we do price it, we --

The Chairman. Just specifically for the novel therapy.

Mr. McCarthy. For the novel therapies, we specifically have to assess the value that that therapy brings. And then when we negotiate with the plans, whether it is a sole source or not sole source, they have significant negotiating tools to, as I said, they can either accept us on formulation, they have tools to restrict us, prior authorization, step therapies, others, or they can, in some cases, exclude us from therapies. But even --

The Chairman. But I mean is there anything specific, and then I will ask the same of Mr. Niksefat, anything specific that you would recommend for these novel therapies?

Mr. McCarthy. Well, one solution I included in my

written testimony on these novel therapies is we say we price according to the value. We are willing to stand behind that and to agree to get paid based on that value and not get paid if it doesn't work.

So I think moving to value-based agreements, where we are standing behind the value that we set, is a strong market-based way to keep those prices in check.

The Chairman. Mr. Niksefat?

Mr. Niksefat. Thank you, Chairman Pallone.

Since I have been at Amgen, the products that we have introduced into marketplace have either already faced competition once we were there or were going to face competition shortly thereafter.

And so I don't have any specific policy proposals for you but we would be happy to check with our team and get back to you.

The Chairman. Oh, yes, I mean any of you are more than encouraged to get back to me on any of these questions through the chair.

But I mean clearly, we need better tools to drive down prices, particularly when there is a lack of competition with these novel drugs. So this is going to be one of the main things that we are going to be looking at.

Thank you, Madam Chair.

Ms. Eshoo. I just want to comment that Amgen has gone to court to tie up biosimilars. That should be understood here.

I now would like to recognize the gentleman from Kentucky, Mr. Guthrie, for 5 minutes.

Mr. Guthrie. Thank you, Madam Chair. Thanks for the opportunity to be here and thanks to you all for being here today.

And I just want to comment, one, as we move forward in this and I am the O&I Subcommittee here and we have already had one hearing on insulin, specifically. So we are trying to figure out how all this works and what public policy needs to move forward to make it more affordable and transparent.

But I think Mr. Hessekiel said one thing that we are one country that no other -- I know a lot of people try to compare our health system to other industrialized countries but we are one that produces miracles out of our health system. Dr. Burgess mentioned hepatitis C. I don't think it is a Medicare Part D procedure but I heard yesterday that, essentially, the people who have gone through a sickle cell anemia have been cured. Their blood type doesn't even show that they have sickle cell anemia after that.

So we have a lot of stuff happening in our country and we have to be careful as we move forward that we do protect consumers and we make sure consumers are moving forward but we don't have unintended consequences, as you mentioned, of moving forward.

The one thing that because I am kind of going back, some of you were in O&I, our Investigation and Oversight Committee and it seemed when we were talking that PBMs say the pharmaceutical company sets the price and we negotiate discounts. Well I have heard, I don't think it was in that meeting, but talking to pharmaceutical companies, well we have to raise our price because if we don't get our price high, we don't get on the formulary because they are driving for the discounts. And so we are just trying to figure out what the correct answer in that is.

So I want to start with -- and Ms. Bricker, thanks for coming. We appreciate your willingness to be here today, and Mr. Eberle.

So just an example, when there is a generic available on the market at a lower price than the brand price, do you always include the generic, the brand product, or both on your formulary and why would you choose one over the other, if you do make that choice?

Ms. Bricker. Yes, thank you for the question.

The consideration is one of net price. We look at the list price minus any discounts.

So in that example that you provided, we would look at the list price of the generic versus a branded product that offered a discount and then determined the best price for clients.

Mr. Eberle. And similarly, we would definitely look at the overall net cost. In almost every situation, a generic is going to have that lower overall list price. We will then also look at in clinical efficacy is there a clinical advantage that the brand has over the generic or vice-versa? And that could take a part in terms of a step therapy protocol, a prior auth protocol to ensure the lowest cost product is used first.

Mr. Guthrie. Okay. Well, Mr. McCarthy, did you all have instances of what you could view as like generic or lower priced drugs that you can't get on the formulary? Because I have heard people from manufacturing side say that the rebates drive the list price. All you really care about is the net price as well? It seems like both sides only care about the net price because that is what you receive but it seems like, for some reason, we are having increase in the

list price. And insulin has gone up 200 percent over the last few years and that is not a blockbuster drug that we are moving forward.

So would you all comment on have you had trouble getting lower priced drugs on a formulary with the PBM? And so I guess the point, with the rising cost of the list price for insulin isn't driven by the PBM. It is driven by the manufacturing company.

Mr. Niksefat. Sir, we don't have any experience failing to get a lower generic type drug on our formulary. We have had some experience having difficulty getting our low list price option of Repatha on the formulary and we believe that is at least in part due to the fact that our feeling is in a competitive marketplace that we have to compete both on lowest net price and largest total rebate. And that lower list price can result in a lower total rebate overall.

Ultimately, we think that the discounts that are provided into the marketplace need to be provided to the patient at the pharmacy counter when they pick up their drug.

Mr. McCarthy. And we have had significant challenges getting biosimilars on formulary. And these are much lower cost biologic products and we bring them at a significant discount. But because of rebate strategies for the

innovative biologic, it makes it very difficult for us to get on formulary.

So while Congress has done a fantastic job approving a great pathway for biosimilars, these products are still not delivering their potential in savings because they are not being used in the marketplace.

Mr. Guthrie. Would you all like to comment on that last comment?

Ms. Bricker. Yes, I disagree with that position. It is in the net cost that we would take the consideration. And so as biosimilars come to market, they have to bring value. They have to be less expensive, as we would expect a generic product to be less expensive than the innovator.

And so I would encourage the manufacturers here to my right to consider that, as they are launching their list prices and especially those of biosimilars.

Mr. Eberle. I agree.

Mr. Guthrie. Okay, I only have 8 seconds left so I won't ask another question.

So I appreciate you all being here today. It is important for us to try to figure this out.

Thank you.

Ms. Eshoo. I thank the gentleman.

I now would like to recognize the gentlewoman from Florida, Ms. Castor, for 5 minutes of questioning.

Ms. Castor. Thank you very much, Madam Chair, and good morning.

This committee has been very focused on how we can lower drug prices and it is a top concern for my neighbors back home. Rarely does a trip to the grocery store or a constituent meeting go by when this issue is not raised.

Now the committee has heard expert testimony that brand manufacturers are using deceptive litigation strategies and gaining regulatory requirements to keep competition out of the market. One example of this behavior is the pay-for-delay agreements and I am very concerned how pay-for-delay settlement agreements complicate drug pricing.

And my colleagues on this committee are concerned as well, if you have been following the activity in this committee. That is why we passed Congressman Bobby Rush's legislation that would prohibit these types of agreements in a bipartisan vote last week -- last month. And we are not the only ones who are concerned. FDA Commissioner Gottlieb, before he left, raised concerns with the effects of the agreements and appeared before Congress and said we do not know when generic products would have entered the market if

the patent litigation had continued and the companies had not settled with an agreement to delay marketing.

The Federal Trade Commission is also clearly very concerned about the anti-competitive effects of these agreements. FTC did a study that found that these anti-competitive deals cost consumers and taxpayers $3.5 billion in higher drug costs every year. The FTC also brought cases against many manufacturers that have entered into these agreements, most notably, FTC v. Actavis. That was decided by the Supreme Court in 2013. That involved a 9-year pay-for-delay that was finally settled just recently.

The Supreme Court, in those cases, they were also clearly concerned. You had Justice Scalia and Kagan, they raised concerns during oral arguments that the Hatch-Waxman framework had unintentionally reduced the incentive for other generics to continue litigating, once the first applicants had settled.

And finally, the HHS Secretary is concerned with these agreements. Secretary Azar acknowledged the need to address and discourage them and the administration's budget proposal included a policy to disincentivize manufacturers from making these arrangements.

So I want to ask you all are you in agreement with all

of the experts, and this committee, and the FDA, the FTC, Supreme Court? I want to ask you all yes or no and I will start with Mr. McCarthy.

Do you believe that patent settlement agreements have resulted in prolonged periods of higher prices for at least some drugs in the supply chain; yes or no?

Mr. McCarthy. Yes, we believe Hatch-Waxman got it right, that we should protect innovation during the period and when that expires, we should remove barriers to generic entry.

Ms. Castor. Okay, thank you. Yes or no?

Mr. Niksefat. I am not aware of any instance where Amgen has participated in pay-for-delay. Amgen --

Ms. Castor. Just yes or no. Here, I will read it again. Do you believe that patent settlement agreements have resulted in prolonged periods of higher prices for at least some drugs in the supply chain?

Mr. Niksefat. So I am not part of Amgen's intellectual properties and so I can't answer that.

Ms. Castor. Okay, yes or no?

Mr. Hessekiel. Yes.

Ms. Bricker. Yes.

Mr. Eberle. Yes.

Ms. Castor. Thank you. I hope we can all agree that these agreements sometimes defy the goals of the Hatch-Waxman framework.

Mr. McCarthy, Pfizer has said publicly that it only enters into agreements like this when they allow for earlier generic market entry. Can you explain what led Pfizer to this policy?

Mr. McCarthy. Yes, thank you for the question.

As I said, we fully believe that Congress got it right with Hatch-Waxman and we respect that.

We vehemently believe we should protect that incentive for innovation, and that should be respected, and we should be able to have that period of patent protection during the life of the patent. But when it expires, we need to welcome and remove barriers to generic entry because a healthy innovative industry depends on a healthy generic industry, and visa-versa.

Ms. Castor. Thank you.

Mr. Niksefat, does Amgen have a similar policy? If not, can you explain why not?

Mr. Niksefat. So again, ma'am, I am not part of our intellectual property team but I am aware that Amgen has never participated in pay-for-delay.

Ms. Castor. And you don't know why not? Or you don't know do they have a similar policy that --

Mr. Niksefat. I am sorry. In my job, I am just not exposed to that. So I can get back to you.

Ms. Castor. Okay. Well, please do on Amgen's position because we are all concerned about the market effects of these type of agreements. I mean 9 years, that was litigated for 10 years. That is not any help to the consumers, given the widespread interest in curbing this type of abuse. I hope we will see Congressman Rush's bill pass the House and Senate and be signed by the President shortly.

Thank you.

Ms. Eshoo. The gentlewoman's time has expired.

It is a pleasure to now recognize the gentleman from Illinois, Mr. Bucshon -- wrong. Billy, Mr. Long. How could I have missed that? He was here before I was.

Mr. Long. I am small, a lot of people miss me.

Ms. Eshoo. Yes, he is just small and quiet, never noticed. But you are recognized for 5 minutes of questioning.

Mr. Long. I do want to apologize I had to step out but I stepped out for a very good reason. We just had a presser with the Gold Star Moms over on the Triangle. And Debbie Lee

spoke and Debbie's son was the first casualty Navy Seal of the Iraq War. And it was a very moving ceremony and we need to do everything that we can to support our Military and our Gold Star Moms and widows. And with this being Mother's Day, I felt like my attendance was required over there.

Ms. Bricker, thank you for being here today. And I know that some of your counterparts didn't want to come for one reason or another but, as we look at ways to lower the cost of prescription drugs which everyone in this room, that is their goal, there is a lot of discussion about rebates and if PBMs should move rebates to the point-of-sale.

I have got kind of a three-part question here. Could you talk about the level of flexibility you offer on how your plan sponsors can use the rebates? Number one, do you make point-of-sale rebates available to your clients; and if so, what are the trends and how are those rebates -- how do they use those rebate savings?

Ms. Bricker. Thank you for the question, Congressman.

Yes, so Express Scripts has supported rebates at the point-of-sale for nearly 20 years. Today, we have over 3,000 clients. Those are unions, they are employer groups, they are health plans. And this is available to all of them but very few have opted to do this.

Instead, they take the value of those discounts that we are able to negotiate with manufacturers and deploy them in different ways. They create lower copay and coinsurance programs and also offer lower premiums to both employees, as well as to beneficiaries in the market.

Mr. Long. What are you seeing in terms of changes in premiums and out-of-pocket costs among these plans that apply rebates differently?

Ms. Bricker. Every plan is different and the considerations that they will take as part of their overall benefit design varies.

I will say that the proposed rule by HHS is troubling in that requiring rebates at the point-of-sale actually doesn't address the key issue, which is overall cost of product. It just rearranges really where the value is deployed.

And as I mentioned previously, you know ten percent of products that are dispensed are brands and of those, only 25 percent get a rebate. And so it is a misconception that by putting the rebates at the point-of-sale that patients will somehow benefit. All will have to be faced with a higher premium and only a few will actually benefit at the point-of-sale.

Mr. Long. Okay. During the Oversight and Investigation

Subcommittee hearing on insulin, you know that Express Scripts has a Patient Assurance Program that caps copays for insulin at $25. What other disease conditions can this program be initiated for and can we do this in Medicare; and if not, why not?

Ms. Bricker. Yes, so we are really excited about our Patient Assurance Program and able to offer affordability for all patients with diabetes and excited to explore other disease states in partnership with manufacturers. The best candidates are those that have really high list prices and still offer a rebate. And so we are looking at, as we explore both heart disease as well as inflammatory conditions, to name a couple.

It is not available today for Medicare. As mentioned previously, concerns around Anti-Kickback statute are namely the concerns that prevent us from being able to deploy the same tool for the government business.

Mr. Long. Okay. I need to move on to this next gentleman because his mother-in-law can throw a rock and hit my house in Springfield.

So Mr. Niksefat, could you talk about the current barriers to value-based contracts and what can we do to improve the ability of manufacturers to enter into more

value-based agreements?

Mr. Niksefat. Yes, thank you, Congressman, and say hello to my mother-in-law, please.

We think there are two things that can be fundamentally done. One is addressing some of the issues that were brought up earlier around the Anti-Kickback statute, along with how Medicare performs certain reconciliation of payments that would allow for greater use of value-based contracting in the Medicare program, specifically. We have over 35 different value-based contracts within the U.S. but the population we can offer to Medicare is limited because of these issues.

The other piece that we believe needs to be put in place is potentially additional flexibility around Medicaid price reporting, which makes these programs very hard to determine an actual net price within the best price construct and, again, limits us on the total time period that that is available for a value-based contract to play out, especially in a disease that may have a significant time before an outcome is measured.

Mr. Long. Okay. And what would the more creative value-based agreements look like and how could they deliver savings and better care if we remove the current regulatory barriers?

Mr. Niksefat. Yes, we think right now our value-based contracts largely supplement existing discounts in the marketplace. What we think could occur is that these value-based contracts could actually completely replace them by allowing for different types of mechanisms that measure the long-term outcome of an entire population and allow us then to adjust the price to see if what we are seeing in the real world does something different than what we saw in clinical trial.

Mr. Long. Okay. And now that I have taken care of the rock-throwing situation, I will go back to Mr. Bricker, and I know my house windows are safe now.

Ms. Bricker, we have had a number of hearings looking at the drug supply chain and what could be done to lower drug costs. What would be some of the policies you think Congress could take in the next few months to lower drug prices for consumers?

Ms. Bricker. And so we have a few ideas that I shared in written testimony but, to name a few, allow the tools that are working really well in Medicare Part D to be applied in Medicare Part B.

Looking at modernizing the Medicare Part D benefit, we have mentioned the catastrophic phase and the incredible

burden that beneficiaries are faced with when in the catastrophic benefit. And so those were a couple.

I see I am out of time but I will follow up with additional ideas that we have.

Mr. Long. I am out of time. I wish I had time to ask Mr. Niksefat why I live in Missouri with his mother-in-law and he lives in California but I will let him explain that later.

I yield back.

Ms. Eshoo. Separation of emotions.

The gentleman yields back.

I recognize Mr. Sarbanes of Maryland for 5 minutes of his questions.

Mr. Sarbanes. Thank you, Madam Chair.

I want to thank you all for being here. I know you think a lot about competitive advantage in your various industries. Obviously, that is important to your success.

I wanted to ask you to reflect with me for a moment on a different competitive advantage, which has to do with sort of access to policymakers, the ability to influence legislation up here in Washington. The public has a perception, which I think is fairly grounded in reality, that industries like the PBM industry, the pharmaceutical industry, there are many

more but, just for today's proceedings, have undue influence on how policy gets made in Washington with respect to drug pricing and all kinds of other things.

That influence comes from many things but, among them, and I think high on the list of things that the public is reacting to, is the tremendous amount of money that goes into purchasing lobbyists, which are deployed here. I think the pharma industry has one of the highest ratios of lobbyists to Members of Congress of just about any industry out there. So that is part of the public's grievance, as well as a lot of money that just flows up here in the form of campaign contributions, et cetera. There are no saints here. We are all on the receiving end of this ecosystem.

But I would just be interested for you to comment, if you would, on whether you think that the ability to channel so much money into lobbying, into other things does give you a competitive advantage over other points of view on policy that could be brought forth by folks who maybe don't have the same kind of deep pockets and resources.

And if you want to say yes, it does give us a competitive advantage, I don't begrudge you that because I get it. If you can find a way to have an advantage up here in terms of influencing policy, why wouldn't you want to use

that for the benefit of your bottom line?

But if you could maybe just speak to that because all of you certainly allocate a certain amount of your budget to making sure you get the access and you have the influence that can make a difference in terms of how your business operates. And I will start with you, Mr. McCarthy.

Mr. McCarthy. Okay. To be honest with you, it is not my area of responsibility so I am not sure if I can comment on whether it gives us a competitive advantage or not. But I do think all of us at Pfizer feel like we have a responsibility to play a role in the regulatory and legislative process.

I can't comment on whether it gives us a competitive advantage or not.

Mr. Niksefat. Likewise, sir, I am not part of our Government Affairs team and have no influence or insight into their resourcing overall. So I can't comment but we can get back to you.

Mr. Hessekiel. Thank you very much for your comment, Congressman.

So that is exactly why we are here. So I speak for a section of the pharmaceutical industry that few people actually appreciate, especially given the statistics that I

referenced that two out of three new drugs approved by the FDA last year actually originated in companies that are small biopharmaceutical emerging companies. And we don't have a voice in Washington. Exelixis is not a member of PhRMA. We are a member of BIO. And we don't hear the realities, the pains and challenges that are faced of bringing an important new drug to market represented in the debate because I think a lot of people take for granted that it is all great big companies with huge budgets and throwing a lot of money at problems.

Mr. Sarbanes. So you may be an example of someone who is at a competitive disadvantage because you don't have the same resources to deploy into those activities that I was talking about.

Ms. Bricker?

Ms. Bricker. I don't believe that it results in a competitive advantage. From Express Script's perspective, the reason I am here today is to help be part of the solution and to educate lawmakers like yourself on ideas that we have in the supply chain to actually bring down cost. And so any amount of time that is spent here is really with the idea of helping to educate and to bring solutions forward.

Mr. Sarbanes. Well, I appreciate that. I wasn't as

focused on the time spent as the money spent, in terms of how that influences things up here.

I am out of time, so I yield back. Thank you all very much.

Ms. Eshoo. The gentleman yields back.

Thank you, Mr. Hessekiel, for what you said. Your company is -- that model is replicated throughout my congressional district in Silicon Valley. So, I certainly understand it and I think is one of the reasons that we wanted you here today, so that the small bio people would have a voice in the hearing and in policymaking.

I now would like to recognize the gentleman from Indiana. And this time you are really going to be recognized, Mr. Bucshon.

Mr. Bucshon. I appreciate that.

Ms. Eshoo. Yes.

Mr. Bucshon. First of all, I want to start out and agree with Ms. Castor that the bills that we passed in a bipartisan way in our committee recently should pass the House, and pass the Senate, and be signed by the President. However, at this time, it appears that those bills will not be brought to floor standalone. And so the opportunity for that to happen is going to be minimized, especially in the

Senate. And I would encourage the majority to reconsider that decision and bring bipartisan bills that will actually address the problem to the floor standalone so that we can all be supportive of those.

A question I have for Mr. McCarthy and Mr. Niksefat is: Does direct-to-consumer marketing increase the demand for a drug?

Mr. McCarthy. I am not sure if it increases the demand for the drug but we do believe that advertising does create awareness of diseases and available treatments.

Mr. Niksefat. We agree with Mr. McCarthy. It increases awareness and availability of treatment.

Mr. Bucshon. Okay because, as a physician, you probably know my position, I don't like direct-to-consumer marketing because I think it confuses patients and it makes them ask physicians for primarily new, very high-priced drugs. And then if you don't provide those, they just go to somebody else who does.

So with that question, if that is true, it brings awareness and it is going to increase demand, would you think that that would increase the price? Does that have any effect on that, the price of the drug?

I mean if you have a product that has no demand, there

is no price. If you have a product that is in high demand -- it is a supply and demand question.

Mr. McCarthy. I don't believe direct-to-consumer advertising has impact on the price.

Mr. Bucshon. Okay.

Mr. McCarthy. It is not a part of our pricing decision.

Mr. Bucshon. Okay, fair enough.

Mr. Niksefat. The same, we do not consider a direct-to-consumer advertising when setting the price of a product.

Mr. Bucshon. Okay. Yes, I am not saying it is directly. I am saying as part of an increased demand. That is what my question is.

The same two, do PBMs ask you to increase list prices? Do you get calls, and letters, and stuff from PBMs saying you need to increase your list price because our margin isn't where it should be?

Mr. McCarthy. I am not aware of any such request.

Mr. Bucshon. Because we could, the committee could ask for any communications between your companies and PBMs and see if that is the case. We could. I am not going to ask for that today.

But I mean I have been told that by companies like yours that one of the factors is that PBMs put almost daily

pressure on the list price. Now the PBMs will disagree with that; I understand that.

Mr. Niksefat. I am not aware of any of those instances.

Mr. Bucshon. Okay. Is there formulary pressure to increase your list price? Because that is another avenue. It is not just the rebate. It is pressure to say well, sorry, but we are not going to have your drug on formulary if you don't do this or that.

Mr. McCarthy. There is certainly competitive pressures to raise rebates, or discounts, as the chairwoman would like me to use the term.

Mr. Bucshon. Discounts, okay.

Mr. Niksefat. Like I laid out in my testimony, we feel like we have to compete both on lowest net pricing and total discount.

Mr. Bucshon. Okay. And Ms. Bricker, do you want to respond to that?

Ms. Bricker. Yes, I would.

Mr. Bucshon. Give your perspective on that situation.

Ms. Bricker. Yes, we have called publicly and in private conversations with every manufacturer for them to take action to lower list price and we stand by that here today as well.

Mr. Bucshon. Okay, great.

Ms. Bricker. And agree that I think they are making my point, that formulary decisions are based on net cost, which is the list less any rebate that is offered or discount that is offered.

Mr. Bucshon. Okay, fair enough.

And I am interested, Mr. Eberle, in your business model, do you feel like -- you know again, there is a disagreement about whether rebates increase pressure on list price and if we eliminate rebates like HHS is proposing, or Members of Congress are proposing in some cases, that that will lead to companies increasing, you know it will be an uncontrolled increase in list.

You have a different model. Do you see that happening? Do you see within your model that that results in increased list?

Mr. Eberle. I do think that from a PBM perspective, with our pass-through model or with the traditional model, rebates are a tool to help lower costs. If that tool is taken away from us, it does take away a very significant lever that we have to work for on behalf of our client.

Mr. Bucshon. Because your model doesn't rely on rebates, right?

Mr. Eberle. It doesn't rely on rebates for revenue. We don't generate any revenue from it.

Mr. Bucshon. That is what I am talking about.

Mr. Eberle. Right, no. So from an Navitus perspective, rebates or a change in rebates would not impact our bottom line.

Mr. Bucshon. Correct.

Mr. Eberle. Our concern is that it would drive up the cost of care for our plans and their members.

Mr. Bucshon. Based on what?

Mr. Eberle. Based on if the rebates go away, what is the controlled pressure on manufacturers to compete on pricing?

Mr. Bucshon. Well you still have your formulary part, right?

Mr. Eberle. We do. So I think what you are arguing is that there may be another way, either rebate or discount, to do that. And that would be great but there has to be some mechanism to encourage the manufacturers to participate in lowering their prices in competitive products.

Mr. Bucshon. I would disagree with that but I appreciate your perspective.

Thank you. I yield back.

Ms. Eshoo. The gentleman yields back.

I now would like to recognize the gentleman from New Mexico, Mr. Lujan, for his 5 minutes of questions.

Mr. Lujan. Thank you, Madam Chair.

And I thank everyone who agreed to be before us today and I would ask that you make your responses as concise as possible. I want to talk today about the concept of value-based arrangements.

Mr. McCarthy, in your testimony, you defined what a VBA would like. You say, I quote, if our medicines do not produce all the results we expect, we would be paid less and if they produce those results, we would be paid more. If done correctly, these arrangements focus on the appropriate therapeutic areas, can align the interests of patients, health plans, and biopharmaceutical companies around one shared goal: ensuring positive health outcomes for the patient. Closed quote.

What is the difference between a value-based payment and an outcome-based payment?

Mr. McCarthy. Well, I think they are very similar. So I will give you an example of a couple of the types --

Mr. Lujan. Very similar, actually, answers the question.

Mr. McCarthy. Yes, very similar. Yes.

Mr. Lujan. If they are very similar we can jump into that a little bit later.

Mr. McCarthy. Oh, okay.

Mr. Lujan. Which one of these is described in your example, an outcome-based payment or a value-based payment?

Mr. McCarthy. Well it is hard to distinguish them and I will tell you why. If you improve the outcomes, it is delivering greater value. So I think it is just a different way of saying the same thing.

Mr. Lujan. So does your statement include both, then?

Mr. McCarthy. Yes.

Mr. Lujan. Okay.

Mr. Niksefat, in your testimony, you state that Amgen is the leader in value-based partnerships with over 120 of these agreements. I believe you are also the arbitrator for these negotiations.

In those 120 agreements, how much money have you saved patients?

Mr. Niksefat. So the 120 number is worldwide. Within the U.S. I know of over 35. And those discounts can provide, again in certain cases, like our Repatha outcome-based rebate, 100 percent refund of the --

Mr. Lujan. Can you get me a dollar amount of how much money --

Mr. Niksefat. I don't have a dollar amount on me, sir.

Mr. Lujan. No, can you get back to us?

Mr. Niksefat. We can look into it and get back to you.

Mr. Lujan. You can get back to me with an answer?

Mr. Niksefat. We will look into it and get back to you, sir.

Mr. Lujan. Well, that is not certain. Will you get an answer to me of how much money the 35 agreements you have in the United States have saved patients?

Mr. Niksefat. We can look into that. Many of them are very new and they have not yet paid out because the period over the term of the contract has not completed yet.

Mr. Lujan. There is a dollar amount of money you have saved or you have not saved and what I am asking is that you get that back to us.

What data are you tracking for patient savings?

Mr. Niksefat. We track the total discount that we would pay under these outcome-based arrangements for patient savings.

Mr. Lujan. I appreciate that.

Ms. Bricker, in your testimony, you state that you are

the head of all value-based contracts at Express Scripts. In your role with this PBM, what is the baseline against which you are measuring savings and how was this data developed?

Ms. Bricker. So the baseline is we compared those that are participating in the value-based programs versus those that are not. We, today, cover over ten disease states, many of them the highest cost or specialty classes, and working with manufacturers to put their value, as mentioned, if a product isn't working or if we are not meeting certain metrics, then refunds or value goes back to the payer.

Mr. Lujan. So I have heard a lot about list price today and this is complicated. I get that. So I am trying to make sense of it, especially in a way that I can understand it so I can explain it to my mom and to my constituents.

The list price sounds like the highest price. Is that correct? Would the list price translate to the highest price, Mr. McCarthy?

Mr. McCarthy. Generally, yes.

Mr. Lujan. Mr. Niksefat?

Mr. Niksefat. It is the highest price by which we sell the medication.

Mr. Lujan. So if the conversation today is about how we get to the lowest price, why don't you just start with the

lowest price?

You start with the highest price and then you negotiate all these wonderful benefits for the American people and you say oh, we are going to give you a rebate or, as our chair points out, we are going to give you a discount. But it is based on some price that is the highest price.

So if we are talking about setting up a system that is ultimately going to get the lowest price, let's start with that because, correct me if I am wrong, you have one highest price, one list price. Is that correct, Mr. McCarthy?

Mr. McCarthy. We have one list price, that is correct.

Mr. Lujan. Mr. Niksefat?

Mr. Niksefat. Yes, that is correct.

Mr. Lujan. Mr. Hessekiel?

Mr. Hessekiel. That is correct.

Mr. Lujan. And Mr. Eberle, Ms. Bicker, is that your experience is that there is one list price?

Ms. Bricker. Yes.

Mr. Eberle. Correct.

Mr. Lujan. Is it fair to say there are many lowest prices? Depending on each agreement that you have with each plan, do you establish a lowest price for each one of those contracts, Mr. McCarthy?

Mr. McCarthy. There is a net price that is negotiated for each of the contracts.

Mr. Lujan. Is it fair to say that different agreements have different lowest prices?

Mr. McCarthy. Different agreements, yes, have different net prices that are generally lower than the list prices, if there is a rebate involved.

Mr. Lujan. Is that true with you as well, Mr. Niksefat?

Mr. Niksefat. Yes.

Mr. Lujan. So there are many different lowest prices. So the question that I also have is for Ms. Bricker, as my time runs out: How do we know that patients/customers are getting the full rebate and are you willing to disclose whatever is negotiated with the pharmaceutical companies and are the pharmaceutical companies willing to disclose publicly what is negotiated with the partners that you are entering with publicly?

Ms. Bricker. Yes, so the people that hire us, our clients have full visibility into the discounts that we negotiate, yes.

Mr. Lujan. And Mr. McCarthy and Mr. Niksefat, are you willing to disclose publicly what those negotiated rebates are?

Mr. Niksefat. Again, we believe that all of these discounts should be available to the patient at the pharmacy counter, which will shed light onto the prices in the marketplace.

Mr. Lujan. Are you willing to disclose them publicly?

Mr. Niksefat. That would represent a public disclosure.

Mr. Lujan. Are you willing to disclose them publicly --

Mr. Niksefat. Yes.

Mr. Lujan. -- not through the policy you are talking about, which requires a change in Congress. You can voluntarily do that today.

Are you willing to disclose that price publicly?

Mr. Niksefat. We are not willing to do that today, unless that price makes its way to the patient at the pharmacy counter.

Mr. Lujan. Mr. McCarthy?

Mr. McCarthy. We have, I believe, disclosed the total amount of rebates that we pay.

Mr. Lujan. I appreciate that. Thank you for the time.

Ms. Eshoo. The gentleman yields back.

I now have the pleasure of recognizing the gentlewoman from Indiana, Mrs. Brooks.

Mrs. Brooks. Thank you, Madam Chairwoman.

I am going to continue on my colleague from across the aisle's questions about the pricing specifically and I want to focus on the lowest net cost.

And so while he focused on the list price, Ms. Bricker and Mr. Eberle, can you tell us how you determine lowest net cost? Ms. Bricker?

Ms. Bricker. Sure. We take the list price less any discount that is offered by the manufacturer.

Mrs. Brooks. Mr. Eberle?

Mr. Eberle. Very similar. It does vary by brand and generics. Generics have a different -- there are not rebates on generics so we are looking at what the pricing of a generic is available in the marketplace. So we do surveys to determine what pharmacies are actually buying that drug for. We look at that.

On a brand drug that is rebated, it is the list price minus any rebates/discounts that we receive from manufacturers and pharmacies. That combined with the -- that sets the net cost. And then we look at things in terms of clinical value. How does that cost and value compare?

Mrs. Brooks. We heard earlier in testimony about administrative fees and I believe the pharmaceutical companies talked about administrative fees.

Do you include administrative fees, Ms. Bricker and Mr. Eberle?

Ms. Bricker. Yes, all discounts that are provided by the manufacturer are in consideration.

Mrs. Brooks. So I am getting a little bit confused about discounts and administrative fees.

Ms. Bricker. So the manufacturer admin fees are also discounts.

Mrs. Brooks. How are administrative fees discounts?

Ms. Bricker. They are providing that as additional value towards the list price. So it is a reduction of list price.

Mrs. Brooks. And so let me ask the pharmaceutical companies, how do you -- do you agree with that statement --

Mr. McCarthy. Yes.

Mrs. Brooks. -- that the administrative fees are something that you just include in your discount?

Mr. McCarthy. We tend to talk about them, yes, in the same general category of rebates or discounts.

Mrs. Brooks. Okay and everyone agrees with this? I am just trying to make sure we are all talking about the same thing.

Mr. Niksefat. We describe them as administrative fee

discounts, ma'am.

Mrs. Brooks. Okay.

Mr. Hessekiel. I would like to -- it is important to draw a distinction between discounts and fees for services at fair market value.

Mrs. Brooks. That is what I am struggling with. So thank you for acknowledging that.

So a discount, in normal vernacular, is taking an amount off of whatever the actual price is and a fee is something additional that you pay for the work being done or for the administrative work. What makes up administrative fees, then?

Mr. McCarthy, what do you believe -- what is an administrative fee? How is that defined?

Mr. McCarthy. So it goes to the PBM for administering the services around managing the formulary for our medicine. I believe Ms. Bricker mentioned, as an example, some of the programs they are administering around affordability, and copay costs, and participating in those programs. For example, there would be a fee arrangement involved to participate in those additional programs. So that would be one example.

Mr. Niksefat. We view them as from the perspective of

that they are included in the request for proposals that we receive from the supply chain. And again, we treat them as just administrative fee discounts because we don't believe that they represent services to the manufacturer.

Mrs. Brooks. Okay. Anything further?

Mr. Hessekiel. Nothing further from me.

Mrs. Brooks. And so are there differences, then, in how the various PBMs define lowest net cost? In the various PBMs you deal with, are there differences in how they define lowest net cost? Is that always negotiated?

Mr. McCarthy.

Mr. McCarthy. Yes, every negotiation is different with every PBM customer, yes.

Mrs. Brooks. But and there are different facts that go into that negotiation.

Mr. McCarthy. Generally speaking, you know the main point of our negotiation with the PBMs is to do one thing. It is to secure access for our medicine. So in that respect, that is the common denominator that permeates through every negotiation we have with all of our PBMs.

Mrs. Brooks. And how about the differences between the types of things you are negotiating? Can you discuss the types of items you are negotiating in trying to get to the

lowest net cost?

Mr. Niksefat. We are discussing formulary placement, cost-sharing tier, the route by which a patient will get access through step therapy and prior authorization. So it is a multitude of different items across the entire supply chain, not just with PBMs.

Mrs. Brooks. Thank you.

My time is up. I yield back.

Ms. Eshoo. I thank the gentlewoman for her questioning. She yields back.

The gentleman from Oregon, Mr. Schrader, is recognized for 5 minutes for his questions.

Mr. Schrader. Thank you, Madam Chair. I appreciate it.

Mr. Eberle, I am very interested in the transparency of this drug supply chain. I appreciate everyone stepping up and being here today, particularly with the PBMs because they are the intermediary that negotiates with the pharmacies and the pharmaceutical companies.

One proposal that has been put out there to address the issue would publicize the aggregate price data by class of drug. Do you think this would help at all in demonstrating the variability of the prices and get to where we need to be?

Mr. Eberle. I am not familiar with the details but yes,

I believe that concept would have value.

Mr. Schrader. Okay.

Okay, Mr. McCarthy, talking about out-of-pocket costs and the caps, and you get to Part D and the catastrophic pickup. Currently, the Feds pick up 80 percent; the insurers, 15 percent; and the individual, 5 and no cap actually on the out-of-pocket costs for them. Do you have a proposal about or how do you think that should be shared as we get into that catastrophic phase?

Mr. McCarthy. I believe the best way to approach it would be to think about collapsing the benefit design in Part D so that we would eliminate the coverage gap, where currently the manufacturers pay 70 percent in the coverage gap, and moving that into the catastrophic to help fund the gap. So we would go right from coverage limit to catastrophic, where there would be a cap on patient out-of-pocket cost. And then the financial burden in that phase would be shared between the manufacturers, the plans, and the government.

Mr. Schrader. Mr. Niksefat?

Mr. Niksefat. We would welcome the opportunity to work with the committee on modernizing the Part D benefit but I don't have any specific proposals around the restructuring

with me today.

Mr. Schrader. Would your company be willing to be part of the solution and help out paying it?

Mr. Niksefat. Absolutely, we look forward to being part of the solution.

Mr. Schrader. All right, very good.

Value-based agreement -- the biggest cost concern I see facing the United States of America, patients as well as the Federal Government, is the great new specialty drugs you all are bringing to market at this point in time and they are a life-saving opportunity for many folks that had no hope before but they affect a very small population and, as a result, recouping the investment becomes difficult without high prices.

So there have been discussion. You have offered up being part of the solution and having value-based agreements. So to that end, it is difficult to write those agreements. And the question would be maybe three different questions.

How would you mitigate the risk in this day and age when a patient is likely to move from one carrier to another, Mr. McCarthy and then Mr. Niksefat?

Mr. McCarthy. Yes, so that I think is a really excellent question. I don't have a solution for how we

manage he liability as patients go from plan to plan.

And I think that is going to be a difficult question for us, especially as we move to even more advanced technologies like gene therapies, where these therapies could be curative over a lifetime. And then if there is a value-based agreement associated with that, which I fully expect there will be, how do we track those patients and how does that liability for those patients? I don't have an answer to that but I would very much like to work with this committee on a solution to it.

Mr. Schrader. Okay, Mr. Niksefat.

Mr. Niksefat. Congressman, similar when patients move from plan to plan, although it does actually happen fairly infrequently in the commercial marketplace, it is very hard to follow that patient across the spectrum and ensure that the value-based contract can actually still apply. We have made some attempts but it is not perfect at this point.

Mr. Schrader. Similarly, FDA approval data, including safety, effectiveness, et cetera, how do we or how would you suggest policy assist in adjudicating some of the disputes that might come up over metrics and outcomes, Mr. Niksefat?

Mr. Niksefat. In several of our agreements today we build in a third-party firm to help as part of that process.

It is not always necessary. Many of the outcomes that can be tracked can be tracked very easily within existing data infrastructure but when it gets more complicated, we usually at least have the option of a third party to help at the end of those contracts.

Mr. Schrader. Mr. McCarthy, a comment?

Mr. McCarthy. No, I agree and I believe that the more we rely on real-world evidence and real-world data, the better off we will be able to define those outcomes and to measure them.

Mr. Schrader. The last question in my remaining few seconds on the rebate system for Ms. Bricker and Mr. Eberle.

Can each of you speak to whether you include patient cost-sharing information in calculating the net cost for purposes of determining what drugs will be covered and whether it will placed on the formulary?

Ms. Bricker.

Ms. Bricker. We do not.

Mr. Schrader. Okay.

Mr. Eberle. We do when we look at tiering. We first determine the net cost but we do look at member cost-share in terms of formulary placement.

Mr. Schrader. Very good.

Well, thank you all very, very much again.

And I yield back, Madam Chair.

Ms. Eshoo. I thank the gentleman.

I now would like to recognize the gentleman from Oklahoma, Mr. Mullin, for 5 minutes of his questions.

Mr. Mullin. Thank you so much.

I have got a follow-up for my colleague, Mrs. Brooks, from her questioning. If you guys consider the PBMs administrative fees to be a discount, is that fee also passed along to the insurance companies and the clients?

I don't know who wants to take that on.

Mr. Niksefat. We don't control what is passed on to the clients, sir.

Mr. Mullin. So who does control that? Is that the PBMs?

Mr. Niksefat. That would be the member of the supply chain we negotiate with, in this case, a PBM, yes.

Mr. Mullin. Most of the time the way that I understand administrative fees, is this just another way to get more out of the consumer? Why wouldn't an administrative fee just be part of the drug? I mean why would we consider that a discount? Isn't that part of it? Isn't an administrative fee part of delivering the product?

I mean in our companies, I can't charge the customer for administrative fees on top of what I am charging them. I mean the administrative fee is part of it. Is that not accurate?

You guys are looking at me like a deer in the headlights.

And I am going to go back to what Chairman Burgess said earlier, that if you guys -- if we don't figure out how to do this, we are going to do it ourselves because all of us, regardless of what side aisle we are on, we are all getting just peppered with our constituents about these prices. And so you can either choose to be part of the solution or we are going to consider you part of the problem and that is not what we are trying to do. We really are trying to help here.

But the PBMs and you guys are both pointing to each other and no one is taking the responsibility here. So someone help me here. Is the PBMs the problem here? Are they adding value to the customer or are they adding cost to the customer? Because what I am seeing is they are charging administrative fees and it seems like to me they are adding cost and that defeats the purpose of a PBM.

Mr. Niksefat. Congressman, let me try.

The RFPs that we receive from several members of the

supply chain include minimum bid requirements. In many PBM RFPs, it includes this administrative fee discount and it is a condition of being able to respond.

Mr. Mullin. How is an administrative fee on top of the cost be in a discount? I don't know what world that is considered a discount.

Mr. Niksefat. Again, it is an additional percentage off the list price that we offer as a discount and it is categorized as an administrative fee.

Mr. Mullin. But if we can discount it later on, why can't we just discount it to begin with?

Mr. Lujan from New Mexico and I never agree on anything. This is the first time I am ever going to say we actually agree on something.

Why can't we just start there and then the discount starts from that point?

Mr. Niksefat. Congressman, we believe that ultimately all discounts in the marketplace should be passed on to the consumer and the patient at the point-of-sale at the pharmacy.

Mr. Mullin. Well if you believe that then why don't we do that? And I am sorry, you are the one talking to me. Anyone can jump in here.

Sir, I saw you shaking your head yes. Your thoughts on this?

Mr. Hessekiel. As I said before, and thank you, Congressman, in my mind, there are two categories. There is either fees for services that are provided at fair market value or there are discounts. And I think it is as simple as that.

Mr. Mullin. So how do you have fees and discounts at the same time?

Mr. Hessekiel. I don't have an answer to that question.

Ms. Eshoo. What about your mother?

Mr. Mullin. That is right. And I am not opposed, guys, to anybody making a profit. That is the whole idea of being in business. But it is interesting to me, after we had a hearing on insulin and the cost of insulin going up, I had a parent of a Type 1 diabetic child call me and say it is funny that my insulin dropped in half today. Literally, the day after the hearing. And I thought, gee, that is ironic.

I don't agree with all the hearings you do but that one worked.

I get back to the point, though, people, we are going to have to figure this out. And I am not wanting to come against businesses. That is not what I am trying to do but

from Mrs. Brooks' questions to my questions, and the questions before me, I am really not getting the answers. We are talking around in circles.

Words of solution, help us help you. Give me something that we can do in Congress that can help lower the cost and I will run with it.

Mr. McCarthy.

Mr. McCarthy. Congressman, as I laid out in my written testimony, when we set the price, we set it based on the value. We then negotiate to get formulary access with the PBMs and there is a discount that is negotiated as part of it. That is the competition. That is the market forces at work.

I think the failing here is that those discounts on those medicines we are negotiating, one, the patient is not aware of them; and two, they are not benefitting them.

So our recommendation is --

Mr. Mullin. Well that still goes back to the question why don't we just start with a discount to begin with and so the patient can always have access to it because you don't have to research at that point. Get the prices at the best value to begin with.

Mr. McCarthy. If we just tried to lower our price now,

it would jeopardize -- under the system as it exists today, it would jeopardize our ability to get formulary access. And we have tried it. We have tried lowering the list price.

Mr. Mullin. Give me on thing. How can Congress simplify it to get it directly to the patient without all the middlemen in-between? What is something that we need to eliminate?

Mr. McCarthy. Well I would recommend, as I said, a passing rebate reform that enables the patients to benefit directly from those discounts.

Mr. Mullin. Can I ask one more question?

Ms. Eshoo. Sure, go ahead.

Mr. Mullin. Would eliminating the PBMs, would it help?

Mr. McCarthy. I think the PBMs play a role and administer a service that if they don't exist, someone is going to have to replicate. They administer -- they do a lot more than negotiate a rebate and if the PBMs are eliminated, the plans and the sponsors would have to replicate those services.

Mr. Mullin. My time is up. Madam Chair, thank you.

Ms. Eshoo. I thank the gentleman.

I just want to comment that I love the questions of members from both sides to just peal, layer-by-layer the

onionskin back on this. And it is so important for us to do it. It really is the essence of having a hearing.

I now would like to recognize the gentleman from Vermont, Mr. Welch, who if there is anyone that has done a deep dive on pricing, it is he. You are recognized for 5 minutes of questioning.

Mr. Welch. Thank you.

Ms. Eshoo. Fasten your seatbelts, witnesses.

Mr. Welch. No -- thank you -- not really. Look, the bottom line here is that the pharmaceutical industry creates a life-saving and -extending drugs and pain-relieving drugs. That is a good thing. You are killing us with the price and that is on both sides -- both sides -- and we are trying to get to the bottom of this.

And there is some practices that might have been really outrageous. There appears to be in this room common agreement on two things. There ought to be transparency -- transparency on the rebates and, I think, transparency on how much is really spent on R&D because that is the pitch that is always made. We want to have innovation but we are never told how much is spent on R&D versus advertising and everything else.

So is anyone here opposed to giving us transparent

information about the rebates, about the R&D, what it really is? Raise your hand if you are.

All right, I am going to take that as a yes. All right.

There are some practices I am curious to know whether you are okay with. On this question of R&D, oftentimes it is not R&D, it is the leveraged buy-out or it is just an acquisition of another company. A good example of that was when Gilead, who spent not a nickel on R&D, purchased the company that in fact had created a drug sofosbuvir, which is of course for hepatitis. Gilead bought it, and never put a nickel into it, and then marketed it as Sovaldi at $84,000 a treatment, way higher than the price that you would pay in England, and essentially paid its acquisition price back in a year.

I am just going to ask you, Mr. McCarthy, is that a practice that you think Pfizer should emulate if it had an opportunity to do that?

Mr. McCarthy. Congressman, what I can say is Pfizer is a science-based company. We have research discovery labs in Cambridge, in California --

Mr. Welch. No, I understand that. We talked yesterday and I am impressed with that.

Mr. McCarthy. Yes.

Mr. Welch. But this has nothing to do with research. It is just the green eyeshade people with Harvard MBAs figuring out a good company to buy where they know they have got incredible pricing power and then they are going to have the Medicare program pay for it. They are going to have employer-sponsored healthcare people pay for it. I don't see that as R&D.

But I will go on to another question. I will talk to you, Mr. Niksefat. Amgen did something that, in my view, was pretty outrageous. They had a really good drug. And you guys do some tremendous research, I will give you that, but you did in 2013, when this Congress had to pass a fiscal cliff bill in order to keep the lights on in government, in the dark of night what Amgen was successful in doing was getting a provision put in a bill that exempted it from the Medicare pricing restrictions because it had expired. You got 2 more years on it. It cost taxpayers $500 million -- 500 million bucks.

So where is the R&D in that? That is just leveraging and it is what Mr. Sarbanes was talking about earlier. I mean what is your view on what Amgen did in that particular case?

Mr. Niksefat. Sir, I am not familiar with that

situation so I can't comment.

Mr. Welch. Yes, I would be interested in having somebody from Amgen who is familiar with that case telling us how they managed to get $500 million out of the taxpayers.

There has been some discussion also about other patent abuse, where we have passed legislation. So I will pass on that.

But let me ask about -- you gave very good testimony, Ms. Bricker, about how this rebate system works. But are there pay walls out there? It is like what Mr. McCarthy was talking about from Amgen. They came up with a competing drug that they were unsuccessful in getting past the rebate wall because of the effectiveness of Johnson and Johnson bundling together various drugs so that they got on the formulary and kept, in this case, Pfizer with its lower cost but effective alternative in getting on.

Can you comment about that and whether that is a practice that you see as having any benefit to consumers and taxpayers?

Ms. Bricker. At Express Scripts, we don't negotiate by bundle. So I don't negotiate -- I look at the net cost of an individual product independently of all other products in a portfolio.

And so while I am aware that there some that do turn to those practices, we do not.

Mr. Welch. Tell us a little bit about that pay wall practice that pharmaceutical companies will employ in order to get them on the formulary and keep others off the formulary?

Ms. Bricker. Again, we don't do this today but what I understand the practice to be is that a manufacturer would negotiate that it would give us certain discounts, so long as all of their products were included on the formulary or a subset thereof.

Mr. Welch. Okay, my time is up. I just want to make a comment.

All of us have a concern about a formulary. Is that going to restrict patient access? What we have are formularies where we don't have a clue as to why the formulary is what it is. And that is another area, in my view, we need transparency.

I yield back and I thank the witnesses.

Ms. Eshoo. I thank the gentleman.

I now would like to recognize the gentleman from Georgia, Mr. Carter, for 5 minutes of questions.

Mr. Carter. Thank you, Madam Chair. Thank you and

thank you for having this hearing today. And thank each of you for being here.

I want to start with you, Mr. Niksefat. You know we have heard a lot about list prices. I am familiar with AWP, AMP, net cost, all these other things. But the list price that we are talking about here, in fact Ms. Bricker, in her opening statement, said the problem starts with list price, not with rebates or discounts, if you will.

As I understand it, you actually lowered your list price here recently on one of your products. Is that correct?

Mr. Niksefat. That is correct. For our flagship cardiovascular product Repatha, we introduced an option into the marketplace at a 60 percent reduced list price.

Mr. Carter. Well, that is exactly what we want you to do. So you did that.

Mr. Niksefat. We did, sir, and we did it with the hope of improving patient affordability, especially for Medicare patients, where their cost-sharing is tied directly to the list price.

Mr. Carter. Did it increase patient access?

Mr. Niksefat. We have seen it increase patient access in certain areas but uptake has been slower than you would expect. Overall, only about half of commercial beneficiaries

can have access today to the lower list price option of Repatha and only about 60 percent of Medicare beneficiaries can have access today.

Mr. Carter. So when you decreased the list price, it put you on the formulary and put you into a different tier, correct?

Mr. Niksefat. In certain instances, we have not yet gained formulary access for the low-list price option.

Mr. Carter. Why not? That is exactly what we want you to do is to decrease the list price so that you can have better access and patients can have better access to that. I am having trouble to understand that it wouldn't automatically go on to a different tier and become more available.

Mr. Niksefat. We are trying, sir. We have ensured that our low-list price option is always available.

Mr. Carter. Well, let me ask you this. I don't mean to interrupt but let me ask you this.

It is my understanding that after you lowered that, that you got notification from the PBM that you need to give them 7 quarters' notification before you can decrease the list price.

Mr. Niksefat. So I am not going to comment on any

specific contract document that we received around confidentiality but I will say that we have seen new more exotic constructs some in from across the supply chain around discounts that appear to be creating hurdles to list price reductions.

Mr. Carter. Mr. McCarthy, have you had any experience with that?

Mr. McCarthy. We, as I mentioned earlier, we have experienced difficulty getting our biosimilars on formularies.

Mr. Carter. Okay, let's don't. Let's talk about just--let's leave biosimilars out of it right now and concentrate on this.

It is my understanding that the PBMs are requiring you, before you decrease the list price, to give them a 7-quarter notification. Have you seen anything similar to that?

Mr. McCarthy. We have seen -- we have received one letter to that effect, yes.

Mr. Carter. Okay. So let's just take it the opposite. What about when you increase the list price, do you have to give them any notification? Certainly, they would want notification before you do that.

Mr. McCarthy?

Mr. McCarthy. Yes, that would be part of our annual negotiations with the plans as part of the formulary.

Mr. Carter. But do you have to give them any notification that you are increasing a list price?

Mr. McCarthy. I don't believe so.

Mr. Carter. Okay but you have to give them notification that you are decreasing it. I am appalled here. I am not following this. Because that is exactly what we want to do.

Because if you decrease the list price, then that is going to decrease the amount of whatever you want to call it, the rebate or the discount and, therefore, they have got to know this.

Mr. Niksefat, you decreased the price on Repatha and then still you weren't -- your drug, even though you discounted it, the competitors stayed as the option there, as the preferred. Is that correct?

Mr. Niksefat. Our primary competitor in this case remained at their original list price for a period of about 5 months and has recently matched our moved and also added a low-list price option in the marketplace. But the competitive dynamic did create a situation where we found it tougher to negotiate to get formulary access when we were competing against someone who could offer a larger net rebate

to get to the same net cost.

Mr. Carter. I want to ask you -- I will ask Mr. Eberle. Mr. Eberle, do you -- and this is a simple yes or no, if you don't mind. Does your company ever ask for an advance notice of a manufacturer decreasing their price?

Mr. Eberle. No.

Mr. Carter. Okay, Ms. Bricker, does your company, Express Scripts, ever ask for an advance notice of a company decreasing their price?

Ms. Bricker. Absolutely not.

Mr. Carter. Now you are saying absolutely not.

Ms. Bricker. Absolutely not and I would implore them all to lower them today.

Mr. Carter. Okay, you are on record as saying that. I want to make sure you understand that.

Ms. Bricker. I understand that.

Mr. Carter. So there is no clause that says that you have to give them a 7-quarter notice in any of your contracts.

Ms. Bricker. Absolutely not.

Mr. Carter. Okay, that is fine if that is the way you want to answer that.

Let me ask you something, Mr. McCarthy. One of the

arguments that I have heard that has been made here is that the pharmaceutical rebates at the point-of-sale that is being proposed by CMS, one of the changes that they are going to make, that those rebates, discounts, if you will, that they are not going to get to the patient, that the manufacturer is going to keep them. How would you respond to that?

Mr. McCarthy. In our written testimony, we are strong supporters of passing those discounts through to the consumer, so that they benefit from the lower net prices, which are going down.

Mr. Carter. Would you agree that that would be beneficial and that the increase in transparency with the discounts being given at the point-of-sale will benefit consumers?

Mr. McCarthy. Yes.

Mr. Carter. Mr. Niksefat?

Mr. Niksefat. Yes.

Mr. Carter. And finally, I am sorry, Mr. Weberly.

Ms. Eshoo. Eberle.

Mr. Carter. Eberle, I am sorry -- not Eberle. The third manufacturer. I am sorry. Please excuse me.

Mr. Hessekiel. Hessekiel, yes. Thank you Congressman.

Mr. Carter. At the point-of-sale.

Mr. Hessekiel. Yes.

Mr. Carter. That you would agree?

Mr. Hessekiel. I would agree.

Mr. Carter. Absolutely.

Ms. Bricker?

Ms. Bricker. Only a subset of patients will benefit. All will have an increase in premium.

Mr. Carter. All will have an increase in premium?

Ms. Bricker. Yes, that is supported by the administration's --

Mr. Carter. Why is it that when Secretary Asar testified before this committee he said the single best tool we have to completely change how drugs are priced in this country would be changing this rule? And you disagree with that?

Ms. Bricker. I think there are many agencies that have confirmed the cost associated with doing that.

Mr. Carter. And finally, Mr. Eberle -- Eberle. Excuse me.

Mr. Eberle. I agree, the change in the rebate process will only benefit a subset of patients and will also only benefit a subset of patients that have high deductibles and coinsurances, where approximately 50 percent of the patients

today have flat copays.

So if you have a $100 drug with a $50 rebate but the member only has a $20 copy, where does that $50 go?

Mr. Carter. But the point is is that you would agree that transparency will help in the system. You are 100 percent pass-through, so it is not going to impact you at any point whatsoever.

Mr. Eberle. It will not impact our bottom line at all. Our concern is representing our clients, who pay for pharmacy benefits and they are risking the increasing cost that it may give them.

Mr. Carter. Right. Okay, I am way over.

I appreciate your indulgence, Madam Chair. Thank you very much.

Ms. Eshoo. Let the record show that you were given 2-1/2 extra minutes because I thought you were on a roll.

Mr. Carter. Trust me.

Ms. Eshoo. How is that?

Mr. Carter. Trust me, we are going to let the record show about the testimony that was just given here.

Ms. Eshoo. Yes, I know. Well, I am a patient chair.

Five minutes goes by very quickly when you are trying to ask penetrating -- not only ask a penetrating question but

get a full answer. So I have a deep appreciation of that.

With that, I recognize the gentle doctor from California, Mr. Ruiz, for 5 minutes of questions.

Mr. Ruiz. Thank you. Thank you very much. This is a very important topic, of course, and I am going to give it a different twist. It is going to be about step therapy and how that relates to this conversation.

But overall, the unifying theme is asking ourselves the question: What is best for the patient? And what is best for the patient is the patient's experience, not only in their health -- are they improving? Are they living well? Are they preventing illnesses? And also, how much does it cost for the patient out of pocket?

I was very disappointed when I spoke with a pharmaceutical company the other day and we talked about the high prices. And the way that they start talking about it is while their net prices, overall revenue have gone down. We should never have a conversation about our healthcare system starting off with what the net profit of a corporation is and that is going to be the anchor of our conversation. It should always start off with what is the population's health. What is the burden of disease? What is the burden of pain and suffering from patients from illnesses that we cannot

prevent or that we cannot treat, either because it is too expensive or a system is primarily focused on other things like corporate profit?

So that is why today I want to talk about step therapy, in the sense of what is best for the patient. Step therapy is a means to save insurance companies money by creating a step-wise fashion of forcing patients to use cheaper drugs first, and then step-wise getting them more expensive drugs before they finally get to a drug that perhaps may be the best for them.

The problem is that these bureaucracies are so strict that patients sometimes have already tried all those previous drugs and because of a change in insurance companies, they have to go back and use those. And that is detrimental to their health if those drugs had significant side effects, did not work, did not improve outcomes, had a high noncompliance rate because they were too cumbersome to take. So that doesn't allow the physician or the patient to determine what is best for them.

And oftentimes, these drugs are determined through formularies. So I want to ask you, Ms. Bricker, and then you, Mr. Eberle, what is your role in designing step therapy and managing those formularies with the insurance companies.

Ms. Bricker. Yes, thank you for the question. So our step therapy edits and prior authorizations are determined by a team of clinical pharmacists and physicians. To the point you made around someone that is being asked to try something that they have already attempted and have failed, we have a process for the physician to communicate that and then that is then overridden.

And so we think it is really important that --

Mr. Ruiz. So what is your role as PBMs? Do you have a role or is it just that you select the medications that go into the formularies?

Ms. Bricker. We certainly design formularies and then we support clinical edits and clinical criteria in order to --

Mr. Ruiz. Do you have veto in that?

Ms. Bricker. Veto?

Mr. Ruiz. Do you have input into which drugs they use first, and second, and third?

Ms. Bricker. Yes, it is in support of the formulary and clinical education.

Mr. Ruiz. Okay, so you are part of that team that decides which medications to use first, second, and third.

Ms. Bricker. I am not, personally, no.

Mr. Ruiz. No, not you but PBMs.

Ms. Bricker. Yes.

Mr. Ruiz. Somebody from the PBM company.

Ms. Bricker. Yes.

Mr. Ruiz. Okay, and you?

Mr. Eberle. Yes, we utilized a P and T Committee that has an independent group of physicians and pharmacists that determine which products are appropriate for step therapy or prior authorization.

Mr. Ruiz. Okay, so what safeguards do you have in place to protect the patient from having to repeat a harmful or ineffective treatment because of step therapy requirements?

Mr. Eberle. Absolutely. So our step therapies are designed to catch new starts, someone who hasn't been on any existing therapy. So if we get information that says for all the reasons you mentioned that it may not be appropriate, we have controls to allow that as a part of our quality accreditation.

Mr. Ruiz. Oh, so if somebody was on a more expensive medication now moves to the insurance company of your client, it is not on your formulary, will you allow them to use that more expensive medication that works for them?

Mr. Eberle. Right, so that is part of the criteria

review process. So if the generic is not appropriate for them, yes, that is when an exception will be made.

Mr. Ruiz. What determines not appropriate for them?

Mr. Eberle. The rules from the physicians on the P and T Committee determine what --

Mr. Ruiz. Okay, so I get a sense that they are not consistent throughout the industry.

Mr. Eberle. I would -- each PBM, each health plan --

Mr. Ruiz. Okay, so they are not consistent.

Mr. Eberle. There wouldn't be.

Mr. Ruiz. Another thing is how do you measure the impact in a patient's health that these step therapy and prior authorizations are having?

Mr. Eberle. It is very tricky to do and we would definitely look at adherence and compliance as being some of the metrics that we have. If we have access to medical data, we will incorporate that into the review as well. We do rely heavily --

Mr. Ruiz. Well, you work for health insurance companies. You should have access to health outcomes.

Mr. Eberle. Correct. Some of our clients are health plans but not all of them.

We do rely heavily on the physicians on our committee in

helping us make those decisions.

Mr. Ruiz. Well you know I know patients who suffer from complex chronic illnesses who are being forced to start over with a drug they have already used, or a drug that had a pretty significant side effect profile, or a drug that they had to take four to six times a day when they work out in the mines or out in the manufacturing, where it is difficult to keep track while you are constantly having to focus on what you are doing at hand, and it is not working for them.

Mr. Eberle. Right.

Mr. Ruiz. So I am working on a bill with Dr. Wenstrup, a Republican physician in Congress, to create a set of exemptions based on the doctor and patient experiences so that we can make sure we get the right medication to the patient for their benefit.

Mr. Eberle. We would support that and love to be part of that process.

Mr. Ruiz. I yield back. Let the record show I only went over a minute and 1/2.

Ms. Eshoo. I see that. I see that.

Mr. Ruiz. So let the record show you have favorites.

Ms. Eshoo. I am going to get myself into trouble because on who got more in the overtime. But anyway, you

received some and thank you for your great questions.

This issue of step therapy is something that every member on both sides of the aisle has spoken to. And we had MedPAC that testified their mission is fiscal responsibility but I reminded the gentleman that came to represent them that there are people that have actually lost their lives because they were put in the wrong step for this exercise that is, I understand, meant to constrain costs but there isn't a balance with what some very, very sick patients need and they lose their lives.

So we have go to bring some sensibility back to this and it is a worthy subject for you to have raised.

With that, I would like to recognize the gentleman, and he is a gentleman, Mr. Gianforte, from Montana. I always love to say his name, Gianforte. Isn't that beautiful? Thank God for the Italians.

Mr. Gianforte. Thank you, Madam Chair. And Chairwoman Eshoo, I want to thank you for holding this hearing today. I think it is an important topic.

I continue to hear from Montanans about the burden of high drug costs and I look forward to digging. I am going to take a little different angle today, hopefully a new topic will be good here.

I am interested in common sense solutions. I have heard from many of our rural hospitals about waste they incur with drugs from oversized drug packaging. These hospitals run on a very tight margins and every dollar in their operation is vital.

I have also heard from eye care providers about the high cost of prescription eye drops and waste they have when their patients get oversized bottles of eye drops.

In 2016 alone, it is estimated that between private insurers, patients, and the government, about $3 billion was spent on unused cancer treatments that were just thrown into the garbage. These medications are incredibly expensive and, at the end of the day, these costs are passed on to patients and taxpayers.

So Mr. McCarthy, at Pfizer, what are you doing to decrease drug waste?

Mr. McCarthy. Well first of all, I agree there is a tremendous amount of waste in our healthcare system. Specifically, I am not -- I want to be able to give you a really factual answer. And to be honest with you, I would rather go back and talk to my manufacturing colleagues and really get you a more fulsome explanation of some of the things we are doing in our manufacturing facilities to

address waste.

Mr. Gianforte. I would ask you to do that.

Mr. McCarthy. Yes.

Mr. Gianforte. I know you create many different products. Are you aware of any single-dose medications that you sell in multiple sizes so that the rural hospitals can order the ones that are appropriate for their patients?

Mr. McCarthy. I really, I would like to get back to you and just to give you a more fulsome and thoughtful answer to that.

Mr. Gianforte. Okay but the research I had indicates that you do this in other countries but you don't do it here in the United States. A 250-pound man needs a different dose than a 130-pound woman for the same drug. These are very expensive drugs and yet, hospitals end up having to order a single size and the remainder gets thrown in the trash, costing taxpayers, insurance, and patients billions of dollars each year, according to the data we have.

So I would very much appreciate that feedback and, if you do have practices in place to right-size these dosages so that we are not throwing stuff, so much expensive drugs in the garbage, that would make more available for other patients, obviously.

Mr. McCarthy. True. Okay.

Mr. Gianforte. Ms. Bricker, PBMs are hired to manage drug benefits of clients to bring their costs down. Can you talk about drug waste and what you are doing to reduce it?

Ms. Bricker. Yes, thanks for the question.

We are focused on adherence of product and ensuring that patients are taking the right drug, at the right dose, and at the right time, and continuing to stay on therapy as prescribed and as warranted, given their disease or their diagnosis.

We spend a tremendous amount of research and innovation within our Therapeutic Resource Centers, which are Centers of Excellence in our specialty pharmacy, that ensures that, again, patients that have very complex diseases are partnered with pharmacists who are specializing in that disease-state. So we are at the front end, ensuring that patients are on the right dosage and on the right therapy and, if they happen to stop therapy, why. Is it because of cost or a side effect?

Mr. Gianforte. Well, I am particularly interested in this waste issue, where rural hospitals have to order drugs more than they need, they don't have the volume, the remainder goes in the trash. What are you doing to prevent that?

Ms. Bricker. Unfortunately, we don't operate in the Part A or B space. We only operate in the Part D space.

We do believe that if, given the opportunity to operate in you know the management of pharmaceuticals in A and B, we could have greater leverage over manufacturers in this regard.

Mr. Gianforte. Okay, last question, if I could, Ms. Bricker.

Are you aware of any practices today at PBMs that encourage waste that we ought to be looking at? Because this is an area where there is billions of dollars of opportunity that could be returned back to patients.

Ms. Bricker. No. I agree but I am not aware of a practice that PBMs are doing to encourage waste.

Mr. Gianforte. Mr. Eberle?

Mr. Eberle. I am not aware of anything.

Mr. Gianforte. Are you able to order drugs in the right size for individual patients, so that there is no waste?

Mr. Eberle. We can but we are really -- we work in the outpatient pharmacy benefit, where you are typically getting a month's worth of medication and not the inpatient setting, where you may have only one dose.

Mr. Gianforte. Okay. Well, we have to continue looking

at these drug costs from every angle. I think waste is one we ought to be able to address. I would appreciate any suggestions from the committee in a follow-up.

And Madam Chair, I am yielding back, almost on time.

Ms. Eshoo. Excellent. The gentleman yields.

And I have the pleasure of recognizing the gentleman from Massachusetts, Mr. Kennedy, for 5 minutes of his questions.

Mr. Kennedy. Thank you, Madam Chair. I want to thank the witnesses for being here and your testimony.

Mr. Niksefat, I wanted to start with you, if I can. Your testimony, you explain how you price drugs and it was, actually, pretty similar to Mr. McCarthy. And you said, quote, Amgen establishes a list price for our medicines in the context of an established set of pricing principles. These principles guide that the prices of our medicines account for the economic value that is delivered to patients, providers, and payers and unmet medical need, the size of the patient population, the investment and risk undertaken, and the need to fund continued scientific innovation -- those five principles.

So I want to take those one-by-one, as we consider the price of one of your drugs, Neupogen, which sells for about

$300 average sale price for a 300 microgram dose in the U.S., and how that also correlates with a $115 dose in Denmark. And so let's try to walk through as well that, 8 years ago, that price was $239 in the United States.

And so you say that the price is based on economic value to patients. That is presumably the same for American patients as for Danish patients. Is that right?

Mr. Niksefat. When we look in economic value, we look in the context of the healthcare system it participates in, as well as the overall economic conditions of the country that it operates in.

Mr. Kennedy. And so is that why it is three times -- nearly three times as high in the U.S. as it is the U.S. as it is in Denmark?

Mr. Niksefat. I can't comment on that. I wasn't aware of the price in Denmark until you informed me. I will say that most foreign countries have significant price controls, as well as mandated pricing that goes along with the socialized medicine.

Mr. Kennedy. So I appreciate that. Denmark, as it turns out, was rated by Avik Roy as one of the companies that was free and a competitive market for drugs, not a country that engages in price controls. I am not assure if you are

aware of Mr. Roy's analysis.

Mr. Niksefat. I am not.

Mr. Kennedy. So moving on, then, you say that the price is based off of the size of the patient population. Presumably, that means a higher price for a smaller patient population. The population of Denmark is about one-50th the size of the United States. Can you comment as to why that arrow would continue in the opposite direction?

Mr. Niksefat. The population is the population to be treated, not the population of the country.

Mr. Kennedy. And presumably, the population to be treated in Denmark would be smaller than the population to be treated in the United States.

Mr. Niksefat. In total, yes, but we look at it as the total population to be treated.

Mr. Kennedy. You said the price is based on investment and risk undertaken. It is the same product in both countries, so I was wondering if you could explain why the investment and risk undertaken could be different in the two countries.

Mr. Niksefat. The risk and investment undertaken is, in general, one. However, there are specific studies that are done for specific countries.

Mr. Kennedy. Okay. So you say that you need to fund continued scientific innovation. And now setting aside the fact that you are calling on taxpayers to fund an awful lot of those research costs, everyone agrees that the ability to extract those payments to fund your own pipeline has an expiration date. That was in testimony earlier around exclusivity.

Neupogen has been on the market since 1991. That is 28 years. Is it really appropriate to continue to keep charging the taxpayer for those research risks on the back of an old product?

Mr. Niksefat. So Neupogen is subject to direct biosimilar competition and that biosimilar competition now has the vast majority of the market share. And so in my mind, Neupogen is a test case in proof that the biosimilar market and the lapse of exclusivity is working within the United States.

Mr. Kennedy. So if I understand that correctly, though, since the competitive entry of Granix from 2012 and Zarxio in 2015, Neupogen's price has risen and is still the market share leader both in total revenue and unit volume. Is that not the case?

Mr. Niksefat. It is not the case in unit volume, sir.

And in total, Neupogen unit volume, if I remember correctly, is approximately below a third of the entire market.

Mr. Kennedy. And revenue?

Mr. Niksefat. I am not aware of the revenue comparison.

Mr. Kennedy. So but the argument that then you are just making, we just went through those five principles, just to be clear, that economic value to patients, presumably the same, although you pointed to the fact the pricing is per, for that economic cost for the actual health system, it is the size of the patient population, which presumably is going to be higher in the United States than it is in Denmark. It is about the investment and risk undertaken, which is equal. It is about the need to fund scientific innovation, which you pointed to the biologic and biosimilar marketplace, although, at least from the information that I understand, is that it is still the market share leader in total revenue and unit volume, although I will take you at your word on the unit volume part. And the marketplace in Denmark is actually open and free.

So if we are pricing according to those principles, how does this work? What is the justification for a drug on the market for nearly 30 years that has gone up, over the course of the past 8 years, that a biosimilar market does not

actually accomplish what it seeks to do and given your testimony, you said this is open and working successfully?

Mr. Niksefat. Again, sir, on the biosimilar front, we have -- biosimilars have a majority share of the marketplace. And I believe Neupogen is the example of a working biosimilar marketplace.

Mr. Kennedy. And the last question, and I know I am over time, but given that Amgen is also a biosimilar company, do you stand make more money on biosimilars if the price of the brand and biosimilar products stay high or if there is true competition and those prices get pushed lower?

Isn't it ideal for Amgen that a biosimilar competition is weak and you can still charge a high price for Neupogen after 28 years?

Mr. Niksefat. We have not yet faced weak biosimilar competition, where we have faced biosimilar competition, and we believe that we will be able to bring our biosimilars to the marketplace, improve affordability, and save costs based off the level playing field that exists today.

Mr. Kennedy. I look forward to that happening.

I yield back.

Ms. Eshoo. I just want to insert here that I especially appreciate Mr. Kennedy's questionings, especially around the

biosimilar market. Your great uncle and myself were the authors of the legislation to create the pathway for generics, biosimilars. And the Europeans are doing much better with this. We have maybe about 20 products on the market in the United States but there are some darker reasons as to why more are not coming to the market. And I think the committee needs to examine that at some point but I especially appreciate your line of questioning.

I now would like to recognize the gentleman from Florida, Mr. Bilirakis, for his 5 minutes of questioning.

Mr. Bilirakis. Thank you, Madam Chair. I appreciate it very much. Thank you for holding the hearing.

Ms. Bricker, price transparency is key to informed consumer choices, obviously, and it ultimately empowers patients. I agree that patients and their care team should have access to prescription drug pricing, prior authorization, and step at the point of prescribing, not just at the point of dispensing. And I know we have addressed this issue but I think it is worth going over again.

The question is: How many providers have access to this information at the point of prescribing and how might we incentivize more providers to utilize this information in their practice?

Ms. Bricker. Thank you for the question, Congressman. This information is available to all prescribers but, unfortunately, not all are utilizing it from an Express Scripts perspective.

Mr. Bilirakis. And why not?

Ms. Bricker. Because they each use a unique electronic medical record that then has to create connectivity to the systems at Express Scripts. So it is available to them but not all are able to use it because, again, of that just connectivity issue.

From an electronic prior authorization perspective, 60 percent of our prior auths are done electronically and we aim for that to be even higher. It is faster for the patient and it is more convenient for the prescriber.

Mr. Bilirakis. Okay, I will move on to the next question.

Is it true under Medicare Part D that the rebates collected go directly to the beneficiary? Is that correct, the full rebate?

Ms. Bricker. The full rebate is passed to the plan sponsor. So, the health plan, if you will, receives the full rebate.

Mr. Bilirakis. The plan sponsor receives the full

rebate?

Ms. Bricker. Yes.

Mr. Bilirakis. Okay.

Ms. Bricker. And then it makes its way to the beneficiary through lower premiums and lower coinsurances or copays.

Mr. Bilirakis. Okay but the entire rebate makes its way to the beneficiary. Is that the case?

Ms. Bricker. The entire rebate goes to the plan sponsor.

Mr. Bilirakis. Okay. So it doesn't go -- so it does not go entirely to the beneficiary.

Ms. Bricker. It is not going to --

Mr. Bilirakis. It goes to the plan sponsor.

Ms. Bricker. It goes to the plan sponsor and then that, in turn, lowers premiums for beneficiaries --

Mr. Bilirakis. Okay.

Ms. Bricker. -- or out-of-pocket costs at the point-of-sale.

Mr. Bilirakis. Okay but there is no guarantee that it is all going to go to the beneficiary. All right.

Another question: On average, how long does it take your network to fill a prescription?

Ms. Bricker. I am sorry.

Mr. Bilirakis. On average, how long would it take your network to fill a prescription?

Ms. Bricker. My network? I am sorry I don't understand the question.

Mr. Bilirakis. Well, let's say part of your network, let's say a company -- well, a pharmacy that is part of your network, how long would it take to fill a prescription, would you say on average?

Ms. Bricker. I am sorry I don't have those statistics. I would say from my personal experience, anywhere from 15 minutes to 1 day, depending on how busy they are or other factors.

Mr. Bilirakis. Okay. All right, has it taken longer than let's say a couple days? Has that been your experience in some cases?

Ms. Bricker. In some cases it can, if the product is not in stock, or if they need to talk to the physician, or you know get additional information, it could certainly.

Mr. Bilirakis. But how often does that happen?

Ms. Bricker. I think probably Walgreens will be better to speak to this.

Mr. Bilirakis. Okay, I would like to -- okay, yes,

please. Anyone from -- anyone else want to add something to that?

Okay, maybe we can discuss it a little bit further.

Ms. Bricker. Sure.

Mr. Bilirakis. I would like to.

All right, Mr. McCarthy, bringing new prescription drugs to market is an expensive and long process. We have all talked about that. There are 7,000 known rare diseases impacting 30 million Americans; 95 percent of these diseases have no treatment. As you know, 83 percent of the rare diseases affect populations of 6,000 people or less.

Right now, rare disease patients are taking off-label prescription drugs to treat their conditions and there is no guarantee that the off-label prescription drug will be effective or even safe for them because of the dosage, in some cases.

What are the current barriers to repurposing the major market prescription drugs for life-threatening rare diseases and pediatric cancers? In other words, the drug shows promise but we want it to go through the FDA process to make sure they are safe and, obviously, we want the insurance companies to cover so that our patients have access. What are some of the barriers to that?

Mr. McCarthy. So thank you for the question, sir.

Mr. Bilirakis. Sure.

Mr. McCarthy. So Pfizer, as you may know, is committed to conducting research in rare diseases and we just were happy to receive approval this week for a rare disease medicine to treat cardiomyopathy, which is a very rare debilitating condition that leads to death. So we are very committed to doing research on rare diseases.

In terms of your question about repurposing medicines for use in rare diseases, I think the biggest challenges associated with doing so are clinical, demonstrating that the medicine is safe and effective for that use. There are lots of reasons why medicines don't make it to market -- safety, efficacy -- but I believe the biggest barriers would be the clinical barriers in demonstrating that it actually works and is safe in that condition.

Mr. Bilirakis. Okay, very good.

I guess I yield back. You are right, those 5 minutes do go fast, Madam Chair. I appreciate it very much.

Ms. Eshoo. They do. I thank the gentleman. He yields.

And I now would like to recognize the gentlewoman from Michigan, Mrs. Dingell.

Mrs. Dingell. Thank you, Madam Chair. I do thank all

of the witnesses for coming. I think you would probably rather be at the dentist than with us right now. But as you can tell, all of us have the same questions and we are hearing from people every single day.

I am going to use the inhaler, now is I think the latest example of insulin and EpiPens, where I started to hear about it when I was out and about and finally, like the tenth time, when I was at a clinic that helped serve -- that takes care of the underserved, they told me it was the most expensive medicine that they were stocking.

So I walked into three different pharmacies and discovered that it is about $700 to them. Blue Cross Blue Shield's Private or what I would call the autos, is $40 copay; Blue Cross Blue Shield FEP is $80. At town halls, I have had people tell me it costs $400 copay, $350 copay. It is a problem.

And you know the United States pays the highest prescription drug prices of anybody in the world. And each part of the drug supply chain bears some responsibility for what is happening. And I can tell you I don't think any of us -- well, some people out there may say that we are, but I don't think we are stupid and we are trying to understand where each of the costs are coming in and it is simply, it is

not transparent. I think we are all there.

But I am first going to ask Ms. Bricker and Mr. Eberle, building on what my other colleagues have been asking, the question is how would you say PBMs contribute to higher prices and do you believe that there are industry reforms that are needed?

Ms. Bricker. Thank you for the question. I exist to keep prices down and I am hired voluntarily by 3,000 clients that are employers, and health plans, and unions, and local governments to do just that. And so it is counter to our mission to in any way influence an increase in price.

Mrs. Dingell. And so you would say that PBMs are completely blameless and that you don't need any reforms. I forgot to tell you, by the way, this is $7, according to Dr. Ruiz, in Mexico.

Ms. Bricker. Our goal is to lower prescription prices. So we do everything that we can to do that.

Mrs. Dingell. Mr. Eberle?

Mr. Eberle. Similar, our mission is to lower drug costs in a manner that instills trust and confidence with our payers. We work with pharmacies, manufacturers, and everything we can to bring costs down. That is the sole purpose we exist as a PBM.

Mrs. Dingell. Okay, I am now going to go to Mr. Niksefat. In your written testimony, you said the U.S. biosimilar market is healthy and robust. At the hearing that we had last week, we heard testimony from MedPAC that the biosimilar market has brought only modest savings for consumers so far.

Can you explain why you think the current market is robust, when we have heard independent nonpartisan testimony just last week to the opposite?

Mr. Niksefat. Yes, thank you for the question Congresswoman.

Again, with our product Neupogen, we have been facing biosimilar competition for 3 years now and the biosimilars have the majority market share within the market. And our market share has been falling, quarter over quarter, since their entry.

We also see biosimilar competition to our drug Neulasta and are seeing uptake in biosimilars in that marketplace. We believe because we have one of the largest biosimilar portfolios we are bringing into the marketplace, that we can be successful if we price the products right and resource them correctly to ensure uptake in the marketplace.

Mrs. Dingell. Thank you.

Mr. McCarthy -- I am moving fast because minutes go fast -- you said in your written testimony that when a medicine's patent expires, lower cost generics are made available.

At the end of last year, Pfizer's drug Lyrica was scheduled to go off patent. And by the way, I know about it because I have seen the television ads. But instead, the company gained 20 more years of patent protection just because it slightly altered the drug's formula, allowing it to be taken as one pill instead of two or three.

I think that most Americans are fine with companies receiving patents and recouping R&D costs. We all agree there and we want genuine innovation. But are drug companies gaming the patent system? Are they making profit? Do you think changing a drug's formula so it could be taken as one pill instead of two is worth an additional 20 years of higher prices?

Mr. McCarthy. Congresswoman, thank you for the question.

First of all, as I mentioned earlier, we believe that Congress got it right with Hatch-Waxman and that we should have a period of exclusivity and when that expires, generics and biosimilars should come into the market. I am not sure which patent you are referring to but we expect generic

Lyrica in the market in months, not years.

And you know sometimes there are additional patents on formulations and other things that are, if their incremental innovations, are valid but they generally prevent generic competition from coming in from the main molecule. Once that patent expires, generics can come into the market.

Mrs. Dingell. I have more but I am over. And I will let you give the Republicans more time today.

Ms. Eshoo. I thank the gentlewoman. The Republicans are finished.

Now, we have more. I want to recognize the gentlewoman from Delaware, Ms. Blunt Rochester. And then we have two Members that are not members of the subcommittee but great contributors, and have served on the subcommittee before, and the rules of the committee allow them to waive on and ask questions, too.

So now we are going to go to the gentlewoman from Delaware.

Ms. Blunt Rochester. Thank you, Madam Chairwoman, so much for this important hearing. It is obvious by the interest on both sides of the aisle and the fact that this is actually something that we agree on, that we all recognize that there is not one simple fix, or one simple solution, and

that this is a very complex issue.

The future of this debate will increasingly focus on innovative drugs, precise, individually-tailored medicines that treat complex conditions but often at significant cost. And when we talked to stakeholders about this and even in this hearing today, we have heard a lot about value-based arrangements. And so I want to start there with my questions.

Mr. McCarthy, could you talk a little bit about are there any other things that you would change to encourage companies like yours to enter into value-based arrangements under Medicare? I mean we have already heard some about past legislation, Anti-Kickback Laws, but can you talk about any other things that you would do -- that we should do to encourage companies like yours to enter into VBAs under Medicare?

Mr. McCarthy. Yes, thank you for the question, Congresswoman.

And I believe the two ideas we discussed earlier would be very helpful in moving us to value-based agreements would be a change in the Anti-Kickback statute, as well as the best price provisions to enable us to execute those value-based agreements.

Ms. Blunt Rochester. Excellent.

And I just wanted to piggyback on Congressman Welch asked this question of the whole panel about the need for transparency on rebates and how much is spent on R&D. And I noticed that Mr. McCarthy, you had your finger on the button, as if you were going to speak but you didn't. So I want to give you an opportunity, and the rest of you as well, if we really are all on the record in agreement that there should be transparency, both on the rebates and also on R&D.

Mr. McCarthy. Yes, so on both of those points we do publish our R&D figures every year and this year, we spent over $8 billion in R&D. And we publish that every year.

And in terms of rebates or discounts -- sorry, Chairman -- you know we do believe that if the market is working to negotiate these discounts for medicines, that a patient should know about those discounts and should get the benefit of them.

Ms. Blunt Rochester. Okay, I am going to switch to Mr. Hessekiel.

Cancer is one of the areas of medicine where we are seeing very expensive drugs. I have had constituents call crying about the cost of their drugs. And as a pharmaceutical company exclusively focused on cancer, it

seems like your products would be well-suited for value-based arrangements.

Have you entered into any of these agreements?

Mr. Hessekiel. We have not entered -- thank you for the question, Congresswoman.

We have not entered into these arrangements. I don't believe that we have been approached to enter them in any significant manner.

I would echo Mr. McCarthy's comments of we are eager to embrace value-based arrangements but there are going to have to be some regulatory changes in order, frankly, to make all the stakeholders comfortable to proceed.

Ms. Blunt Rochester. Did you want to share any challenges that you feel in addition to --

Mr. Hessekiel. No, I think those are two very significant challenges.

Ms. Blunt Rochester. Okay and this question is for Mr. Eberle. How do you think value-based arrangements will affect the PBM sector and what role does your company expect to play, as they become more prevalent in the pharmaceutical market?

Mr. Eberle. I think the PBM role will kind of play that intermediary role that we do today. So working with our

clients and the manufacturers to negotiate value-based agreements that make sense for both parties, that are practical, can be administered, measured, and I see that as an extension of the rebate contracting we do today.

Ms. Blunt Rochester. That makes me want to shift.

Mr. Schrader talked about the issue of disputes but I want to go to the issue of outcomes and how you really measure them. So, I am going to turn to Ms. Bricker.

If you could tell us a bit more about the types of drugs for which Express Scripts commonly sees VBAs and outcomes that you are seeing. Are patients really benefitting from these arrangements?

Ms. Bricker. Thanks for the question.

We have been administering value-based-design programs since 2014. We have the largest portfolio in the industry of these programs. So I will provide you a list of those and the outcomes as a follow-up.

But to name one, Inflammatory Care Value is one of our flagship programs. It looks at the specialty products for rheumatoid arthritis, for arthritic psoriasis. These products are oftentimes started and then stopped. And we have worked with the manufacturers that produce them and if a patient, in fact, starts therapy and then stops therapy, we

give a refund back to the plan sponsors.

But as highlighted here many times, we are unable to do those in the government space and hope to do that.

Ms. Blunt Rochester. Thank you. I am going to shift to the opioid epidemic. We are fortunate to have testifying at the same time the Director of Public Health for the State of Delaware, Karyl Rattay, and we, in Delaware, have been expressly hit very hard. You know like naloxone has increased 30 percent since 2017. We have seen triple, double, 600 percent increases.

And one of my questions is both for Mr. McCarthy and Mr. Niksefat. What actions do you think could be taken to ensure that in times of crises we can access needed drugs to help America fight back?

Mr. McCarthy. Thank you for the question.

Ms. Blunt Rochester. And I have 13 seconds.

Mr. McCarthy. So I will be quick. First of all, Pfizer proudly has a naloxone donation program. We have donated hundreds of millions of doses of naloxone to help.

And then I also believe on the innovative side, developing new novel pain treatments that don't have abuse potential are two important steps.

Mr. Niksefat. Ma'am, at Amgen, we take the mantra of

every patient every time to make sure that we can always supply the entire marketplace.

I don't have any specific policy solutions for you today.

Ms. Blunt Rochester. One of my big concerns is that when we have these epidemics that price gouging doesn't happen, that we don't take advantage of a crisis in our country and then benefit from that. And so that is one of the areas that we will be working on and we look forward to following up with you on that.

And I yield back, Madam Chairwoman.

Ms. Eshoo. I thank the gentlewoman and it is such a pleasure to have her as a new member of the subcommittee.

Now, the gentlewoman from New Hampshire, Ms. Kuster, for 5 minutes of questioning.

Ms. Kuster. Thank you, Madam Chair, and thank you for a very informative bipartisan discussion. This has been a long morning for all of you.

I want to dive right in because we are all hearing from our constituents and we have got challenges. Just yesterday in my Concord, New Hampshire office, we heard from a constituent. A mere 6 weeks into 2019, she hit her catastrophic limit in Medicare due to therapy she needs

related to asthma. Asthma is about as common as any preexisting condition. Twenty-five million Americans have asthma.

And I want to try to capture some of what we have talked about today but I think I would go further. The chair said let's use the term discounts. I would use the term volume discounts because I think people may have been listening to this hearing today and not really understand what is at the core of these negotiations. If you buy more of something, you are going to get a better price.

And it is not the topic of what we are here for today but I just want to say for the record that I would like to see the Federal Government get the best price with the volume that they have, including Medicare Part D, federal employees, the VA, and everything else included.

So I think there is an advantage and that is really what PBMs are about. Our role is how to get that to the consumer.

So I want to address the sort of perverse incentives in the supply chain and we have danced around this a little bit today with starting with the list price. Recently, I saw an earnings report of a PBM who is not here today. So I want to make that very clear for the record. We are not talking about the PBMs who did have the courage to come forward and I

appreciate it.

This report showed that the adjusted operating income is expected to decline for this company for the year, citing, quote, lower brand inflation as a factor. Brand inflation, meaning that drug manufacturers did not increase the list price prescription drugs as much as the PBM had anticipated; thus, negatively impacting the PBM's earnings.

So Ms. Bricker and Mr. Eberle, can you explain this in the context of your business? Can you help elucidate why this would happen or what it is referring to?

Ms. Bricker. Historically, manufacturers have taken, oftentimes, double-digit price increases and there was a trend year over year of that continued level of price increases. This year and the year prior, we have seen moderation in price increases, likely because of the spotlight and the pressure that is being put on those list prices.

Ms. Kuster. Can you get at because the fees are based upon a percentage, and I think this was maybe the point that was made earlier, that the higher the list price, the greater the fees -- the greater the revenue?

Ms. Bricker. Certainly, the revenue because the pricing of the medication is based off of a derivative of the list

price. And so that is not to say the profits of that company or our company but the actual revenues associated are impacted certainly by the list price.

Ms. Kuster. To Mr. Eberle.

Mr. Eberle. Our organization takes a very different approach with that. Our only revenue is the admin fees we charge our clients, so the PBM services. So as drug prices go up or down, that has zero impact on our profit and loss, on our P and L. And we did that --

Ms. Kuster. And would you say that is your competitive advantage in the marketplace vis-a-vis other PBMs?

Mr. Eberle. It is definitely one of our differentiators, yes.

Ms. Kuster. Okay, thank you.

What I wanted to follow-up for Mr. McCarthy and the others, along the same lines, is there financial pressure on your side to increase list price and, if so, could you explain?

Mr. McCarthy. I wouldn't say that there is pressure to increase the list price. I would say in a competitive negotiation there is always pressure to negotiate larger discounts, yes.

Mr. Niksefat. I would say there is structural pressure

within the entire supply chain to deliver a bigger and bigger discount every year, without much focus on net cost and net value across the entire system.

Ms. Kuster. So it is sort of a perverse incentive, in a sense, economically.

Mr. Niksefat. It creates and environment that is structured, yes.

Mr. Hessekiel. Thank you, Congresswoman. I am not immediately aware of communications to benefit.

Ms. Kuster. Okay. And for all the witnesses: For the record, is it true that the only person that truly pays the list price, which is often the highest price, would be a consumer that showed up without the benefit of insurance or a discount through a PBM?

We will just go quick down the line.

Mr. McCarthy. Yes but also, even if they have insurance, it is on the deductible or the coinsurance basis.

Ms. Kuster. Yes, okay.

Mr. Niksefat. It is often that the patient is the only one exposed to the list price.

Ms. Kuster. Yes.

Mr. Hessekiel. In our section of the market with -- yes, the patient could be, if there is a high coinsurance

requirement and if they are a Medicare Part D patient, then the very reason why they may be experiencing and even have to abandon therapy might be the high list price.

Ms. Kuster. Thank you.

Ms. Bricker. In our experience, there isn't anyone that is actually paying the list price. Even if you don't have insurance and you go to a local pharmacy and you pay the cash price, there is a discount that they are applying at the point-of-sale. But it is the basis by which those discounts are determined.

Ms. Kuster. Okay, I think I have 45 seconds.

The Congressional Budget Office recently completed an analysis showing that specialty drugs accounted for one percent of prescriptions, but about 30 percent of spending on Medicare Part D, and spending on specialty drugs tripled from 2010 to 2015.

I am wondering, on this end, can you offer your perspective on why you believe specialty drug spending has grown so rapidly and what is the impact that that has on beneficiaries of your products?

Ms. Eshoo. Can I just insert myself in this because you are over by almost 1-1/2 minutes now.

Ms. Kuster. I apologize.

Ms. Eshoo. And it is an excellent question but it is going to take a long answer.

Ms. Kuster. I apologize.

Ms. Eshoo. If the witnesses, because you are responsible for or obligated to answer the questions of members and those that are submitted in writing, would you be willing to take your answer in writing, Ms. Kuster?

Ms. Kuster. Absolutely.

Ms. Eshoo. Wonderful.

Ms. Kuster. I apologize. I yield back.

Ms. Eshoo. No, that is all right. Thank you. No, I have had people go over the line today but there are so many great questions.

Now, I believe Mr. Engel, the gentleman from New York is next and then I hope we can get to the two members that are waving on and be able to dismiss the panel because I think there are going to be floor votes. And then we will come back for the second panel.

So Mr. Engel, you are recognized for 5 minutes of your questions.

Mr. Engel. Thank you, Madam Chairwoman. There are so many things to say and to add. I am going to try to get it all in but it is really hard.

Obviously, I, too, have heard these horror stories from my constituents about not being able to afford prescription drugs. And the aggravating part of that, on top of that, is that our nation, the wealthiest in the world, pays more for the same drugs than our peer countries and you could keep going. Even in some of the medications that I use, you have insurance and then you have to have such a tremendous amount of a copy, it really makes it ridiculous. Other developed nations are able to achieve savings because they are not afraid to leverage the purchasing power of a national insurance program.

So let me say as the chairman of the Foreign Affairs Committee, I travel all over the world and meet with leaders from every corner of the globe and even though these countries negotiate drug prices, they still have access to the same life-saving medications of Americans. So I just think that to begin the next phase of our drug pricing work, I want to encourage my colleagues to work on common sense legislation, which would repeal the Non-Interference clause, it has to be done.

Let me ask this question. In response to rising drug prices, analysts have noted a shift in drug formulary designs in the emergence of narrow formularies. So chronic

conditions, such as asthma, which affects a significant number of my constituents, have multiple treatment options. And I have heard from my constituents who have asthma that narrow formularies often only cover one of the several FDA-approved inhalers and often it is not the one that their doctor thinks is best for them. So as a result --

Ms. Eshoo. Mr. Engel, move your microphone a little closer so that everyone can hear exactly what you are saying.

Mr. Engel. Oh, okay. I am sorry.

Ms. Eshoo. That is fine. Go ahead.

Mr. Engel. We used to share a microphone in the old days. Remember?

Ms. Eshoo. Yes, I remember.

Mr. Engel. Ms. Bricker, let me ask you what steps do you take to ensure that your formularies did not restrict access to medications that a physician determines is best for his or her patient?

Ms. Bricker. Yes, thank you for the question.

So we leverage the council, the independent panel of physicians and pharmacists on our P and T Committee and they determine which products need to be included on formulary.

Once we develop the formulary, we are also then looking at clinical criteria to support that formulary. If a patient

is established on therapy and they are unable to or have already tried a preferred product on formulary, that information can be shared with us and then we will grant that as part of an appeal.

Mr. Engel. All right, thank you very much.

I want to touch on one more thing and, that is, I am going to ask you a question, Mr. McCarthy. According to the Census Bureau, they say that about 6,000 of my constituents are uninsured. For life-saving drugs, such as a hep C cure, can amount to $1,000 per pill and the price increases have really hurt these people the most, since they have to pay every penny of that increase. A significant number of Americans, as everyone knows, are underinsured, meaning that their health plans don't provide adequate coverage.

So Mr. McCarthy, in your written testimony, you highlight the challenges that these families face by citing a recent L.A. Times survey that found half of insured Americans could not meet their deductible or coinsurance. So in setting the list price for a drug, what steps do you take to ensure that uninsured and underinsured Americans can afford their medications?

Mr. McCarthy. Thank you for the question, Mr. Congressman.

So as I mentioned earlier and you acknowledged, we take affordability into consideration when we set the list price and we do everything we can to make sure that patients who are uninsured or underinsured can afford their medicine. We have a program called Rx Advances that allows patients, who are underinsured or uninsured who are 400 times the poverty level, obtain our medicines at low or no cost. And we have helped millions of patients get access to our medicines who have trouble affording them.

Mr. Engel. Okay, thank you.

Madam Chair, thank you for having this very important hearing. We are all hearing the same thing from our constituents. They don't care how we get there but they want us to get there. They want to be able to afford their medications. And I believe it is unconscionable that in the richest country in the world, where we have a technology, so many people just cannot get their meds because they simply cannot afford them and that really must change.

And knowing you for just a few short years, like 25, I know this is a priority of yours as well and I look forward to working with you, Madam Chair, and changing the system for our country. Thank you.

Ms. Eshoo. We are all going to work together on that.

I thank the gentleman and also, obviously, for his leadership of one of the most important committees in the Congress and that is Foreign Affairs. Thank you.

Now, I think -- yes, there is a vote on the floor. I will stay as long as I can. And let's get the questions from the two Members that have waived on. The gentleman from -- oh, Ms. Schakowsky is first.

The gentlewoman from Illinois, Ms. Schakowsky is recognized for her 5 minutes of questions.

Ms. Schakowsky. Thank you, Madam Chair. Thank you for letting me waive on to the committee.

Mr. Niksefat, in the testimony you originally submitted to this committee, you claimed that one of Amgen's drugs, Repatha --

Mr. Niksefat. Repatha.

Ms. Schakowsky. -- Repatha, is unavailable to your company's employees because of your multi-year agreement with a PBM that favors high rebates. Is that true, yes or no?

Mr. Niksefat. Ma'am, our benefits team spoke to our PBM team yesterday and received clarification for this misunderstanding --

Ms. Schakowsky. So you did change things.

Mr. Niksefat. -- which is why I corrected my testimony

to ensure that it was correct for the record.

Ms. Schakowsky. Right. Well so one hour later, after learning that your PBM, Express Script, who is also here today, planned to call that statement, quote, flat out false, you did submit new testimony and removed that claim. And that is what you were just saying.

Mr. Niksefat. Again, ma'am, we received notification late yesterday afternoon that the misunderstanding -- of the misunderstanding and we corrected the testimony accordingly.

Ms. Schakowsky. So though I believe that we need greater transparency in the rebate process, it is just unacceptable that you were willing to tell a falsehood in your official congressional testimony the day before you were called out. It just makes us wonder if we can expect our witnesses to tell the truth, how we can believe anything.

Mr. Niksefat. Again, ma'am, our benefits team received clarification after months of discussions late yesterday and we corrected the testimony to ensure that it was accurate.

Ms. Schakowsky. I understand. I understand.

So taxpayers absolutely deserve more transparency about why their drug prices are very high. Last month I introduced a bill called the Fair Drug Pricing Act with Republican Representative Francis Rooney. I hope you will all take a

look at that. This bill would require pharmaceutical manufacturers to notify HHS and submit a transparency and justification report 30 days before they increase the price of certain drugs, actually depending on their price, by more than 10 percent or by more than 25 percent over 3 years.

This bill will, for the first time, give taxpayers notice of price increases and bring basic transparency to the process. Again, Mr. Niksefat, would you be willing to submit a public and truthful transparency and justification report to HHS that includes the manufacturing research and development cost for the drug whose price you plan to increase, the net profits attributable to that drug, the marketing and advertising spending on that drug, and other information as deemed appropriate?

Mr. Niksefat. Ma'am, I am not familiar with that policy and I don't make those decisions on behalf of Amgen. So unfortunately, I can't comment on that.

Ms. Schakowsky. Well, I certainly hope that those of you that are in the drug-pricing business will take a look at that information because we hear all kinds of reasons to justify why these prices are skyrocketing, why people literally are dying because they can't afford their drugs and, at the very least, we have other bills that would

actually require the lowering of prices.

This is just to shine a light on that. And this bill or certainly some transparency bill is going to be required if we are going to move forward on what is the number one issue of consumers right now. All the polling before the 2018 election said that the price of prescription drugs is the main problem that people are facing. I, myself, have stood behind people at the drug store who have turned in their prescription and then had to walk away.

We know that compliance with drugs is way down, especially with things like insulin, people trying to make it on less than the prescribed amount that they are supposed to have. We have the names of people who have died.

And so all of you need to be looking at what are you willing to do and studying what you may be forced to do, if you don't do it on your own.

And so again, I appreciate the opportunity to be here. Thank you. I yield back.

Ms. Eshoo. I thank the gentlewoman for making the time to come and question today.

I now would like to recognize the gentleman from Florida, Mr. Soto, for 5 minutes of his questions.

Mr. Soto. Thank you, Madam Chairwoman.

So we are here today deconstructing the drug supply chain. I have got to say it is pretty dizzying when you look at this whole system. As best I could see it, manufacturers develop cures, pharmacy benefit managers negotiate on behalf of federal health plans, insurers, and plan sponsors, group purchasing organizations, negotiating on behalf of hospitals and physicians. Physicians meet with patients and get paid by the plans, the insurers, and the sponsors, as well as the hospitals. Then they meet with the pharmacist and the pharmacists finally distribute those prescription drugs to patients.

So as you could appreciate it, it is pretty hard for the average American, let alone the average Member of Congress to really sort through all this stuff. So I appreciate you being here to go through this.

First, Ms. Bricker, you all had mentioned the high deductibles. And obviously, there is a proliferation of junk plans. So, this is also a big driver of a lot of the costs. Is that correct?

Ms. Bricker. Benefit design certainly impacts what the patient will pay at the counter. And so yes, to the extent that there is a high deductible health plan or a coinsurance, we would expect beneficiaries to be subject to higher out-of-

pocket.

Mr. Soto. And Mr. Eberle, let's say your company gets a reduction of $1,000. How much of that is passed on to a health plan?

Mr. Eberle. $1,000.

Mr. Soto. And how much of that $1,000 reduction is guaranteed to be passed on to the patient?

Mr. Eberle. That is up to each health plan and how they decide to do that but they typically use those dollars to control premiums and control copays.

Mr. Soto. So it is a wide range of differences in how much of that savings gets passed down?

Mr. Eberle. It doesn't get passed down directly to that member. It is spread out across the entire plan, typically.

Mr. Soto. So it wouldn't be a lower overall cost that they would have then less out-of-pocket expenses?

Mr. Eberle. It would result in a lower overall premium that they are paying.

Mr. Soto. But not a lower out-of-pocket expense. Okay.

And you know we have seen the huge increases in insulin prices. A while ago, many of us were shocked by the increase of the anti-parasitic drug, Daraprim from $13.50 to $750. Obviously, people went to jail related to things like that.

Mr. McCarthy, should we be regulating the difference between keeping older, well-established drugs that have already been researched, already been out there, lower as opposed to newly discovered drugs where a bunch of research has just happened? Should we be making a distinction in regulating the prior, these older well-established drugs from huge spikes?

Mr. McCarthy. So it is a very good question, Congressman and it there are very different dynamics in those two markets. In the generic marketplace, the generic prices in the U.S. are probably lowest in the world, which creates a different problem because those are very, very low price and it is hard for competitors to sustain investments in generic drugs and that is why you end up with single-source drugs.

So something to be done to continue to promote competition and new entries in the generic drug space I think is something that would be valuable, yes.

Mr. Soto. What about you, Mr. Niksefat, should we be distinguishing between really cracking down on great increases in older, well-established drugs versus these new drugs that are just rolled out?

Mr. Niksefat. This isn't a policy I have personally studied within my role, Congressman, but our team would be

happy to get back to you.

Mr. Soto. And what about you, Mr. Hessekiel?

Mr. Hessekiel. I would have to say the same, we are a manufacturer of innovative drugs and that dynamic hasn't presented itself to us yet.

Mr. Soto. Thanks.

So we heard from MedPAC about how this is really an area where we are seeing increase in cost. Some of these drugs have been researched years ago. They have been beyond break even to profit and then we see just spikes for no other reason than there are companies that can do that. We certainly get that compared to a new breakthrough drug that took billions of dollars of research and we want to continue to have that research done. But I think this committee definitely needs to draw a big distinction and make sure we are not seeing these surprise spikes and increases of drugs that have been out there for many years with no new research or costs associated with them.

And with that, I yield back.

Ms. Eshoo. Okay, we have votes on the floor. We have completed not only the testimony of the witnesses but the questions of all of the members of the subcommittee, which I think are outstanding. The members are not in the hearing

room but I want to salute each one of you, everyone on both sides of aisle, as well as the members that waived on.

And to the witnesses, we always make an announcement that members have 10 days to submit their written questions. You have the wonderful obligation to respond to those questions in full.

So everyone has thanked you. I began by thanking you. I want to close by thanking you because you said yes to come. And even though Mrs. Dingell said at this point you probably would rather be at the dentist having a root canal, yes there are tough questions but they are legitimate questions and thank you for working hard to answer them.

We have challenges in our country. And I have always thought no matter how tall the challenges are, because it is America, we can meet them. We can meet them and we are going to in this case. We have learned from you and we have learned from the answers that we don't necessarily agree with. In other cases, the answers were really enlightening.

But Congress is going to move and we want to move together so that we end up keeping the promise to the American people that their prescription drug will not bankrupt them or allow them to die without them because that is really what it is. While we protect the efficacy of

drugs, that we have them be affordable, but also that we not kill innovation in our country because that is where the hope comes from.

So I thank the witnesses and with that -- well, we don't really adjourn. We are going to recess until I call the subcommittee back to order. Thank you, everyone.

[Recess.]

AFTERNOON SESSION

Ms. Eshoo. We will call the Health Subcommittee back to order.

Let me start out by thanking each one of you for your willingness to be here today to testify. It is an important day for the subcommittee. We did a deep dive this morning, which spilled over into this afternoon and I did mention to someone here, I think to Dr. Eschenbacher, this isn't called the healthcare industry for nothing. There are many, many parts and you represent important parts of it.

Our overall goal, as you know, on both sides of the aisle is to see to it that the Congress produces effective legislation that will actually lower the price of prescription drugs for the American people. There are so many working parts, layers, and each one has more than one thing tucked into it. But I think the deep dive and your presence to help us do that is really essential to do essentially an MRI on the system and you are here to help us.

So, I welcome you. And I want to -- I am not going to make any statement so that we can get right to the witnesses.

Would you like to make a statement, Dr. Burgess?

Mr. Burgess. I am good.

Ms. Eshoo. Okay, thank you.

So with that, we want to welcome Dr. Estay Greene. He is the Vice President of Pharmacy Services at Blue Cross Blue Shield of North Carolina; Dr. Lynn Eschenbacher, she is the Chief Pharmacy Officer at Ascension; Doctor -- we have lots of doctors -- Dr. Jack Resneck, Chair of the Board of Trustees for the American Medical Association; Dr. Richard Ashworth, President of Pharmacy at Walgreens -- I have one maybe a mile from my home. There are always long lines there, by the way. I think business is good. Ms. Leigh Purvis, who is the Director of Health Services Research at AARP, thank you for being with us.

We look forward to the testimony that each one of you are going to provide.

So we will start with Doctor -- well, why don't we start from the left, Dr. Greene? Yes, so we will start with --

Mr. Bilirakis. Madam Chair.

Ms. Eshoo. Yes.

Mr. Bilirakis. Before we proceed, I just want to recognize Dr. Greene and say that he is a good friend and constituent from North Carolina. We welcome him to the committee.

Ms. Eshoo. Isn't that wonderful? And thank you.

Mr. Bilirakis. Yes.

Ms. Eshoo. Thank you for sending our colleague to the Congress and that we are blessed to have him on this committee for his leadership.

Mr. Bilirakis. Thank you.

Ms. Eshoo. Would you like to recognize someone?

Mr. Burgess. Well I just also want to acknowledge Dr. Greene's presence. I think he worked with Dr. Patrick Conway, who used to be at CMS and was, obviously, a good friend to this committee after his time at the agency. So send our best to Dr. Conway. Thank you.

Ms. Eshoo. Wonderful. Okay, away we go.

Dr. Greene, you are now recognized for your 5 minutes.

I don't know how many of you are familiar with the light system. The most important light is the red one and that means stop. Okay? Thank you.

And you are welcome to summarize your written statement, if you care to, abbreviate it. If you want to say something orally that you don't have in your written testimony, we welcome all of it.

So you are recognized, Dr. Greene, and thank you again for being with us.

STATEMENTS OF ESTAY GREENE, VICE PRESIDENT, PHARMACY SERVICES, BLUE CROSS BLUE SHIELD OF NORTH CAROLINA; LYNN ESCHENBACHER, CHIEF PHARMACY OFFICER, ASCENSION; JACK RESNECK, M.D., CHAIR, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION; RICHARD ASHWORTH, PRESIDENT OF PHARMACY, WALGREENS; LEIGH PURVIS, DIRECTOR, HEALTH SERVICES RESEARCH, AARP

STATEMENT OF ESTAY GREENE

Mr. Greene. Good afternoon. My name is Estay Greene and I am the Vice President --

Ms. Eshoo. Turn your microphone on. I have to turn mine on to tell you to turn yours on.

Mr. Greene. Good afternoon. My name is Estay Greene. I am the Vice President of Pharmacy Services at Blue Cross and Blue Shield of North Carolina.

I would like to thank Chairwoman Eshoo and Ranking Member Burgess for their leadership in holding today's hearing and providing the opportunity to discuss key ways to improve patient access and affordable prescription drugs.

Since 1933, Blue Cross of North Carolina has offered its customers high-quality health insurance at a competitive

price and has led the charge toward better health and more consumer-focused health care in our State. We are a not-for-profit company and we employ more than 4,700 North Carolinians and serve more than 3.89 million customers. We are active in the group, individual, State, federal employee, and Medicare marketplaces. We will soon be entering the Medicaid marketplace as well.

In my remarks today, I will address how Blue Cross of North Carolina engages with the drug supply chain, Blue Cross of North Carolina activities to help patients afford prescription medications, and policy solutions to address rising drug prices.

First, Blue Cross of North Carolina holds ownership of a PBM, Prime Therapeutics, along with 17 Blue Cross Blue Shield owner-clients. Prime Therapeutics, a not-for-profit, assists with the administration of the pharmacy benefit, including a variety of services to Blue Cross of North Carolina's members, such as handling pharmacy claims, contracting, and developing preferred and non-preferred retail pharmacy networks, providing customer assistance, and developing formularies and utilization management programs.

The most significant PBM role is to leverage its volume of covered lives when negotiating with manufacturers for

discounts on prescription drugs to secure the lowest net prices for our health plan and, ultimately, for our members.

Second, Blue Cross of North Carolina is engaged in several initiatives to improve member access to prescription drugs, including by lowering drug costs and enhancing transparency. I would like to highlight three of these initiatives today.

Our company made a decision, starting on January 1st of 2019, to pass back drug rebates directly to customers when they buy rebated drugs. Here is how it would work for a member who hasn't yet met their deductible: If you are taking a prescription drug that costs $300 and there is a $100 rebate on the drug, you will now pay $200 for that medication. In the first quarter of 2019, we passed back $3.13 million to our members in rebates. But even with passing back more than $3 million in the first quarter, Blue Cross of North Carolina and those same members still paid more than $33 million for rebated drugs in that same time span.

We recently launched a transparency tool around prescription pricing, where we sent information to members about lower cost options available to them. The tool uses claims data to track members' prescriptions. When a less

expensive, equally effective alternative is identified, the member is notified by email or text message. The tool, called Rx Savings Solutions, has generated $10 million in member savings and has an average savings of $153 per prescription.

For the last initiative I will mention today, we waived the deductible on the purchase of preventative care medications to help members with high-deductible health plans save on drug costs. Currently, we waive the deductible on preventative medications for cancer, cardiovascular events, osteoporosis, and asthma.

While our policy changes will help, much more must be done. In just the last 3 years, drug manufacturers have increased the cost for our customers by $360 million but only increased rebates by $130 million, pocketing the $230 million of those cost increases.

To significantly address high costs, we have to address the main driver: expensive prescription drugs. We believe that proposals that increase competition in a pharmaceutical industry are necessary to bring lower-cost, equally effective medications to patients. Policies we support include:

The CREATES Act, which is a bipartisan market-based solution that confronts some anti-competitive behaviors that

are keeping lower-priced drugs off the market, such as brand-named drug manufacturers refusing to sell their drugs to generic competitors. Generic manufacturers need access to brand-name products in order to develop generic alternatives and get FDA approval;

Legislation that prohibits anti-competitive pay-for-delay arrangements, where brand-name drug manufacturers pay a generic manufacturer or make other financial arrangements with a generic manufacturer not to bring lower cost alternatives to the market;

And lastly, legislation banning patent abuses that are unduly delaying generic and biosimilar entry. In some cases, brand-name drug manufacturers are filing dozens of patents that extend a product's lifecycle and monopoly pricing power. Congress should restore the balance of the Hatch-Waxman Act and address this gaming.

Thank you for the opportunity to discuss how Blue Cross of North Carolina provides our members with access to affordable drugs and our ideas to improve the prescription drug market and patient access.

I welcome your questions and further discussions.

[The prepared statement of Mr. Green follows:]

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

The clock shows that you have 3 minutes and 11 seconds left but we didn't turn the clock on. So I think you -- I think we are even. How is that?

Mr. Greene. I agree.

Ms. Eshoo. Wonderful. Thank you for your testimony.

Now it is a pleasure to welcome Dr. Eschenbacher and you have 5 minutes to present your testimony.

STATEMENT OF LYNN ESCHENBACHER

Ms. Eschenbacher. Thank you.

Chairwoman Eshoo, Ranking Member Burgess, and members of the subcommittee, thank you for the opportunity to testify before you today.

My name is Lynn Eschenbacher and I am the Chief Pharmacy Officer for Ascension. I am a pharmacist with 20 years of experience across multiple sites of care. On behalf of Ascension, I want to start by thanking the committee for your bipartisan and thoughtful work to address the critical issue of high and rising drug prices.

Ascension is a not-for-profit Catholic health system with approximately 165,000 associates and 40,000 aligned providers. We operate more than 2,700 sites of care, including 151 hospitals.

Ascension's mission, vision, and values guide us in everything we do. Ascension's mission is to deliver to compassionate personalized care to all, with special attention to persons living in poverty and those most vulnerable. To carry out our mission, we cover all out-of-pocket costs for patients with incomes below 250 percent of the federal poverty level and on a sliding scale for patients

with incomes between 250 and 400 percent of the federal poverty level. Last year, Ascension provided nearly $2 billion worth of community benefit programs and care for persons living in poverty.

Managing the cost of our supply chain is critical to what we do to carry out our mission. Drug costs are the fastest growing part of our supply chain. In the span of 4 years, Ascension, alone, has had to mitigate against a cumulative 34 percent increase in drug costs totaling $564 million and that is after 340B discounts.

Price increases are frequent and unpredictable. They add to the direct cost of care and create administrative burden. For hospitals, inpatient stays are generally reimbursed through a fixed bundle payment that are set by payers in advance to cover the total cost of an admission. Generally, these bundle payment amounts are not adjusted during the year when costs go up. When drug costs go up, the bundles do not, so we must make adjustments elsewhere to make ends meet and to continue to deliver high-quality care.

We typically experience up to 40 new price increases each week and see upwards of several hundred price increases each January and July. In January, we saw thousands of price increases this year. Just to name one, Tysabri had a three

percent increase, which will cost an unbudgeted $640,000 this year.

We manage this unpredictable and costly situation in a number of ways. A common misperception is that systems like ours are able to leverage our size to get significant discounts on drugs. The fact is, manufacturers are only willing to negotiate the price for about half of the drugs we buy. We have no leverage when it comes to drugs that face no competition. Manufacturers know this. In fact, of the half that we do have contracts, about 70 percent of those don't lock in the price even for a full year.

When the cost of a drug spikes, we explore lower-cost alternative therapies that we can implement without compromising patient care. If that is not possible, we are forced to absorb the higher cost of the drug.

If we are able to identify a clinically appropriate alternative, it is a long and involved process that takes months to implement. This process includes clinical evaluations, physician buy-in, caregiver education, drug stocking, updating the medical records. During that time, we continue to absorb the higher price and the administrative burden on our clinicians. At the end of the day, these are our only options. Manufacturers know this and that is why

they will only agree to a price on a small percentage of our contracts. In those cases, we are told that is the price and that is that.

With the finite resources, high drug costs make it harder to carry out our mission. That is why the 340B program is so crucial. We use all of those savings to provide medications at low or no cost. We offer free medical care. We embed nurse services in our local school districts, and we operate Medical Missions at Home, and more.

We greatly appreciate the bipartisan work that this committee has already done on CREATES and pay-for-delay. We agree more can and should be done. My written testimony offers a more comprehensive set of recommendations but I would like to highlight a few.

To spur competition, Congress should support faster FDA approval and market-entry generics and biosimilars, increase funding to public and private research on drug pricing, and value, and in patent and data exclusivity of uses. Congress also needs to address the fragmentation and artificial barriers that exist in the pharmacy marketplace. As we move to more value-based care, ensuring continuity of care is essential to lowering overall costs. To do so, Congress should look at policies that would enable a common pharmacy

network design across multiple sites of care.

Thank you for your time and leadership. I look forward to answering any questions you have.

[The prepared statement of Ms. Eschenbacher follows:]

**********INSERT 7**********

Ms. Eshoo. Thank you very much, Doctor.

It is now my pleasure to call on Dr. Resneck and you are recognized for 5 minutes.

STATEMENT OF JACK RESNECK, M.D.

Dr. Resneck. Thanks, Madam Chair, for the invitation.

I am Jack Resneck, Chair of the AMA's Board of Trustees and a practicing dermatologist at UCSF.

Physicians see every day that costs are a major obstacle to our patients getting the right medication at the right time. High prices for drugs occur across many segments of the pharmaceutical industry, from new specialty drugs, to older drugs that inappropriately extend the market exclusivity, and yes, even to off-patent branded and generic medications. What do these share? A lack of pricing transparency. We need basic public information to inform policy solutions.

Some of my patients with melanoma and severe psoriasis need new targeted biologics. We expect new life-altering discoveries to be expensive but I have watched as costs continue to escalate years after these drugs launch.

I currently have a patient unable to afford the Enbrel or Humira that would alleviate his psoriasis and his painful psoriatic arthritis. The list price for a year of these drugs, both of them out for more than 15 years, has quadrupled to about $80,000 and his PPO specialty drug copay

is 30 percent until he reaches his deductible. That percent copy is based on the full list price, not the secret post-rebate price, so he stopped his treatment. This market is broken.

You heard from the last panel this morning that PBMs, whose retained rebate is typically a percentage of the drug price, incentivize manufacturers to have higher and higher list prices, paired with higher rebates, in order to get on formularies. That is not a functional market.

Health plans have responded to high drug costs by imposing more utilization controls that further limit patient access and delay treatment, such as frequently changing formularies, step therapy, and prior auth. Physicians around the country now spend a lot of time responding to prescriptions that cannot be filled. The average physician completes 31 prior authorizations per week that takes them and their staff about 15 hours a week.

And soaring prices are not limited to innovator therapies with recent R&D costs. Frankly, most of the patients I see simply need topical or oral medications that have been around for decades and used to be inexpensive. But thanks to price spikes, even many generics now require prior auth.

This month I saw a patient with severe eczema that had flared and become infected with staph. She needed clobetasol, a generic cream launched 34 years ago, and doxycycline, an oral antibiotic approved in 1967. They are each made by multiple companies, available in both branded and generic forms, and used to cost pennies a day. At the pharmacy, she was told that both prescriptions required prior auth or would, otherwise, cost her a combined $600. She didn't fill the prescription. She called me more than a little frustrated.

Four days later, after many phone calls failed to find formulary alternatives and a detailed prior auth request had to be faxed in, the insurer did eventually approve the request. But meanwhile, she suffered several sleepless nights of severe itch, made worse by spreading contagious staph infection, until the generic decades-old prescriptions were authorized.

And often, first prior auth requests are actually rejected, which leads to a lengthy telephone appeal trying to convince the person at the other end of the phone, who usually knows very little about the skin diseases I treat, to overturn the denial. Every hour I spend arguing about prior auths is an hour not spent with my patients. And it is not

just my time. My practice has several medical assistants and nurses who help do this work.

I am baffled -- baffled that it is nearly impossible for me to know at the point of care, sitting with a patient, which treatment options are on the constantly-changing formularies and what a patient's copay will be. For the most part, the manufacturers, the PBMs, and the insurers haven't made it possible for us, as physicians, to see this information in our EHR right while we are prescribing and when it does show up, it is often wrong.

In a world where we are measuring physicians on both their quality and costs and where some medical practices are assuming risk for the total cost of care, doesn't the physician also need the basic transparency of knowing what medications actually cost the health plan? With real-time formulary and cost information on each of my patients' options, I could make rational choices -- rational choices to help my patients get treated sooner, rational choices to help the taxpayer, health insurer, or purchaser to save money, and to save countless hours of staff work in my office.

The AMA has several additional policy recommendations outlined in our written statement. I hope we will have time to chat about many of those today.

I want to applaud this committee for its work on drug pricing and for the bills that have already come out of committee. And we at the AMA welcome the opportunity to work with you on behalf of our patients.

Thanks so much.

[The prepared statement of Dr. Resneck follows:]

*********INSERT 8**********

Ms. Eshoo. Thank you very much, Doctor. It is refreshing to me to hear from a panel that shares our frustrations. And I am not suggesting that others don't understand what we are saying but you know each one of you has your feet on the ground. You are in the field and you are dealing with this daily. And the people that you are talking about are the ones that tell us of their experiences that you are describing. So thank you very much.

And now I would like to recognize Dr. Ashworth for 5 minutes for your testimony, sir. Thank you.

STATEMENT OF RICHARD ASHWORTH

Mr. Ashworth. Thank you, Chairwoman Eshoo, Ranking Member Burgess, and members of the subcommittee for the invitation to speak today.

My name is Richard Ashworth. I am the President of Operations for Walgreens, and I began at Walgreens over 27 years ago as a service clerk, and then worked my way up to be a pharmacist. And now I serve in an executive role but helping patients has always been my passion and the heart of what I do.

Today, Walgreens has 9,500 locations all across the U.S. and we serve nearly 8 million customers and patients across the country. Our core purpose is to champion the health and wellbeing of every community in America and we are eager to help this subcommittee find ways to help patients afford their medications and stay adherent to their treatments.

Pharmacists work hard every single day to find lower out-of-pocket cost solutions for our patients. However, under the current system in Part D, pharmacies are limited in what they can do. Pharmacists rely on information that PBMs and health plans return to the pharmacy through the claims process. That claim guides the pharmacist on what to charge

the patient, provides some coverage and out-of-pocket cost information. We present that information to our patients right at the counter in communities. Unfortunately, the work of our pharmacist to find additional savings occurs within a system where incentives artificially increase the price of prescriptions.

Let me explain. Walgreens views the issue of drug-pricing through two guiding principles: Number one, drug prices have to be transparent as they move through the entire supply chain; two, savings must be passed on to the patient to lower their out-of-pocket costs. These principles are essential if we want to deliver affordable prescriptions to Americans.

Many transactions often occur after the point-of-sale and can increase that final cost of the drug, as the patient has higher out-of-pocket costs. These transactions include manufacturer rebates and discounts and pharmacy price concessions, negotiated and collected by PBMs. These are known as direct and indirect remunerations or DIRs.

Manufacturer rebates are typically offered under a PBM contract to exchange a placement on a formulary, which we heard this morning. Similarly, pharmacy price concessions are fees that PBMs charge pharmacies outside of the normal

administration fee process that typically relates to network participation and sometimes performance arrangements.

Patients pay cost-sharing amounts on the pre-DIR-negotiated gross price. Let me give you an example. If a patient comes in and has a drug cost of $300 and the patient's copay is 20 percent, she would pay $60 at the pharmacy counter for that drug. But if that same drug had a 50 percent DIR discount, whether it be rebates from manufacturers or pharmacy price concessions, that price would have dropped to $150 and her coinsurance would have been $30--half -- at the pharmacy counter.

When extrapolated to more expensive specialty treatments, that cost-sharing obligation gets much higher. That pre-DIR gross price can result in patients abandoning their treatment altogether.

Patient beneficiary cost-sharing amounts need to be based off the net price, not the gross. That does not happen today. Out-of-pocket drug costs are a key predictor of medication adherence. Studies show that when patients cannot afford their copay or their coinsurance, they abandon treatment. In fact, approximately one in five prescriptions, on average, are abandoned because they can't afford it. Not taking medications as prescribed costs our country over $300

billion annually. We need a more transparent approach that would eliminate misaligned incentives that currently exist in the Med D program. This approach is currently being contemplated under proposed regulations through CMS and HHS.

We believe a benefit design data clearinghouse could introduce next level transparency, ensuring patients, along with prescribers and pharmacies, have the most accurate information they need.

Today, benefit design and drug pricing information are held exclusively by the PBMs and the plans and only limited information is shared with either the physician or the pharmacy at the point-of-dispensing. Prescribing doctors don't have access to this information either and they could help give their patients better information to navigate their treatments. Now, some PBMs share benefit tools and level information with their members through portals and online tools but this information is limited and many patients don't even know that they exist.

A benefit design data clearinghouse, though, would enable better decisionmaking with the patient ultimately benefitting with lower, out-of-pocket costs and a greater level of adherence.

In conclusion, increasing drug prices and patient out-

of-pocket costs, and that impact on medication adherence, is too important to go unaddressed. Walgreens believes passing on the savings from manufacturer rebates and discounts, as well as those pharmacy price concessions, to patients are the best policy solutions currently under consideration. This will lead to greater transparency. This will lead to avoiding the misaligned incentives that exist today and are taking hold. Thank you very much and I look forward to working with you on this important issue.

[The prepared statement of Mr. Ashworth follows:]

*********INSERT 9**********

Ms. Eshoo. Thank you very much, Doctor.

So this afternoon's panel, as you all have heard, we have representation from pharmacies, from health plans, from a hospital system, from physicians, and from a patient. And the patient is next.

Ms. Purvis, thank you very much for being here. You are recognized for 5 minutes for your testimony.

STATEMENT OF LEIGH PURVIS

Ms. Purvis. Good afternoon, Chairwoman Eshoo, Ranking Member Burgess, and members of the subcommittee.

My name is Leigh Purvis and I am the Director of Health Services Research in AARP's Public Policy Institute. AARP is a nonpartisan, non-profit, nationwide organization with nearly 38 million members in all 50 States, D.C., and the U.S. Territories. Thank you for the opportunity to talk about rising prescription drug prices and their impact on older Americans.

Prescription drug prices are a high priority for AARP and its members. Medicare Part D enrollees take an average of 4.5 prescriptions per month, often for chronic conditions. At the same time, Medicare beneficiaries often have an annual median income of just over $26,000; one-quarter have less than $15,000 in savings. This is a population that simply does not have the resources to absorb rapidly escalating prescription drug prices and many are facing the very real possibility of having to choose between their medication and other basic needs, such as food or housing.

Meanwhile, today's drug prices are part of what appears to be a never-ending race to the top. High-priced specialty

drug approvals have exceeded traditional drug approvals since 2010 and the number of people using such drugs is growing. Meanwhile, the research pipeline is full of products like orphan drugs, biologics, and personalized medicines that face little competition and will undoubtedly command even higher prices.

Thus, it should come as no surprise that our members consistently tell us that they cannot afford the medications they need. In fact, a recent poll revealed that 72 percent of our members are concerned about being able to afford prescription drugs for themselves or a loved one in the future.

We also hear from our members directly. One member, Larry Zarzecki from Maryland, suffers from Parkinson's disease, which forced him to retire from law enforcement 10 years ago. Even with his insurance, he pays $3,200 every month for his prescription drugs. In his words, he pays for his medications with credit cards, and juggling Peter to pay Paul, and has recently started tapping his IRA to pay for his prescription drugs.

As part of our long-standing efforts to address this challenge, AARP has been tracking the prices of widely-used prescription drugs since 2004. A recent Rx Price Watch

Report found that the retail price increases for widely-used brand-name drugs have exceeded the corresponding rate of inflation every year since at least 2006. This problem goes beyond a few bad actors. Virtually all of the manufacturers we track have consistently raised their prices over the past 12 years.

We also examined how drug companies' relentless price increases add up over time and found that the average annual cost for widely-used brand-name drugs, now around $6,800, would have been just under $2,200 if retail price changes had been held to general inflation between 2006 and 2017.

In contrast, our most recent Rx Price Watch Report focused on widely-used generic drugs and found that the vast majority saw price decreases in 2017. We also found that the average annual price of a brand-name drug was more than 18 times higher than the average annual price for a generic drug. This massive price difference has been growing over time and is exactly why AARP is so focused on eliminating unnecessary barriers to generic competition.

AARP is mindful that high and growing prescription drug prices are affecting all Americans in some way. Their cost is passed along to everyone with health coverage through increased healthcare premiums, deductibles, and other forms

of cost-sharing. We have also seen massive increases in Medicare spending on prescription drugs. According to MedPAC, this spending growth has been driven by both higher prices for existing drugs and higher launch prices for new drugs. These escalating costs will eventually affect all of us in the form of higher taxes, cuts to public programs, or both. In other words, every single person in this room is paying for high prescription drug prices, regardless of whether you are taking a medicine yourself.

Current prescription drug prices are simply not sustainable. There is no reason that Americans should continue to have to pay the highest brand-name drug prices in the world. No one should be forced to choose between buying groceries and buying the prescription drugs that they need.

That is why AARP launched its Stop Rx Greed campaign. Our campaign calls on State and federal legislators to enact solutions that target the root of this problem, the prices set by drug manufacturers. At the federal level, AARP is focused on three key priorities: increasing generic competition, imposing an out-of-pocket cap for Medicare Part D, and allowing Medicare to negotiate for the price of prescription drugs covered by Part D.

While there is no silver bullet to a problem of this

magnitude, we believe that it is imperative to make prescriptions more affordable for older Americans and taxpayers and help protect critical programs like Medicare and Medicaid. It is long past time for Congress to take action to rein in high drug prices and we appreciate the leadership of this committee.

Thoughtful efforts to help reduce prescription drug prices could save tens of billions of dollars for patients, taxpayers, and our healthcare system. More importantly, they will help ensure that all Americans have affordable access to the drugs that they need to get and stay healthy.

Thank you and I look forward to your questions.

[The prepared statement of Ms. Purvis follows:]

**********INSERT 10**********

Ms. Eshoo. Thank you very much.

All right, well that concludes the testimony of our witnesses. And now we will go to questions of the members.

And I will recognize myself for 5 minutes for questioning.

Dr. Greene, Blue Cross Blue Shield of North Carolina holds an ownership of a PBM called Prime Therapeutics. Is that correct?

Mr. Greene. Correct.

Ms. Eshoo. You had that in your testimony.

Does Prime Therapeutics receive any money from drug manufacturers during its negotiations?

Mr. Greene. You mean in the form of rebates, whenever we are negotiating the rebate contracts?

Ms. Eshoo. Well you know they claim that is not money. They call it a rebate. I say it is a discount. But is there anything other than this famed discount that is exchanged between you and the manufacturers?

Mr. Greene. With our relationship we have with our PBM, we receive all of the discounts that are passed to the PBM back to us that we can give to our customers.

Ms. Eshoo. And so it goes to the patients?

Mr. Greene. Starting on January first of this year, we

started passing back rebates at the point-of-sale to our customers. So whenever there is a rebatable drug, we pass that back for our fully insured's line of business.

Ms. Eshoo. Well aren't most of the drugs that you enter into -- it seems to me that you are negotiating with yourself because you have your own PBM. So it is a little bit of a different model and I am fascinated by it.

Why did you go to that? Let me ask you that -- probably for all the obvious reasons but I think it is still worth asking for the record.

Mr. Greene. We moved to that model because of the transparency that we get by having partial ownership in that PBM, having full insight into the negotiations that occur with the pharmaceutical manufacturers so, again, we have full insight to the true total net cost of the product.

Ms. Eshoo. I think you said it was a non-profit.

Mr. Greene. It is a non-profit.

Ms. Eshoo. And so there isn't -- it is not a profit-making at all. I mean there are some organizations that are in the Tax Code that are called non-profits and then I think of the community organizations on the ground in my district. They really are non-profit.

So there really is not a profit made by the PBM?

Mr. Greene. Correct. It is owned by 17 other Blue Cross and Blue Shield entities that are also non-profit.

Ms. Eshoo. I see and services -- it is exclusively for Blue Cross Blue Shield.

Mr. Greene. Prime Therapeutics does have whole contracts with other PBMs and other employer groups but our relationship, we are a partial owner in that PBM.

Ms. Eshoo. Now what is the difference? The PBMs that were here today, well one of them had a very unique non-profit model, but the big PBM, Express Scripts, said that they claim that they do have great value because they pass on the savings, the discounts that they negotiate with the manufacturers, and that they move them along. Well, they move them along to other organizations that are part of this chain but I fail to see that the patient is the one ends up being the beneficiary of it.

Of all of your negotiations, do they all go directly to reduce the price of the prescription drug or are they going to an organization and then, if it is up to them, then they may pass along the crumbs?

Mr. Greene. We are receiving 100 percent of the rebates, the discounts that our PBM is negotiating, and starting on January first, we started applying them at the

point-of-sale.

Ms. Eshoo. Uh-huh.

Mr. Greene. Previously in the past, we have used all those rebate dollars that actually translate into our State filings for medical loss ratio calculations because discounts are considered part of the medical expense that would actually buy that down, which would actually decrease that medical expense.

Ms. Eshoo. Okay, I appreciate that.

I want to get to Dr. Ashworth at Walgreens. You dispense millions of prescriptions to the American people. How does Walgreens buy its drugs?

Mr. Ashworth. Thank you for the questions. So we buy--

Ms. Eshoo. And how do you negotiate the price to pay the drug manufacturers?

Mr. Ashworth. We do that two ways. So for the majority of our branded drugs, we buy that through a wholesaler. And our wholesaler we use is AmerisourceBergen.

Ms. Eshoo. Uh-huh.

Mr. Ashworth. And for all of our generic drugs, we buy that ourselves. So we have our own buying group that negotiates directly with generic manufacturers to procure medicine.

Ms. Eshoo. Now the patients that come to Walgreens, obviously, to buy their drugs. That was the line that I was referring to. It is constant, no matter what time I go to the -- stop by Walgreens.

Who determines the price that Walgreens charges the patient?

Mr. Ashworth. So a good question. So the manufacturer sets the list price, which was the discussion this morning. The insurers and the PBMs negotiate with that and then they are the ones that dictate the actual price that the patient pays at the pharmacy counter. That is what we get back in that adjudication process that I mentioned.

Ms. Eshoo. Well my time is up. I could do seven rounds with this panel but that is not the way it works here. So I will yield back.

And now I would like to recognize the ranking member of the subcommittee --

Mr. Burgess. Let's go to Mr. Shimkus first.

Ms. Eshoo. Okay, at your suggestion, Dr. Burgess, I would like to recognize the gentleman from Illinois, my pal, Mr. Shimkus, for 5 minutes.

Mr. Shimkus. Thank you, Madam Chairman. Yes, that is great.

How many of you were here for the first panel? Were you all here? So, okay. That is good and that is helpful also. So that is going to shorten my question.

I focused on some of the stuff that the government -- that we do that might affect this and the two provisions of Stark and the Anti-Kickback. So can you go through, from left to right, Dr. Greene, and say what you feel on the Stark and Anti-Kickback; and, if we made changes, would that be helpful?

Mr. Greene. Yes, changes are necessary.

Mr. Shimkus. And helpful, that would be helpful.

Ms. Eschenbacher. We favor the modernization of Stark and Anti-Kickback. We have actually written a white paper on it and would be happy to share and be involved in anything going further.

Mr. Shimkus. Thank you.

Dr. Resneck. We appreciate at the AMA that the administration and Congress, through the administration's proposal, actually brought attention to the rebates and the issues around PBMs. We do have some concerns with some of the specifics and the potential impacts on premiums and other things. So we would like to engage in follow-up discussions around how to move this forward.

But fundamentally at the end of the day, we do see that the current PBM rebate and retained rebate, the portion of it that they don't pass back to the health plan, unless the health plan owns them, does create incentives that are further keeping this from being a functional market. So, we do believe that needs to be fixed.

Mr. Shimkus. Dr. Ashworth?

Mr. Ashworth. Pharmacies, we would have an opportunity to lower out-of-pocket drug costs with some of the adjustments that could be made. So we are supportive of that conversation.

Ms. Purvis. AARP has raised a fair amount of concerns about the proposal and, more specifically, about the fact that we would see premium increases across the board, as well as substantial increases in federal spending, which is what was confirmed by CBO.

We also have concerns about the fact that not -- we don't have a clear picture of exactly how many beneficiaries would benefit from eliminating rebates. And we also, drawing from the CBO analysis, have noticed that it is not going to have an impact on list prices and it does seem like prices are going to continue growing.

Mr. Shimkus. Yes, I am just getting help from my expert

behind me. We may be mixing apples and oranges and you may be referring to the value pricing aspect, not just these two provisions. And we should visit on that to make sure we are clear because I think from the first panel, I mean obviously there is great diversity in this debate from the first panel and this panel, the providers, there seems to be consistency on it from across the board that it is helpful. So let's make sure we understand exactly what we are talking about so that we -- if there is an outlier, we need to know why but, if there is not, then that would give us a fundamental to look at, I would think, Madam Chairman.

And I love this transparency debate but I would also ask, like because we ask this question in a lot of different arenas, so in hospitals, Dr. Eschenbacher, when we go into your waiting room, do we see a poster that says an MRI costs this much?

Ms. Eschenbacher. I know that we are working towards providing more transparency around that.

Mr. Shimkus. But the answer is no. I mean we have been trying to push that, cash prices for services versus negotiated -- you are on the same dilemma that these pharmaceutical folks are because there are contractual services by insurance services that are negotiated for

hospital services. And so the full transparent price of someone getting -- having a cash payment versus a subsidized insurance payment, we don't know what that is.

That is a fair statement.

Ms. Eschenbacher. As the Chief Pharmacy Officer, I am not as much involved with MRIs, or services, or things like that. But around the medications, just as Dr. Resneck --

Mr. Shimkus. Let me go, then. I mean I think we have answered. Dr. Resneck, same thing when you go into a doctor's office.

Dr. Resneck. As a physician on the front lines, sitting down with individual patients every day, I would love more transparency on multiple fronts.

Mr. Shimkus. But when I go into my doctor's office, I don't see a list price if you are going to have a checkup or--

Dr. Resneck. And we believe in transparency around that as well but --

Mr. Shimkus. I understand. Okay, what is good for the goose is good for the gander.

Dr. Resneck. Absolutely, I totally agree with you.

Mr. Shimkus. Okay.

Dr. Resneck. But I will tell you the dilemma I face,

which is that the place I work happens to contract with more health plans than I can count. And when I am sitting down with a patient and they ask me how much something is going to cost --

Mr. Shimkus. That is the dilemma.

Dr. Resneck. -- the health plans have made it really tough for me at the point-of-care to know that as well.

Mr. Shimkus. Sure. Yes, I mean I think that is why we are having this. It is more difficult, I mean it is a very difficult process and procedure. And it is easy to call for transparency for others and difficult when you realize you are under the same type of rules, and regs, and competing insurance companies and you are asked to do it for yourself.

We have been trying to address transparency in healthcare delivery because I do think people will make choices.

But with that, madam Chairman, my time has expired and I appreciate it. I yield back.

Ms. Eshoo. I thank the gentleman and he returns his time.

The gentleman from North Carolina, Mr. Butterfield, 5 minutes for questioning.

Mr. Butterfield. Thank you very much, Madam Chair, and

thank you to the five witnesses for your testimony this afternoon. I am not sure I will use my full 5 minutes but I will get right to it.

Starting with you, Dr. Greene, good to see you. Thank you so very much for coming.

You mentioned Prime Therapeutics in your testimony and I very quickly looked it up on the Secretary of State's website. Did I understand you to say that it is a non-profit organization?

Mr. Greene. No, not-for-profit organization.

Mr. Butterfield. Well, that is the same thing -- non-profit/not-for-profit.

Mr. Greene. Blue Cross of North Carolina is a not-for-profit, which means we are also fully taxed.

Mr. Butterfield. But Prime Therapeutics, that appears to be a for-profit corporation. Does that sound right or not right?

Mr. Greene. Not right. It should be a not-for-profit organization.

Mr. Butterfield. All right. Well, we will look into it. Is it Prime Therapeutics Specialty Pharmacy, LLC?

Mr. Greene. That is a subsidiary of Prime Therapeutics. That would be the pharmacy of Prime Therapeutics.

Mr. Butterfield. I see. I see that is a subsidiary. All right, I am okay with that.

Dr. Ashworth, let me go to you very quickly. I didn't realize that there was a high incidence of unfilled prescriptions. I knew it existed but I didn't realize it was as high as it is.

Do you have any data, any hard data that shows who actually walks away from unfilled prescriptions?

Mr. Ashworth. Yes, I appreciate the question. So we do and we could follow-up with more information to help you understand how those things look.

There is another side to that equation, which is 30 percent of the time pharmacists get rejected when we try and fill the prescription. So we are doing the prior auths and the step therapy discussions that we were talking about before. We partner with our physician partners many times to try and understand formulary changes and different choices that patients have. That is why we are advocating for that data benefit clearinghouse, so that everybody has access to that information at the point when the drug is being dispensed, or written by the physician, or when they are at the pharmacy counter. It would make a big -- it would be next level of transparency for the whole system.

Mr. Butterfield. So is there a correlation between prior authorizations and treatment abandonment? Is there a correlation between those two?

Mr. Ashworth. That is a good question. I haven't looked at specific data. The intuition tells me yes but we can definitely look at that.

Mr. Butterfield. Someone mentioned one out of four. Did someone mention that earlier?

Dr. Resneck. I don't have data on that but I can speak from my experience, which is we see this all the time. So again, because of the lack of transparency, and you heard on the previous panel somebody suggest that at the point-of-care there are products out there that can help physicians see formularies and see patient copays. Unfortunately, they are small proprietary products that work for one health plan or one PBM and they are not integrated with our EHRs. And so you would have to have dozens of different log-ins and it is very difficult.

So we, unfortunately, spend an inordinate amount of time on the phone with our colleagues at pharmacies because their computer system, unlike ours, can run individual drugs and we just have to try one after the next and waste a ton of their time.

So my patients who get stuck in that situation waiting for a prior auth or waiting to deal with a non-transparent formulary, many times, after several days by the time I have worked it out, I have at least get me out for a while.

Mr. Butterfield. Does the prior authorization process need to be reformed?

Mr. Ashworth. I would comment on that.

Mr. Butterfield. Major reforms or just tweaking around the edges?

Mr. Ashworth. No, we would be up for major reform. In fact, thank you, Chairman Eshoo, for shopping at Walgreens. But the line you are in is because of this problem right here, is that our pharmacists are spending an inordinate amount of time on the phone trying to obtain that prescription for the person in front of you.

Mr. Butterfield. Last but not least to our friend from AARP, thank you so very much for coming; a great organization that I have supported for many years, not just because of my age but because of the work that you do.

AARP has been investigating the impact that rising drug prices has on its members. We all know that. How are drug prices contributing to racial disparities? Do you have any data on that?

Ms. Purvis. I think to the extent that there are economic disparities within those racial disparities, that certainly could play a role, or just in the type of coverage that you have. If you have a plan that doesn't provide adequate coverage for the drugs that you need, that can certainly contribute to not having access to the drugs that you need.

Mr. Butterfield. Thank you.

Madam Chair, I yield back.

Ms. Eshoo. I thank the gentleman. I want to join with you in praising AARP because they really represent seniors in our country very well. They also do a fabulous job of knowing how old you are and 10 years before you ever retire, they are right in the mail with their invitation to join the organization. So you are really spot on.

Mr. Butterfield. Data privacy.

Ms. Eshoo. Anyway, thank you.

Let's see, we don't have anyone on the Republican side.

Mr. Burgess. Except for me.

Ms. Eshoo. Yes, Mr. Burgess. I am sorry. What is the matter with me? I think this is hearing weariness, nothing to do with the panel but maybe I need to run around the block and wake myself up.

The ranking member is recognized for 5 minutes for his questioning.

Mr. Burgess. Well, I do need to, for full disclosure, point out that I am a dues-paying member of both the American Medical Association and AARP. And like many of the rank and file of those organizations, I am not always in agreement with their leadership, however, I do appreciate -- well, I appreciate all of you being here today and helping us with this question.

Dr. Ashworth, you have brought up something that I was not familiar with, the benefit design clearinghouse that you talked about. Is there any way to interface that with Dr. Resneck's electronic health record which we required him to buy several years ago?

Mr. Ashworth. Yes, great question. I believe the answer to that is yes. What we need is an industry solution, not a proprietary solution by each pharmacy benefit management company or insurer.

Mr. Burgess. Well if I may, then that is part of the problem because, as you know, we are down to just very few vendors in that EHR space and they are fairly proprietary about everything that they do, not to mention anyone's initials but you know who I am talking about.

I would like to alleviate Dr. Resneck's burden. I feel his pain. He wants to prescribe the right thing for his patient. He can't keep every formulary in his head. And even if there were just a single national formulary, even then, that is a burden to put on the doc who is trying to take care of a clinic full of patients.

How does that end up in his workflow, as he is finishing up his interaction with that patient?

Mr. Ashworth. Yes, I think from a government perspective, there is an opportunity to take the Medicare and Medicaid programs that are being delivered and to make sure that is on one comprehensive program.

The point you bring up on the commercial marketplace is still, if you have an industry solution that is that efficient and connects the whole supply chain together with the information that is required, then the EHR vendors, the pharmacies, the physicians would actually draw to that.

Because it is proprietary, that is what makes it so challenging.

Mr. Burgess. And there would be a concern that there would be movement in -- you would be able to move something in a specific direction that might favor one product over another. So that would be a concern, I could just imagine,

that people would have.

You know the data privacy is an interesting thing. I mean somehow AARP not only knows when you are turning 49-1/2, they also know when you are turning 65 and you start getting those Medicare supplement advertisements like clockwork about a year before. It is valuable because people do need to sign up for Medicare within 3 months before or after their 65th birthday and, if they don't, they are assessed an additional charge for the rest of their lives. So there actually is a late enrollment penalty in Medicare Part B that many people are not aware of. So you do perform a public service but I did tire of receiving the notices.

Dr. Resneck, let me just ask you on the prior auth stuff, I mean I don't hear about that a lot. And again, I feel your pain. I want to help. I am not sure exactly what we have at our disposal from agency rulemaking or from legislation but I would certainly be interested in your thoughts and, obviously going forward, lines of communication should be open.

Dr. Resneck. Yes, it is a mess and I can't overstate what a big mess it is. And again, it has expanded into areas we never anticipated. We expect there is going to be -- when I write a prescription for a really sick patient who has

melanoma who needs a $50,000 oncologic, I get it. When I am writing a generic cream that has been around for 40 years, that is getting ridiculous to get a prior auth for that.

When I prescribe common medications like a retinoid for acne and there are silly prior auth rules well if the patient is over age 18, we don't believe they have acne so you have to complete a prior auth just to get it. The list goes on and on.

I had a patient with eczema who needed a new drug called dupilumab that has been miraculous for her. And at the one year point, her prior auth expired so I dutifully submitted another one. And it said how is she doing? What is her current disease severity? And I said, thinking it would help get it approved, the drug is doing great; she is doing wonderful. And they rejected it saying she didn't meet the criteria for the drug anymore because she had improved.

So people don't believe it but this is what we go through every day.

So we sat down with -- at the AMA, we brought in major health plans from around the country and said can we just find some areas of agreement to bring some sense to this broken system. And we did come up with some areas of agreement for things that get approved 97 percent of the

time; they shouldn't be on the prior auth list.

Mr. Burgess. Right.

Dr. Resneck. For individual docs, who get 99 percent of their prior auths approved because they are practicing high-quality medicine, they should get gold-carded to protect patients from midyear formulary changes or prior auths all of a sudden when the formulary changes. But we have been disappointed to see that even though we released a joint document with some health plans, we haven't seen movement and action on this.

The administration, HHS and CMS did put in a Part D rule recently that is actually coming back to the transparency at the point-of-care piece, a requirement that you be able to see the benefits. But it was one of those situations where, again, it was just for one plan for each Part D plan.

So we would love to work with you and follow-up on ways to make this better. We have got a lot of ideas. We are working in a lot of State legislatures as well around protecting patients who get subjected inappropriate prior auth and step therapy. We call step therapy fail first because you are essentially requiring patients, potentially with major malignancies and other things, to try something that we already know for some legitimate reason isn't going

to work or that they failed.

So we look forward to continuing to work with you.

Mr. Burgess. Just for the record, I hate step therapy. As an asthma patient, I know it often doesn't work. I don't need to prove that again if I change insurance time, and time, and time again.

And from the disparity standpoint, there are some African Americans -- a higher proportion of African Americans who are albuterol-resistant for their asthma and we shouldn't make them demonstrate that every time they change an insurance plan.

I yield back.

Ms. Eshoo. Thank you, Dr. Burgess, for yielding back.

Now I would like to recognize the gentlewoman from California, Ms. Matsui for 5 minutes of questioning.

Ms. Matsui. Thank you, Madam Chairman, and I am glad to see the witnesses on the second panel here, and I am curious after we heard the first panel.

Thinking about the rebate rule and what your perspective might be on this, particularly the administration's proposed rule that we eliminate certain rebates from that Part D program. The administration's Office of Actuary found that if the rule were to be implemented, federal spending would

increase by $196 billion in premiums, for Part D beneficiaries it would increase by $50 billion. The Office of Actuary also noted that manufacturers may use this regulatory change to recoup lost revenue streams from other legislative changes.

And the CBO separately analyzed the proposed rule and reported last week that they estimated that the rule would increase federal spending by $177 billion.

So should the rule go into effect, it is likely to really significantly alter how we pay for drugs in the Part D program.

Ms. Purvis, I think we all know how AARP might feel about this but can you provide your perspective -- AARP's perspective on the rule?

Ms. Purvis. Sure. Thank you for the question.

This is actually something that has raised a lot of concern for us, for a lot of the reasons that you have already mentioned, which is that CBO has already estimated that this is going to increase federal spending substantially. It is also going to increase premiums across the board.

We have also been concerned by the fact that there isn't a whole lot of information about how many people are actually

going to meaningfully see a reduction in out-of-pocket costs because you are talking about people who are taking a drug with a meaningful rebate, which we have heard there are not many of those, and that drug is also covered under coinsurance. So we haven't been able to get a real firm grasp on exactly how many people we would actually be helping with this rule. And I think the way a lot of people have described it is the juice worth the squeeze.

The other thing that we really have been cognizant of is that the vast majority of the estimates we have seen indicate that list prices will not change. And CBO also included some language that made it seem like price increases will just continue business as usual.

So again, we are not quite sure this is going to get exactly what we are looking for.

Ms. Matsui. Okay. You know my colleagues here know Congress created the 340B drug program in 1992 to help covered entities stretch the scarce federal resource as far as possible, reaching more eligible patients and providing more comprehensive services.

Ms. Eschenbacher, you mention in your written testimony that Ascension has hospitals that participate in the 340B program. Can you tell us how these hospitals use savings

from the program to benefit low-income patients?

Ms. Eschenbacher. Absolutely. Everything that we do, we put back towards those low-income patients, and the poor, and vulnerable. That is part of our mission. That is part of everything we do.

We do anything from free or low-cost medications and, contrary to popular belief, the 340B price for a medication, a lot of our low-income and indigent patients are not able to even afford that price.

We do free medical care. We put nurses in local school districts. And we do something called a Medical Mission at Home and that provides comprehensive care, dental and vision, for patients at need.

Ms. Matsui. That is good. Thank you.

One way the 340B entities, which include hospitals, Federally-qualified Health Centers, Ryan White Clinics, Black Lung Clinics, and others get drugs into the hands of patients is by contracting with local pharmacies to provide drugs at discounted cost so patients can go to a local pharmacy to access these drugs, rather than rely on a pharmacy that might be out of the way.

Mr. Ashworth, your company, Walgreens, operates many of these contract pharmacies. Can you describe the importance

of these contract pharmacies to patients in rural communities?

Mr. Ashworth. Thank you very much for the question.

A lot of our Walgreen locations actually sit in underserved areas so this is really important to us. And our pharmacists are on the front lines every day helping these patients secure these medications at a very much reduced price. So it allows these individuals to have access to prescriptions they ordinarily would not have been able to get. It is deeply discounted.

The other thing I would just mention is that the mix of prescriptions we see in our 340B, our locations that can also fill for 340B versus ones that do not, has very typical generic dispensing rates and brand dispensing rates. So they are pretty similar in our 340B pharmacies, just like we see in our non-340B pharmacies.

Ms. Matsui. Thank you.

And Madam Chair, I yield back.

Ms. Eshoo. The gentlewoman yields back.

Mr. Burgess. Could we get Dr. Resneck to answer that?

Ms. Eshoo. I was just going to do that.

Dr. Resneck, you, I think wanted to add to the conversation with Congresswoman Matsui.

Ms. Matsui. I am terribly sorry I didn't notice.

Ms. Eshoo. No, that is all right. I want to give you the opportunity to say something about the -- wasn't it the rebate rule?

Mr. Burgess. The rebates.

Ms. Eshoo. The rebates -- the discounts.

Dr. Resneck. At the end of the day, America's physicians want our patients to have access and we want our patients to have affordability. And we know, when we are looking at the parts of the market that are broken, that the rebates and the retained rebates staying with PBMs are creating very bizarre, unhelpful incentives that are raising prices and it is a problem that has to be fixed.

So I just want to say clearly we appreciate the focus on this.

Ms. Eshoo. Yes.

Dr. Resneck. And even if this particular proposal we have some concerns with, and it might affect premiums, it might actually increase costs, and we do have significant concerns with the existing proposal, we appreciate the attention on this and really want Congress and HHS to continue to think about it. We have ideas. We have supported some other things.

So we would love to continue the conversation and actually fix this issue because it is a big one and it is a real one. And just because this proposal is imperfect, we don't want to not think about it anymore.

Ms. Eshoo. Agreed. Thank you.

The gentleman from Kentucky, Mr. Guthrie.

Mr. Guthrie. Thank you very much and thanks for having the second panel here today. We appreciate it very much.

Dr. Greene, I am going to ask you a couple of questions. I am on O&I Subcommittee for the Oversight and Investigation. We are looking into insulin. So we are kind of looking at insulin prices and the way that they are covered.

And so a question is: Does Blue Cross Blue Shield of North Carolina exclude certain insulin products from its formulary? And if so, why does your plan exclude these products and how much will a beneficiary of your plan pay for the insulin product if they have to take it anyway?

Mr. Greene. Yes, insulin is something we have focused on. It is actually one of the key reasons why we started to pass back rebates at the beginning of January first because that is one where we saw a large decrease in the cost, in our net cost based on those discounts, that we were not passing back at the point-of-sale, and we have realized that the

dilemma that patients were having about affording their insulin prices.

We do exclude insulin products. So we are currently, right now in our commercial line of business, we have Novo products as the preferred lines of insulin. That allowed us to negotiate a bigger discount by excluding the Eli Lilly products from the formulary at that point in time.

Mr. Guthrie. Okay. So if somebody -- so your argument is that the insulin is interchangeable. So because you are putting all your customers into one product, people get it cheaper.

Mr. Greene. There is one exception. We do allow the higher unit, the 500 dose that is more concentrated for diabetics that need that, that dose is on our formulary.

Mr. Guthrie. So if someone says this Novo product doesn't work for me, they need that, they are able to go to a different product line?

Mr. Greene. Correct, they can go through our step therapy protocol that we have available online. More than 85 percent of our requests come through online. And 45 percent of our approvals, we actually approve instantaneously at Blue Cross of North Carolina. And that would be a product that a physician could easily check boxes to say that the pen didn't

work. There could be some other problems with the insulin that the member was using that we could automatically approve for that member.

Mr. Guthrie. Okay. And I guess Lilly is having a generic insulin I think they testified coming forward, coming out, or has just come out.

Mr. Greene. They are decreasing the price. They are having an authorized generic of their product, yes.

Mr. Guthrie. And so that would be something you would have to look at as you negotiate moving forward.

Mr. Greene. Where they set that list price at, our discount we are providing at the point-of-sale right now for a Novo product is actually less expensive than what Eli Lilly is offering as an authorized generic.

Mr. Guthrie. Okay. Well, thank you for that.

And another question: Has Blue Cross Blue Shield of North Carolina ever removed an insulin product from its formulary in midyear, mid-contract year? And if so, how did it impact your beneficiaries?

Mr. Greene. Actually, we just did this on April first of this year. There was a similar product called Basaglar. Before we passed back rebates at the point-of-sale, Basaglar was a similar product to Lantus but it had a lower list

price. So members that are on our high-deductible health plan, we allowed them that option. If they wanted to choose to go to the Basaglar product, they could and save --

Mr. Guthrie. Because it had a lower list price --

Mr. Greene. It had a lower list price and they were paying a percent of that. But now that we are passing back rebates at point-of-sale, our preferred product, Lantus, is actually less expensive than Basaglar, so we are routing patients back to that product.

Mr. Guthrie. Okay. So getting to that, where you are giving back to your customers, your enrollees, has your plan made any efforts to increase transparency for its enrollees and physicians regarding the price of insulin? I guess that kind of example of that and the plan-specific.

So I guess it just seem so kind of confusing the way things are priced, that your enrollee would have to know that this list price is cheaper than the rebate until you gave the rebate back. So how did you get that message out or how was it transparent?

Mr. Greene. So whenever we made that change, we actually communicated that directly to the members that were impacted with the option of why that was available.

I know Dr. Resneck keeps bringing up an example of a

steroid cream. When we made a similar change, actually my own son was impacted and received a letter from his dad. We had to change.

And he stayed on the same steroid cream, it just went from an emollient cream to a regular cream. The price of the regular cream was $500 a tube. The price of the emollient cream was $50. So again, we had already met our -- we are in a high-deductible health plan. It looked like zero at the point-of-sale but then next January it would have showed up as a $500 charge.

So again, that is why we make those type of steps. I know some questions are around generics and that is why health plans are now looking at those type of generics where there are those huge price discrepancies of $450 for a tube of cream.

Mr. Guthrie. Well, thank you for that.

Dr. Eschenbacher, I just have a few seconds but in your written testimony you note that one program hosted and funded by Ascension called the Dispensary of Hope recently added insulin to its medication list. Why was it added and what specific products were added?

Ms. Eschenbacher. So it was added and it was from Eli Lilly. It was added because we have a lot of our low-income

patients who are on insulin. We have got stories of family members who are sharing insulin with each other and both of them uncontrolled.

So we felt we needed to do something. And Dispensary of Hope is our process to be able to provide medications to those patients. But since we started -- I have got the numbers -- but we have dispensed thousands of vials so far to our patients.

Mr. Guthrie. My time has expired but I see Dr. Resneck raising his hand. So if the chair allows you to answer, I will.

Ms. Eshoo. I would be glad to, Dr. Resneck, quickly.

Dr. Resneck. Thanks so much.

I just appreciate your bringing up insulin and topical steroids came up as well. They are both very important examples of something that is not single-source, has been around for a while, and where we have seen lock-step price increases and shadow pricing, with dramatic price increase every year.

Ms. Eshoo. What is shadow pricing?

Dr. Resneck. Shadow pricing is where you have three, four, five manufacturers making a drug and if you graph out the price from all of them, it is going up at exactly -- you

know every year by about the same amount. So the graphs look exactly like each other.

On the innovator side, we have seen the same thing with Enbrel and Humira, for example, where they go up about the same every year.

But I think the insulin example and the topical steroid example bring up why, first of all why we are happy with what this committee has done already this year in terms of thinking about fairness, and competition, and generics but also why we at AMA believe additional steps are necessary to give the Department of Justice and the Federal Trade Commission additional authority to go after anti-competitive behaviors and price gouging.

Because while on these two particular examples, I don't know what each individual manufacturer or anybody was thinking, or what actually happened, it is very suspicious to us on the front line sitting down with a patient where we see products that have been inexpensive for years, where every product in the class starts marching up in price together across several manufacturers.

So, I just want to say thank you for bringing up the insulin example because it touches on that.

Mr. Guthrie. I appreciate that. Thanks. I yield back.

Ms. Eshoo. The gentleman yields back. I now would like to recognize the gentleman from Oregon, Mr. Schrader, for 5 minutes of his questions.

Mr. Schrader. Thank you, Madam Chair. Ms. Eschenbacher, you have got your GPO but have talked about difficulty in securing volume-based discounts. Why is that a -- you know, most people would assume greater volume, get a little better deal. What is the problem there? Are there some levers that we could give you to enable more volume-based discounts?

Dr. Eschenbacher. Thank you very much for the question. Yes. You would think that as a system as large as we would -- or we would be able to get those. And as I mentioned, only about half of our medications I am even able to negotiate or we are able to negotiate a price for.

One of the levers that would be very helpful would be biosimilars. And so we ran into this this year. Part of using biosimilars is changing the culture with physicians, prescribers, to use those. So we took it through our organization, Inflectra versus Remicade, and we got the buy-in to use Inflectra. And we started trying to use it.

Every one of our claims was being denied, and so very quickly we had to stop using it. And so that goes back to the payers and the PBMs, and so I would suggest increase the

use and uptake of biosimilars. Thank you.

Mr. Schrader. That is very helpful. Cost effectiveness. We have had a lot of testimony today on value-based reimbursement and going forward there. And I spent some time back in the day with the ACA, with the PCORI institution, trying to at least get good information, theoretically somewhat unbiased. Everyone in the industry got to play into, you know, the evaluation of various drugs and devices.

But we didn't really get into cost effectiveness. You know, Dr. Resneck, do you think that the time has come where we may want to start looking at that?

Dr. Resneck. Well, I am glad you brought up value-based pricing. Thank you for doing that. I just want to say, first, if that means different things to different people, then I want to be -- because we had some folks from pharma here earlier today, and I think from their standpoint it is really predominantly about outcomes-based contracting.

So for them it is about in some cases we are starting to see it used as a justification for increasing price on a drug, that just because it saves money down the line, and it is currently priced at $2,000, maybe we can justify 10. So that we have some anxiety about.

Our focus around value-based pricing is really that

benefit design should be done in a way to limit patient cost-sharing for meds with high benefit, especially for vulnerable patients, low-income patients. We think there is a real impact on disparities there.

And to get to your original question, in order to do that, we need good data in general. And those are data from lots of different sources and data of lots of different kinds, right?

So we are seeing things like ICER and things like DrugAbacus at Memorial Sloan Kettering, and other programs out there that are actually doing this multi-source data intake when they think about value-based pricing.

The data does need to be rigorous. It needs to be evidence-based. The processes need to be transparent. So that is sort of how we are thinking about value-based pricing and the data that we are going to need.

Mr. Schrader. That is what made me think of PCORI as a possibility.

Dr. Resneck. PCORI is going to be a piece of that as well.

Mr. Schrader. Okay. Medication adherence, Dr. Greene, you talked a little bit about the measures you have taken to improve beneficiary utilization, preventative care medications. What type of calculations led to that decision,

and is there an actuarial presumption that you use to come up with, you know, how to establish that?

Dr. Greene. Whenever we are looking at that from the preventative side, we are actually looking at it from an IRS rule for high-deductible health plans that allow us to apply that for preventable medications, because we do not want to prevent access for drugs that can actually have a benefit impact to that member without having them go to the hospital.

So a lot of our medications are cholesterol/hypertension medications, asthma medications that, again, can lead to unnecessary ER expenses. So we don't want to expose the member to the deductible for those high-cost medications, just to co-insurance that is available for them.

And on our Medicare Part D benefit, we actually have ran what we call a Value Stars formulary for a number of years. On a Medicare Part D benefit, those drugs that are at zero cost that have a benefit to the member are actually on tier 6.

So it is counterintuitive, I believe, probably to a physician definitely, and to some of the dispensing pharmacists as well. When they use the formulary tool, that is where -- under guidance, that is where we have to place those drugs is in tier 6, which is typically on a commercial plan where the highest cost-sharing is, but in Medicare it is

the lowest cost-sharing tier.

Mr. Schrader. So it looks like we could tweak the ACA some and make sure that when we are talking about, you know, no-cost preventative counting towards your deductible, we should look at some of these preventing medications.

Dr. Greene. Correct.

Mr. Schrader. All right. I would assume insulin would possibly fall into that category.

Dr. Greene. It would.

Mr. Schrader. Okay. Very good. Very good. Dr. Resneck, in other hearings a little bit I suppose today, there had been discussion about reimbursing doctors ASP plus 6 percent, whatever, and it seems to me to get out of that -- and I know there is an administrative fee or administration fee you already have -- it seems to me you ought to just have an administration fee based on the complexity of the administration process.

Some it is easy; it is a vaccine. Others it is an oncology drug that takes hours. Rather than put the doc in the middle of this, you know, price, you know, how do you value these things, why don't we just give you guys an administration fee for your Part B work?

Dr. Resneck. Well, I think we are willing to look at any plan. At the end of the day, it needs to be a fee that

covers the cost of acquiring and administering the drug, and that is what physicians care about. Frankly, we are not really at ASP plus 6. Because of the sequester, we are at ASP plus 4.3.

Mr. Schrader. Now you are on message.

Dr. Resneck. And they are -- what is that?

Mr. Schrader. I said you are on message.

Dr. Resneck. Well, I mean, it is -- more broadly, I would say that there are many physicians who are already underwater at ASP plus 4.3, because the ASP is not always accurate. At different venues, some people can't actually get a drug for ASP. We certainly have small practices that struggle with that.

So we do think this is an area that needs further discussion, and we are -- but in terms of the proposals that we have seen thus far out there, none of them really have been ones that put forth adequate reimbursement to deliver the care just to cover the cost even. So, but we are open to taking a look.

Mr. Schrader. Okay. I am still good here? No, I am past time. Is that right, Madam Chair? I am sorry. I will yield the time back. Thank you.

Ms. Eshoo. The gentleman yields back. I now would like to recognize the gentleman from Virginia, Mr. Guthrie, for --

Mr. Griffith, for 5 minutes of his questioning.

Mr. Griffith. We do appreciate you all being here. Thank you. Lots of good information. Dr. Eschenbacher, in your testimony, you, by voice inflection, indicated some concern that 340B might be in trouble. I don't think that it is, particularly for what you all are doing. The concerns that we have had and that we have had some hearings and we will probably have -- continue to have discussions is that it appears that some folks have been gaming the system and not using that savings to help the low-income folks.

You all are not doing that, and one of the things that we have looked at is just having the ability to say, okay, here is the amount of money we saved, and here is how we helped low-income folks. And I think that is what a lot of us are concerned about.

But we are not trying to get rid of 340B. We are just trying to make sure that we are not having folks taken advantage of in the process.

Dr. Eschenbacher. Yes. We are not afraid of transparency. We are signed up for the AHA Stewardship Principles. We will be having a website. We are actually going to publish all of our savings and exactly how we are using. However, we don't believe that legislation is needed based on what we have seen.

Mr. Griffith. Well, if we could get everybody else to do what you are doing, I would agree. But if we can't, we might have no choice. That is the problem we get sometimes.

Dr. Ashworth, I want to talk to you about DIR fees. Now, for folks watching back home, because oftentimes we forget that somebody will be watching this 3 or 4 days from now in the middle of the night or over the weekend when there is nothing else going on, believe it or not, big viewership in the --

Dr. Ashworth. I trust you on that.

Mr. Griffith. -- middle of the night. And so that is the direct and indirect remuneration, the way that pharmacies get paid. And then the whole number gets rejiggered later, refigured out later. And one of my complaints has always been, particularly from my community pharmacists, that sometimes they get a bill because they have changed the DIR fee after the fact, and then they end up holding the bag.

They are not going back to their customer and saying, "Oh, by the way, that drug actually costs more, so we are going to have to charge you an additional fee. Please come in and pay it before you get your next medication." That is not happening, nor should it happen. But that seems to be an unfair process.

You raised a whole new winkle in this for me today, and

that is is that if they come in and the fee has not yet been determined, and they are paying a percentage co-pay or a percentage of what the drug costs, fascinating that the insurance companies can calculate exactly how much they overpaid, under the new DIR, the pharmacy, particularly the small community pharmacists. And I know it hurts Walgreens, too, but you all are bigger and can absorb some of that better than some of my, you know, one- or two-person pharmacy shops in the rural parts of southwest Virginia.

But that being said, it is fascinating they don't come back and give a refund to that patient who overpaid because the DIR fee had not yet been calculated. I am just wondering, do you think we should just get rid of the whole concept of DIR fees, as I think you indicated, at least in part, in your testimony?

Dr. Ashworth. Yes. A great question. It was -- and I agree with virtually everything that you said. And independent -- small independent pharmacies are aligned with chain pharmacies in this regard, which is all of the money that sits on the off-adjudicated price, right, so DIR fees are broken into two areas. One is the manufacturer rebates and discounts, and the other one is pharmacy price concessions. They are both DIRs. All of that money should go and help for patient out-of-pocket costs.

For pharmacies, many times we don't know what we are actually getting paid.

Mr. Griffith. Right.

Dr. Ashworth. It is a very strange business dynamic to do a service and then not know exactly what you are going to get paid on the back end. The calculation, if you get paid or not, is a proprietary system sometimes. Sometimes the data is available immediately; sometimes it is nine months later; sometimes it is not until the end of the contract year.

So from a pharmacy point of view, we are up for being reimbursed for the service that we provide, and we are up for us doing a better job for our patients to be adherent. But we have got to have -- the rules of the system have got to be more clear and more structured.

Mr. Griffith. Well, don't you think in a modern age that we should have a computer system that, you know, pharmacy X or pharmacist X can go to the computer at the time that the patient is standing there in the drugstore and plug in and find out what that cost is both to them and to the patient in real time as opposed to getting something a year -- and I have had pharmacists tell me they get a notice a year later that they owe $50,000 for all of the different prescriptions they have done.

Dr. Ashworth. Yes.

Mr. Griffith. That is really devastating in a small rural community where the economy is not particularly strong.

Dr. Ashworth. I understand. I am 100 percent aligned, and that is exactly -- what you just described is a data benefit clearinghouse that is transparent and open for everybody to have access to. The information is available, and the technical expertise does exist.

Mr. Griffith. All right. So my time is just about up. If you will work with me and my office, we will try to figure out how to do that. And I really don't see that that would be an obstacle for having that concept put into something. It may not need to be legislation, but we need to get it done one way or the other.

Dr. Ashworth. Happy to follow up.

Mr. Griffith. Thank you very much. Appreciate it. I yield back, Madam Chair.

Ms. Eshoo. The gentleman yields back. Time again to recognize our passionate advocate on this entire issue of reducing the price of pharmaceutical drugs, the gentleman from Vermont, Mr. Welch.

Mr. Welch. Thank you. And on those DIR fees, I endorse everything that my colleague, Mr. Griffith, said, and appreciate you being willing to work with him. I mean, that

is truly bizarre what happens. It really is.

There was a story in Politico that was very promising. It was about President Trump meeting with Secretary Azar and other people, talking about trying to get the prices down. One of the things that he talked about was drug importation, and, obviously, this would have to be safe. But a lot of the drugs that we have in this country are manufactured abroad, and we have mechanisms in place to assure the safety of the product.

Ms. Purvis, would you endorse what seems to be Presidential interest in allowing for drug importation plans as a way of putting some lid on the prices?

Ms. Purvis. AARP has been a long supporter of importation, with the caveat of course that we, like you, want to make sure that the safety of those products is ensured. So we want to make sure that FDA plays a robust role in ensuring the safety and the quality of the products that are brought in.

Mr. Welch. My view is the safety issue is a red herring because I haven't heard anybody anywhere who is in favor of unsafe products, whether they are manufactured here or manufactured abroad. But it suggests that if products are manufactured abroad, somehow we can't address the universal concern about safety. Would you agree with that?

Ms. Purvis. We have certainly been aware of comments of that nature as well, yes.

Mr. Welch. Yes. And Dr. Resneck?

Dr. Resneck. Yes. So the AMA, through our house of delegates, has passed policy actually in support of reimportation. But we are also looking for accompanying security, so we do want a closed distribution chain. We do want strong track and trace.

But I would say that technology has come a long way in the last few years, and I don't think those need to be obstacles anymore.

Mr. Welch. Yes.

Dr. Resneck. And we are getting to a point where this is realistic. And, frankly, compared to some of my other patients who can't afford medications, who do it on their own on the internet, this is much preferable to that, because I do see examples where they get --

Mr. Welch. You know, that is --

Dr. Resneck. -- that are not the medication --

Mr. Welch. Why don't you elaborate on that? Because I have constituents who resort to the internet because otherwise they get nothing and they are desperate.

Dr. Resneck. Yes, that happens. You know, we have patients who are sick and need help and can't afford their

medications, and they turn to that and try and do it on their own. And we do not have a system in place to guarantee the safety of them doing it under those circumstances, but we have great sympathy for the situation that our patients are in that requires that.

So, again, if we had more security around track and trace and an actual system put in place to be able to report it, that would be --

Mr. Welch. Thank you, doctor. That is fantastic about the AMA. I mean, that is the kind of support that your patients need, and I think we need here, to make some steps to bring those prices down.

Dr. Greene, transparency is -- again, the Trump administration is proposing an advertising of products. They have to tell what the price is, and that is a small step on transparency. This morning we had a panel before you where there was discussion about transparency and how much the rebates were.

There was a request for transparency on how much, in fact, the pharmaceutical companies spent on research and development, because we never really know, yet all of us want to make certain that they can continue to do research and development for innovation. What is your view on the role that transparency could play in helping us get lower or

fairer prescription drug prices?

Dr. Greene. We believe in supplying transparency to our customers. That is why we started passing back rebates on January 1. And also, in our transparency tool we recently launched, a member can actually go onto that site and they can pull up the actual drug costs that they are going to experience today, which means if they have met their deductible, we pull up their co-insurance, and it would also be minus their rebate, if it is a rebatable product.

I think earlier today you also heard on our brand-name medications, 90 percent are close to generic while another 10 percent are brand. We only receive rebates on possibly 25 to 30 percent of those branded medications.

Mr. Welch. Right.

Dr. Greene. So that other 70 percent is still at that high list price, especially when you start talking about oral oncology medications and some new specialty medications where the pharmaceutical industry does not negotiate on those prices.

Mr. Welch. Okay. I want to thank the panel, and I want to thank you, Madam Chair, and I will yield back the 30 seconds I have. Thank you.

Ms. Eshoo. Bravo. Thank you. The gentleman yields back. I recognize the gentleman from Georgia, Mr. Carter.

Mr. Carter. Thank you, Madam Chair. Madam Chair, I want to thank you for having this hearing today. This is certainly very needed, and certainly something that is on the mind of a lot of people. And I also want to thank Representative Welch for his attention to this matter. I appreciate everyone doing this.

As you know, currently, I am the only pharmacist serving in Congress, and, therefore, I am probably the only one who has seen this in real life. And one of the things that I have seen is DIR fees. And, certainly, Representative Griffith mentioned that just a second ago, although I have to correct one thing he said.

And that is that -- he was talking about $50,000 a year. We would welcome $50,000 a year. No exaggeration, I have got texts that I can share with you from pharmacists who are getting bills at the end of the year for $300,000, $500,000. Now, folks, that is not a sustainable business model. You just can't do that.

And you talked about, why can't there be a clearinghouse? Well, Dr. Ashworth, you are with Walgreens. You understand how it works now. When we fill a prescription in a pharmacy, we adjudicate the claim. That is, our computer calls their computer. It immediately brings back what we are going to get paid, what we should be expecting to

get paid, and what we are to charge the patient.

Yet a year later we have these DIR fees show up saying that, well, you didn't meet this criteria or you didn't meet this criteria. By the way, those criteria are always changing. The goal posts are always moving. Therefore, you owe us back $500,000 or $250,000. No exaggeration.

Tell me, and I am talking about, you know, small pharmacy chains. I am talking about stores in -- these two instances that I mention here, one owns six stores, the other one owns seven stores. I can only imagine what it is like for Walgreens.

But, Dr. Ashworth, I just want to verify this is not just a small independent pharmacy problem. It also impacts the large chain pharmacies as well.

Dr. Ashworth. Great comments, and I support everything that you just said. So for Walgreens that number is much, much larger, as you can --

Mr. Carter. I can imagine.

Dr. Ashworth. -- imagine. However, I have teams of people who work on this, you know, day in and day out to try and understand what is happening with DIR fees. That is why we support, you know, a lot of the proposals that are coming out of CMS and HHS right now to put parameters around what are the metrics, how does the payment run, how much working

capital do you have to put out in advance, when are you going to get paid, and that there is honesty and integrity in terms of how you are performing. That is really important right now.

Mr. Carter. Absolutely. In fact, we had Dr. Matthews here, the MedPAC director, just recently. And I was just appalled when he told me how much the DIR fees had gone up in over a period of 6 or 7 years. I mean, it had gone up from the millions into now the billions of dollars. Unbelievable. And as I say, this is just not a sustainable -- it is just not a sustainable business model.

And that money, you know, where is it going? Is it going back to the patients? Well, hopefully, when we have the rebates, the discounts, as the chairlady likes to call them, when we have those at the point of sale as CMS has proposed, hopefully we can see -- hopefully we get more transparency.

You know, Secretary Azar has made it clear that this is one of the things that we need, and this can help us in lowering prescription drug prices. Dr. Ashworth?

Dr. Ashworth. Yes. I just agree with that completely, and that is why we support transparency so strongly. Because if we can find out exactly where that money is going -- we know the first step of where that money goes, back to the

pharmacy benefit management companies, but from there we are not certain on where that money actually goes to benefit patient out-of-pocket costs.

Mr. Carter. And I find it interesting that we live in the world of vertical integration that we have now, and that is that the PBM owns the insurance company, and also owns the pharmacy.

So if the PBM is telling me, "Well, we are sending it back to the plan sponsor," well, who is the plan sponsor? Oh, we own them, too. Oh, you are sending it back to yourself? So you are taking it out of this pocket and putting it in this pocket.

You know, I mean, this is just so obvious that we need to do something about this. And I just can't applaud CMS for their actions that they are taking, and I support them 100 percent. I hope we can get rid of DIR fees. I hope we can have transparency with the discounts being at the point of sale.

It is going -- who is it going to benefit? Is it going to benefit the small independent pharmacies? It will some. But who is it going to benefit most? The patients. And let us never forget this is all about the patient. It is all about lowering prescription drug costs.

Folks, I have seen it. I have stood at the counter when

senior citizens had to make a decision between buying groceries and buying medicine. When a mother was in tears because she could not afford the medication for her child. This is not a partisan issue. This is a bipartisan issue.

And I applaud you again, Madam Chair. Thank you for calling this hearing today. It has been very productive.

Thank all of you for being here. Thank you for what you do. We all share the same goal and that is to lower prescription costs for patients.

Thank you, and I yield back.

Dr. Greene. Can I make a clarifying comment on the DIR fees?

Ms. Eshoo. I thank the gentleman. Who is talking? You are recognized.

Dr. Greene. Thank you. Sir, on the DIR fees, under Medicare legislation, we do have to supply that information, N dollars back to the Federal Government. So it has been alluded to here several times that there is some money retained with those DIR fees.

Again, we need to collect and provide that money back, which, again, comes back to the premium calculation to our customers. So, again, if there is any modification --

Ms. Eshoo. What overage is there in DIRs? I don't -- I am not so sure -- I know that it is in statute. But you know

what I am struck by, and I think all of my colleagues are, is that we have an alphabet soup of terms that all have money attached to them. And I think we need to do a really deep dive to follow the money.

There is a saying in politics: follow the money. Well, I think in the healthcare industry, in the pharmaceutical industry, we have to follow the money. This adds up layer by layer by layer by layer. And then to hear what the doctors and the pharmacists are dealing with, it just -- I don't know. Collectively, it makes us all feel like we need to put our heads down in some kind of shame that we -- the system somehow is several-headed.

And I don't have any question that the patient is not receiving any of these goodies that are moving through these layers of the system. I don't think anyone has testified here today to say that they are, with the exception of the not-for-profit PBM, which was small, you have your own, so that you wouldn't have to go through the big guys, but I just want to put up a Beware sign.

I am not in the mood to see any more third parties established in this system. That is we need is another third party. So we have to follow the money, so we can save money and bring some sanity to the system.

So, well, I am glad I got that off my chest.

Mr. Carter. Madam Chair, I apologize. May I ask unanimous consent to add this letter from the National Community Pharmacists Association into the record?

Ms. Eshoo. Yes.

Mr. Carter. Thank you.

[The information follows:]

**********COMMITTEE INSERT 11**********

Ms. Eshoo. And now I would like to recognize the gentleman from Indiana, Mr. Bucshon, for 5 minutes of his questioning.

Mr. Bucshon. Thank you, Madam Chairwoman. Yes. This isn't my name. I am subbing. I am supposed to be down there, but I am subbing here.

Eschenbacher, is that how you pronounce it?

Dr. Eschenbacher. Eschenbacher.

Mr. Bucshon. Eschenbacher. Ms. Eschenbacher, you provided some examples of how your hospitals use 340B revenue. I would like to better understand what patient programs, if any, are in place with your 340B contract pharmacies.

First, how many contract pharmacy relationships do your 50 340B hospitals have?

Dr. Eschenbacher. We have 800, about approximately 800.

Mr. Bucshon. 800. Has that increased in the last couple of years?

Dr. Eschenbacher. I believe it stayed the same, but I could check on that.

Mr. Bucshon. Last 5 years? Because 340B is going like this, right? Are 340B discounts passed to the patient at the contract pharmacy counter?

Dr. Eschenbacher. Not today.

6221

6222 Mr. Bucshon. Not today. Okay. So where do they go?

6223 Dr. Eschenbacher. So when we get the funds back into

6224 Ascension -- so it doesn't happen at the counter. It happens

6225 when they come back to Ascension and all of the programs that

6226 we provide across Ascension. We do medical missions at home.

6227 We do nurses in school districts. We do free medical care.

6228 The comprehensive care of the patient, we use those

6229 monies. Also, contrary to popular belief, the 340B price of

6230 the medication, some of our patients actually can't even

6231 afford that. So we also help to pay for the products for

6232 those patients.

6233 So if they go to a contract pharmacy and they are not

6234 able to afford it there, they come back to our own retail

6235 pharmacies, and we have a National Patient Assistance Program

6236 where we help to care for our patients within own system.

6237 Mr. Bucshon. Okay. Because I was going to ask, is this

6238 the same for all patient types? And you just described--

6239 Dr. Eschenbacher. Yes.

6240 Mr. Bucshon. -- that it is not. Yes. So currently do

6241 you have -- are all of the facilities DSH hospitals that are

6242 participating in 340B?

6243 Dr. Eschenbacher. We have got a variety within them,

6244 some rural referrals, some DSH.

Mr. Bucshon. Oh. So a combination thereof.

Dr. Eschenbacher. Yes.

Mr. Bucshon. The DSH hospitals, do you have to report anything to the Federal Government related to how much profit -- how much margin you have on 340B or what you are using the funds for?

Dr. Eschenbacher. We believe in -- or we are not afraid of transparency. We have signed on to the AHA's --

Mr. Bucshon. Right. The question was, do you currently have to do any reporting? Like some of your -- some of the other types of 340B hospitals have some extensive reporting, right? And your DSH hospitals, do they?

Dr. Eschenbacher. We are developing a website, and we are putting all of that information on a website.

Mr. Bucshon. Okay. But right now you don't have to submit that to Congress.

Dr. Eschenbacher. That is correct.

Mr. Bucshon. Right. Or to the government, right. So that is a level of transparency that you might agree with? The reason I am asking that question is because I already know the answer, because the American Hospital Association last year was not in favor of some of the 340B legislation that was introduced in our committee.

And I am wondering if that kind of -- conceptually, if

people are morphing a little bit on that, realizing there needs to be maybe some transparency?

Dr. Eschenbacher. We don't believe that legislation is needed. From some of the things that we have seen reported, it might create an undue burden and not necessarily improve the program to the patients.

Mr. Bucshon. Okay. And burden on whom?

Dr. Eschenbacher. On the organizations. The reporting --

Mr. Bucshon. Okay. But, for example, the Ryan White AIDS clinics, right, they have an extensive reporting process to the Federal Government because they participate in the program. Is that true?

Dr. Eschenbacher. I am not as familiar with that.

Mr. Bucshon. It is true compared to the others. So I understand that most 340B contract pharmacy claims are retrospectively identified. So how do you identify the 340B patients when they present at the contract pharmacy counter?

Dr. Eschenbacher. That would be a discussion between the pharmacist at the counter and the patient.

Mr. Bucshon. But how would -- does the patient know they are a 340B patient?

Dr. Eschenbacher. In one of our ministries, they have a process where they have a card where they identify the

patients. It looks like a healthcare card that then can identify those patients.

Mr. Bucshon. Okay. Because my understanding is patients don't really have any idea that they are a 340B, that they would be identified as a patient that is a -- the reason is because there is no specific definition for a patient, is there, really?

Dr. Eschenbacher. Well, in order to be part of the program, you do have to be eligible patient, eligible provider. So there are criteria associated with it.

Mr. Bucshon. Okay. Are contract pharmacies paid on a fee basis or a percent of the discount?

Dr. Eschenbacher. It is dependent upon the contract. We believe that the fee -- or the standard fee-based would be the best process associated.

Mr. Bucshon. Fee-based. Okay. Are there contract provisions to avoid duplicate discounts when determining 340B eligibility and managed Medicaid utilization?

Dr. Eschenbacher. That is definitely part of the program, and we ensure that that is heavily looked at, and there are no duplicate discounts.

Mr. Bucshon. Okay. So, I mean, I have an Ascension Hospital in my district -- it used to be St. Mary's; now it is St. Vincent's -- but Evansville, Indiana.

Dr. Eschenbacher. Okay.

Mr. Bucshon. So I know your system well. And I would hope that over time that you would be supportive of some DSH transparency.

With that, I yield back.

Ms. Eshoo. The gentleman yields back. I think it is important to state for the record that transparency in the 340B program is not -- let me put it this way, it is unrelated to this hearing today. We are examining how we can lower the price of prescription drugs. And while there is an interest on the part of some members on this subject, it is --

Mr. Bucshon. Will the gentlelady yield?

Ms. Eshoo. -- let the --

Mr. Bucshon. Yield for just a brief second?

Ms. Eshoo. I would be glad to.

Mr. Bucshon. Yes. My point is is that there is some -- some people believe that because of the dramatic expansion of 340B that it is leading to upward pressure on drug prices overall, and that was the overall connection I was trying to make, so --

Dr. Eschenbacher. May I respond to that?

Ms. Eshoo. Well, I am letting everybody respond to everyone. Might as well be consistent. Of course, Dr.

Eschenbacher.

Dr. Eschenbacher. We do disagree with that premise. From my experience, I have not seen that, so I wanted to respond.

Mr. Bucshon. Fair enough.

Ms. Eshoo. Yes. My staff is reminding me that the 340B program is 2.1 percent of overall drug spending. So 2 percent, given the numbers, is -- it is still something. But let it just stand that transparency in that program is not what the hearing is set up to examine today, and I appreciate everyone understanding that.

Now, let's see, who is next? My friend from Florida, the gentleman from Florida, Mr. Bilirakis, whose father, Congressman Mike Bilirakis, was the chairman of this subcommittee at one time and I served with. And now I have the pleasure of serving with his son. Isn't that wonderful? You are recognized for 5 minutes of questioning.

Mr. Bilirakis. Thank you, Madam Chair. I appreciate it. And thank you for holding this great hearing. It really is great. Thanks for giving all of us the opportunity to answer the question, or ask the questions. So very important to our constituents.

Again, my constituents are telling me that it is difficult -- they are having a difficult time obtaining

prescriptions. They can't -- of course, they can't afford the prescriptions in a lot of cases, or they must wait a long time to get authorization. The process takes too long, in their opinion.

This is actually for Dr. Ashworth of Walgreens. Doctor, when you were behind the counter as a pharmacist, what hurdles were you dealing with that kept you on the phone instead of helping interact or interact with the patients? Because I know that pharmacists at one time were called doctors and they interacted with patients, and they still do.

I know that pharmacists are -- and we have a lot of pharmacists in our family. The patients and customers love their pharmacists. But when you have to spend a lot of time on the phone, it is hard to interact with the patients.

So if you can tell me, what are some of the hurdles that you have to deal with behind the counter?

Dr. Ashworth. Thank you very much for the question.

Mr. Bilirakis. Sure.

Dr. Ashworth. So I remember very clearly doing it myself. I still have a crick in my neck from holding on the phone while I am doing other activities to help the pharmacy keep going.

The first thing that we spend a lot of our time doing is actually ensuring that we get the medication covered for our

patients to subsidize that cost, so that they can afford it. We spend a lot of our time on making sure of the clinical appropriateness of the medication and things like that for sure, but we spend a lot of time talking to physicians' offices to get overrides for step therapies and for prior authorizations.

We spend a lot of time on the phone with pharmacy benefit management companies, understanding alternative therapies and what formularies the health plans or the insurer has for that specific patient. And many times we are on the phone with foundations and advocacy groups to get secondary and tertiary funding areas for patients as well.

Mr. Bilirakis. And, you know, that can't be done by a tech, right? It has to be done by a PharmD; is that the case?

Dr. Ashworth. You know, some of those activities are done by our technicians. Our technicians are beloved by our patients because they work on behalf of them each and every day, right along with our pharmacist. But a lot of times the conversation is around other drug choices, and, yes, that is more appropriate for our pharmacist to handle.

Mr. Bilirakis. All right. Very good. Thank you.

This is for Ms. Purvis. In your testimony, you mentioned how increased competition and access to generics is

critical to controlling costs. Of course, I agree. I am sure the entire committee agrees.

On average, how much more does a brand name prescription drug cost when compared to its generic version?

Ms. Purvis. Thank you for the question. That actually is a fairly high number. When we took a look using our most recent price watch reports, we found that on average the brand name drug price is over 18 times higher than the generic price.

Mr. Bilirakis. Eighteen times higher. Unbelievable. Okay.

Dr. Greene, would you explain the coverage determination process for prescription drugs?

Dr. Greene. Are you specifically asking for the Medicare Part D process, or just in general?

Mr. Bilirakis. In general.

Dr. Greene. In general?

Mr. Bilirakis. Yes.

Dr. Greene. So when a provider wants to request a drug either we have on prior authorization or a step therapy program, we actually offer an online portal. We have offered it for a number of years. We have offered it now for close to 5 years, so we have about 85 percent adoption of using that online portal.

What we are able to do by having that online portal is to build business rules into those requests. So if the patient meets certain benchmarks, we are actually able to provide 45 percent of the approvals in real time, meaning while either the physician or a medical assistant is entering that information, they know right then that the medication has been approved. That way, within the half an hour, they can go to their local pharmacy and pick up that prescription drug.

If it is not going to be approved, we give a message back. Our average turnaround time on all of our requests right now is less than 1 day, and that is our average turnaround time is less than a day right now because of that streamlined process.

Mr. Bilirakis. Okay. Give me some -- tell me some strategies that have yet to be explored that you might recommend in lowering drug costs. And why haven't they been explored if you know of them? What is holding us back?

Dr. Greene. One item that is holding us back, and I think it has been hit on earlier today, is around what we refer to as real-time benefit check, because there are multiple vendors in that space. And that would allow a provider to actually, whenever they are going to e-prescribe that prescription, because the majority of prescriptions are

now sent via the e-prescribe platform, that actually a real-time check can be done with the PBM and come back to that physician.

So they would know actually what the member is going to charge, or if it requires a prior authorization, to provide a link so they can immediately fill out that form while they are in the medical chart.

Most of the roadblocks we have seen there is not that the technology isn't there, not that we don't want to connect with it, it is actually getting into the EMR platform and having that updated within those EMR platforms to make those connections.

We understand that one of the vendors in the EMR space, a rather large one, is making some enhancements on their newest version, but actually is turning that upgrade to allow a real-time benefit check, instead of taking days and a lot of IT hours, into possibly only a 4-hour upgrade that can be done.

But, again, that requires that physician or hospital system to upgrade to the latest version of that EMR system to have that capability. And that was where we would see the biggest roadblock is actually with EMRs.

Mr. Biliraki s. All right. Well, thank you very much. I appreciate it.

And I yield back, Madam Chair.

Ms. Eshoo. The gentleman yields. And now I would like to acknowledge our colleague from Illinois, Congresswoman Schakowsky, who, as I said earlier to the -- I think the last panel -- is a member of the full committee, served many years on this Health Subcommittee, and is waving on today. That is why she is last. But when you hear her, you won't ever think of her as a last.

So I am happy to recognize her for 5 minutes of questioning, and welcome her to the subcommittee where she spent so much time and did a lot of great work.

Ms. Schakowsky. Thank you, Madam Chair, and thank you for the hearing today. As you well know, as everyone in this room knows, the cost of pharmaceuticals has reached a point that no one can really ignore it anymore that is in the policy business, because in 2018 it was really the number one issue that consumers told us, voters told us, was a concern of theirs. It is a life-and-death issue, as we have found.

So I do want to just call your attention to a bill I introduced that has to do with transparency, which I don't think is the be-all and end-all answer -- transparency -- but I think it is a really important beginning.

H.R. 2296 -- I hope all of you will take a look at it. It is bipartisan. My colleague, Republican colleague,

Francis Rooney and I have introduced it, and I am hoping that we are going to get a lot of support.

What this bill would require is that pharmaceutical manufacturers notify Health and Human Services and submit a transparency and justification report 30 days before they increase the price of drugs of a certain cost by more than 10 percent or by more than 25 percent over 3 years.

And the kind of information that we would want includes the -- I mean, not only does it give taxpayer purchases notice, but we want to know the real manufacturing costs, the real R&D. We want to know how much profit is realized from that particular drug, et cetera. So we are pretty prescriptive about what kind of information we want to look at.

Ms. Purvis, one of the things that we are dealing with is that, you know, I volunteer at a food pantry, and by the end of the month you see a lot of seniors lining up. The Social Security check, their pension, whatever they may get, pretty much runs out, and I am just wondering if AARP has seen how much flexible income the average Medicare beneficiary has to spend each month.

Ms. Purvis. So I don't have specific numbers on exactly how much discretionary income they have, but we do have a lot of stories from our members who are making tough decisions,

which is pretty indicative of the fact that their prescription drug prices and costs are completely overwhelming their incomes.

We always like to remind people that Medicare beneficiaries are not nearly as affluent as they are sometimes portrayed, with a median annual income of just over $26,000 and less than $15,000 in saving. One in four have less than $15,000 in savings. So they really do not have the resources to be able to absorb the prices and price increases that we have been seeing.

Ms. Schakowsky. And does AARP have any data on how these older Americans spend -- how much they spend on prescription drugs?

Ms. Purvis. We have average information from MedPAC. If you are looking for something specifically from our members, I am happy to get back to you on that information.

Ms. Schakowsky. Or just in general what seniors --

Ms. Purvis. Generally speaking, we are mostly focused on the people who are really struggling. And what we do have is a lot of data around people who are under Medicare Part D who are facing out-of-pocket costs that exceed $10,000. So when you go back to the median annual income of $26,000 and they are spending $10,000 on out-of-pocket costs alone, obviously, that is not something sustainable.

Ms. Schakowsky. So I am very pleased that AARP has endorsed this transparency bill, and now it has been introduced in the Senate. Senators Baldwin and Braun have introduced it. Again, it is a bipartisan bill.

I am wondering, Ms. Purvis, if it is the view of AARP that this very basic form of transparency will ultimately help lower the prescription drug prices for older Americans.

Ms. Purvis. Well, first of all, thank you for your leadership on this issue. As you know, we have endorsed the bills and we are very interested and intrigued by what it is going to do.

Any level of transparency, frankly, is better than what we have right now, and I think the idea that you would require drug manufacturers to actually justify their price increases, whereas right now we really have no idea what is driving those types of pricing decisions, will be incredibly helpful in terms of looking at prescription drug prices.

Ms. Schakowsky. Thank you. I certainly appreciate AARP working on this, and so many other issues.

Everybody, take a look at the bill.

Thank you. I yield back.

Dr. Resneck. Madam Chair?

Ms. Eshoo. The gentlewoman yields back. Yes?

Dr. Resneck. Can I just have one second?

Ms. Eshoo. For a second.

Dr. Resneck. Just to say that the AMA is supportive of that type of transparency. Thank you for your leadership on this. We would even take it a step further and have also supported the FLAT Prices Act, which in addition to justification and transparency would call on a consequence for large price spikes that would involve a reduction in FDA-conferred exclusivity on drugs that have price spikes of more than 10 percent in a year.

So thank you for your leadership on this, and we look forward to working on it.

Ms. Eshoo. Well, I think that all of the members have been heard from. And on behalf of all of the members of the subcommittee, we want to thank you for your testimony. We want to thank you for your work. We want to thank you for sharing your experiences with us.

Speaking for myself, I have gained an enormous amount of knowledge from this panel today. And as it relates to our work, it will be highly instructive to us. We have a lot of things to fix. We have a lot of things to fix, and there really is an urgency to it.

What gives me -- what is a source of inspiration to me here is that there is bipartisan agreement on this. So we strengthen each other's hands because we agree that this has

to -- this task needs to be addressed. This challenge needs to be met for the American people.

And no matter what age group, no matter where people live in our country, you know, the biologics of the biology of an individual is being held against them. Medicine is part of public health. We have a responsibility to make sure that medicines reach people.

And this is -- whatever -- however this was ever designed, how the system, as it is described, is like a rat's maze. I don't know. I think on my best day I could never dream up this kind of system. I think it would be not a dream but a nightmare.

So thank you for what you have shared with us. You have enhanced our -- broadened our portfolio of thinking.

And now members are going to have 10 days to submit questions to you. As witnesses, you have an obligation to respond, and I have every confidence that you will not only respond but respond fully. Say exactly what you mean and as clearly as possible, and leave out the alphabet soups, okay? Thank you so much.

With that, I request unanimous consent to enter the following letters, testimony, and other information into the record: America's Health Insurance Plans submitted a statement, the American Society of Health System Pharmacists

submitted a statement, the National Association of Chain Drug Stores have submitted a statement, American Pharmacists Association have submitted a statement, and the National Community Pharmacists Association statement as well.

Is that it? Okay. No objection? So ordered.

[The information follows:]

**********COMMITTEE INSERT 12**********

Ms. Eshoo. Thank you, everyone. The subcommittee is adjourned.

[Whereupon, at 4:12 p.m., the subcommittee was adjourned.]