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LOWERING PRESCRIPTION DRUG PRICES: DECONSTRUCTING THE DRUG SUPPLY CHAIN

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTEENTH CONGRESS

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C O N T E N T S

	Page
Hon. Anna G. Eshoo, a Representative in Congress from the State of California, opening statement	1
Prepared statement	3
Hon. Michael C. Burgess, a Representative in Congress from the State of Texas, opening statement	3
Prepared statement	5
Hon. Frank Pallone, Jr., a Representative in Congress from the State of New Jersey, opening statement	6
Prepared statement	8
Hon. Greg Walden, a Representative in Congress from the State of Oregon, opening statement	9
Prepared statement	10
Hon. Eliot L. Engel, a Representative in Congress from the State of New York, prepared statement	223

WITNESSES

Justin McCarthy, Senior Vice President, Patient and Health Impact Group, Pfizer	11
Prepared statement	14
Answers to submitted questions	259
Kave Niksefat, Vice President, Value and Access, Amgen	27
Prepared statement	29
Answers to submitted questions	262
Jeffrey J. Hessekiel, Executive Vice President and General Counsel, Exelixis	41
Prepared statement	43
Answers to submitted questions	271
Amy Bricker, R.Ph., Senior Vice President, Supply Chain, Express Scripts	54
Prepared statement	56
Answers to submitted questions	274
Brent Eberle, R.Ph., Chief Pharmacy Officer, Navitus Health Solutions	68
Prepared statement	70
Answers to submitted questions	278
Estay Greene, Phar.D., Vice President, Pharmacy Services, Blue Cross Blue Shield	137
Prepared statement	140
Answers to submitted questions	283
Lynn Eschenbacher, Phar.D., Chief Pharmacy Officer, Vice President of Medication Management, Ascension	152
Prepared statement	154
Answers to submitted questions	288
Jack Resneck, M.D., Chair, Board of Trustees, American Medical Association	171
Prepared statement	173
Answers to submitted questions	294
Richard Ashworth, Phar.D., President of Pharmacy at Walgreens	180
Prepared statement	182
Answers to submitted questions	301
Leigh Purvis, Director, Health Services Research, AARP	188
Prepared statement	190
Answers to submitted questions	305

SUBMITTED MATERIAL

Statement of America's Health Insurance Plans, May 9, 2019, submitted by Ms. Eshoo	224

Page

Statement of American Society of Health-System Pharmacists, May 9, 2019, submitted by Ms. Eshoo 230
Statement of National Association of Chain Drug Stores, May 9, 2019, submitted by Ms. Eshoo 236
Statement of American Pharmacists Association, May 9, 2019, submitted by Ms. Eshoo 244
Statement of National Community Pharmacists Association, May 9, 2019, submitted by Ms. Eshoo 253

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, DC.

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, Luján, Schrader, Kennedy, Welch, Ruiz, Dingell, Kuster, Kelly, Barragán, Blunt Rochester, Pallone (ex officio), Burgess (subcommittee ranking member), Shimkus, Guthrie, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Carter, Gianforte, and Walden (ex officio).

Staff present: Jacquelyn Bolen, Counsel; Jeffrey C. 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, Oversight and Investigations; 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 five minutes for an opening statement.

OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

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 four decades, his meticulous straightforward reporting helped the American people make sense of the Washington healthcare 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 2products.

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.

[The prepared statement of Ms. Eshoo follow:]

PREPARED STATEMENT OF HON. ANNA G. ESHOO

I want to acknowledge that Robert Pear, the New York Times health reporter, died on Tuesday. For 40 years, his meticulous, straightforward reporting helped the American people make sense of the Washington healthcare debate. He was a giant in his field, and will be very missed.

Some of our witnesses today preferred not to be formally sworn in. I want to reiterate that each witness signed a statement certifying that, I quote, ″Knowingly providing material false information to this subcommittee or knowingly concealing material information from this subcommittee, is a crime.″

Thank you to our witnesses. My staff reached out to nearly a dozen drug companies to testify, and you are the few willing to do so. Express Scripts was the only major PBM willing to testify. CVS Health and OptumRX both said no.

Today's hearing focuses on a health crisis facing American families—the soaring costs of prescription drugs. At this hearing, we will ask each stakeholder in the drug supply chain about the role they play, the impact they have on drug prices, and the value they bring to patients.

We're going to follow the money. We're examining the system from beginning to end because in order to fix it, we must understand it, and then, we're going to act.

We've already taken the first step. The House passed two drug bills yesterday, including a bill I sponsored, to increase drug market competition.

We have a long hearing ahead of us. So, instead of a lengthy opening statement, I want to summarize my questions for the first panel now.

First, we have the drug makers—Pfizer, which earned $53.6 billion in revenue last year, and Amgen, which earned $23.7 billion. We'll also hear from a small cancer drug company, Excelixis (Ex-EL-ix-is), 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, etc. After the costs are calculated, how do you set a price? Who in the drug supply chain do you exchange money with and how?

he next link in the chain—Pharmacy Benefit Managers or 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. In 2017, Express Scripts earned $100 billion in revenue.

My question for the PBMs: What value do you add? You don't invent. You don't manufacturer. You don't conduct research and development. How do you earn your money? Who in the drug supply chain do you exchange money with and how?

On this first panel, we can conservatively estimate that our witnesses represent nearly $200 billion in revenue.

My final question for them: Where do those billions come from and where can we cut the fat, so that Americans can afford their drugs?

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

I will continue to follow the money through the drug supply chain. Thank you all for your testimony.

Ms. ESHOO. So, I'm now pleased to recognize Dr. Burgess, the ranking member of the subcommittee for five minutes of his opening statement.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

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 healthcare 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 the statue that 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 interworking's 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 the 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.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Thank you, Chairwoman Eshoo. I appreciate your work in organizing the hearing we are holding this morning. When the two of us sat down at the start of your term as Chair to discuss bipartisan goals for this Congress, we agreed that the drug supply chain hearing that I chaired in December 2017 was immensely helpful. Today's hearing is similar in nature to that hearing we held last Congress but provides a more company-specific, rather than industry-wide, perspective of each link in the drug supply chain.

I am hopeful that the witnesses here today will impart their firsthand experience and knowledge of the supply chain onto the Members of this Subcommittee and build upon the foundation we laid last Congress.

The nature of the current U.S. drug supply chain system is complex and has multiple stakeholders involved in each step of the price negotiation process. There are also actors who are essential to the supply chain, but that do not affect the price of a medication. Bringing these stakeholders to the table today will provide us with an opportunity to learn about each player's roll in the drug supply chain as well as their impact, if any, on pricing and help to inform our decisions as Congress moves forward in its efforts to address drug pricing.

It is my hope our discussion today is substantive and largely focused on the patients who are prescribed these medications because, at the end of the day, they are who matter most in this conversation. They are bearing the cost of these medications.

Prescription drugs continue to play a vital role in the United States healthcare system, from significantly improving patients' lives to producing healthcare savings through fewer hospitalizations and medical procedures. A patient's access to prescription drugs is a key healthcare issue for Americans, and within that context is the debate over affordability.

Improving access to life-saving treatments for consumers is a bipartisan priority, and I would like to see us continue to build upon the successes that we have seen from 21st Century Cures and other pieces of legislation to spur biomedical innovation. That being said, it is imperative to ensure that our healthcare system is ready

to pay for the treatments and cures in today's development pipelines when they reach patients in tomorrow's hospitals and doctors' offices.

I hope that this hearing will shed some light on the inner workings 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 Orange Book bills passing the House yesterday, but I hope that we can find a bipartisan way to move forward with additional legislation.

The hearing last Congress involved a fair amount of finger pointing among witnesses, and I expect that we will see a bit of that today. I would like to remind our witnesses that our goal is to solve the problem, and that we have invited you this morning to offer quality input so that your voice can be heard.

While 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. 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.

Thank you, Chairwoman Eshoo, I yield back.

Ms. ESHOO. Thank you, Mr. Burgess. The gentleman yields back.

I'm now pleased to recognize the chairman of the full committee, Mr. Pallone, for five minutes for his opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. 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.

[The prepared statement of Mr. Pallone follow:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Today we continue to focus our attention on reducing the price of prescription drugs by closely evaluating the pharmaceutical supply chain. It's 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. This is simply unacceptable.

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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 much different 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.

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care costs, and I look forward to hearing from our witnesses. 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.

Thank you, I yield back.

Ms. ESHOO. I thank the chairman. The gentleman yields back.

I'm now pleased to recognize the ranking member of the full committee, Mr. Walden, for five minutes for his opening statement.

OPENING STATEMENT OF HON. GREG WALDEN A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

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 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 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 healthcare, 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 healthcare 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.

[The prepared statement of Mr. Walden follow:]

PREPARED STATEMENT OF HON. GREG WALDEN

Thank you, Madam Chair, for revisiting this important issue. When I was Chairman last Congress we laid groundwork to help educate Members about the pharmaceutical supply chain and the players involved, many of whom will be represented on our two panels and the role they play in how a product is priced. It was one of our most popular hearings and I want to thank you for building upon that previous work.

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 effects drug prices by hearing from witnesses from each step of the process: manufacturers, payors, pharmacists, providers, and patients. I'd like to welcome to each of our expert panelists that will help us understand the complex journey—from molecular discoveries to patient deliveries—a single dose of medicine takes.

Our committee has done much to help get lifesaving treatments patients. This includes championing the landmark 21st Century Cures Act, led by former Chairman Fred Upton and Congresswoman Diana DeGette. This important legislation sought to modernize the nation's biomedical innovation infrastructure, streamline the process for how drugs and medical devices are approved to get new treatments to patients faster. However, the impact of cutting-edge, lifesaving cures can't be fully realized if they remain largely unaffordable to most patients. While innovation and market competition are the key drivers of price reduction, we must also acknowledge that the complexity of the supply chain has an impact on access, delivery, and cost of drugs.

In the last Congress we reauthorized the Food and Drug Administration, and gave the agency new tools and resources to get generic drugs into the market faster. We've already seen this play out—last year FDA approved a record number of generic drugs, driving competition and giving consumers more choices. Then 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

costs. I hope we can continue to work across the aisle on commonsense policies to address rising drug costs—in doing so, we will rely on the testimony and insight of our witnesses today to help us improve both innovation and affordability.

I look forward to the testimony of our witnesses and hope all Members take advantage of this opportunity to better understand this complicated but so very important issue.

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 five minutes.

STATEMENTS OF JUSTIN MCCARTHY, SENIOR VICE PRESIDENT, PATIENT AND HEALTH IMPACT GROUP, PFIZER; KAVE NIKSEFAT, VICE PRESIDENT, VALUE AND ACCESS, AMGEN; JEFFREY HESSEKIEL, EXECUTIVE VICE PRESIDENT AND GENERAL COUNSEL, EXELIXIS; AMY BRICKER, R.PH., SENIOR VICE PRESIDENT, SUPPLY CHAIN, EXPRESS SCRIPTS; AND BRENT EBERLE, R.PH., 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 me 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 ad-

dress the most challenging diseases 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 healthcare, 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:]

Testimony of Justin McCarthy
House Energy and Commerce Health Subcommittee
May 9, 2019

Chairwoman Eshoo, Ranking Member Burgess and Members of the Subcommittee, thank you for inviting me to testify today. It is an honor to be part of this panel. My name is Justin McCarthy, and I currently lead the Pfizer team which is responsible for reimbursement and market access for our innovative medicines. I have been in healthcare my entire career having been trained as a pharmacist prior to joining Pfizer.

At Pfizer, our purpose is the create breakthroughs that change patients' lives. We currently have over 100 programs in our R&D pipeline and are hoping to bring a wave of innovative new medicines to the market addressing the most challenging diseases and conditions, including cancer, hemophilia, sickle cell disease, and gene therapies that have the potential for treating and curing diseases in a single dose.

However, these innovations will not change people's lives unless they can access them and afford them. That is why we believe our future success will rest not only on the scientific innovations we bring to patients but also on the commercial innovation and solutions we create to enhance access and affordability to our medicines. To achieve this, I believe we need to work in partnership with governments and others in the healthcare sector to identify and implement solutions that relieve patient affordability burdens.

This hearing and others held by Congress, as well as the Administration's focus, has been a catalyst for this much needed collaboration. I am especially pleased to testify before this Committee as it is the one which helped create the modern-day biopharmaceutical industry with the passage of the Hatch Waxman Act, the Prescription Drug User Fee Act and its subsequent reauthorizations as well as the 21st Century Cures Act.

These laws have and continue to deliver tangible improvements in speeding new medicines to market. It would have been difficult to imagine just a few years ago that FDA could approve a drug based on real world evidence. But that is exactly what happened recently when FDA approved a new use for our breakthrough breast cancer medicine, Ibrance, thanks in large part to provisions in the 21st Century Cures Act.[1]

We need to bring that innovation mindset to address what I see as three trends that have emerged over the past several years which are exacerbating the impact of medicine costs to patients.

[1] The FDA expanded the indications for IBRANCE® (palbociclib) in combination with an aromatase inhibitor or fulvestrant to include men with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer.

First, the current system of rebates has increasingly led to perverse market incentives leading to a disconnect between negotiated net prices and prices people pay at the pharmacy counter. This evolution is creating misaligned incentives and market distortions that are driving up costs for consumers.

Second, the growth in high deductible plans and co-insurance are depriving patients of negotiated discounts and putting healthcare out of reach for many consumers. In fact, more than half of commercially insured patients' out-of-pocket spending for branded prescription drugs is now based upon the full list price, not on the negotiated price. And this trend is even more acute for medicines because patients pay higher out of pocket costs for medicines (14%) than for other healthcare costs (2%)

Just last week, a Kaiser/LA Times survey reported that almost half of those with a plan with at least a $3,000 individual deductible or a $5,000 family deductible had trouble meeting their deductible and co-insurance. And more than half of these people lacked savings equal to their high deductibles.

The third factor is that scientific advances have led to the growth of specialty medicines such as cancer immunotherapies, biologics, gene therapies, precision medicines, that weren't contemplated when the Part D design was implemented.

These factors are all coming together to create an affordability crisis for patients. Our healthcare system needs to be simpler and more transparent, and it needs to incentivize innovation while simultaneously ensuring access. And most importantly, we need to put patients first.

Pfizer intends to be a productive participant in policy making and finding meaningful solutions in the government and commercial marketplace. As such, we would like to propose four ideas to drive reductions in costs for patients and the government:

First: Shift Away from Rebates to Upfront Discounts and Pass the Savings to the Patient:

Although the traditional drug distribution and payment system helped constrain overall spending on medicines historically, the underlying mechanics now need to work better for patients. Today's healthcare system has evolved over time with changes in drug insurance benefit designs, as well as changes in the size, role, and structure of the supply chain. The current system of rebates has increasingly led to perverse market incentives culminating with a clear disconnect between list prices and prices people pay at the counter. We believe the Administration's proposed rebate rule is an important first step, but it is only a partial solution and broader reforms are needed. I encourage Congress to consider additional options that will address the distortions in the system and benefit patient affordability.

Research shows that the billions of dollars in negotiated rebates, discounts, and fees do not always directly benefit the patients who are using these medicines. These are the most vulnerable patients with serious medical conditions and they should not be shouldering the burden of subsidizing premiums for everyone. By applying the discounts and fees paid by the pharmaceutical manufacturer to the price paid by patients at the pharmacy, patients can benefit directly. In 2019, Pfizer expects to pay billions in rebates and fees to ensure Medicare Part D and commercial plan patients have access to our medicines.

Though actuarial modeling suggests that moving rebates to discounts at the point of sale will lead to increased premiums in Part D, it is important to put those potential premium increases in context. The average basic Part D premium is $32.50 in 2019, about a dollar less than in 2018. If the proposed rule was finalized, monthly premiums for Part D beneficiaries would increase between $2.70 and $5.64 in 2020, depending on the assumptions made in estimates released by HHS. Additionally, plans will have strong incentives to minimize costs and the lower premium estimates assume that plans would more aggressively manage formulary costs to minimize premium increases.

Contrary to what some analysis has said, the rebate rule is not a windfall to Pfizer or the pharmaceutical industry. We are committing to convert all our rebates to point of sale discounts to benefit what patients pay at the pharmacy counter. In addition to not withholding any negotiated rebates, we also fully expect that plans and PBMs will be able to negotiate even greater discounts above the level of our current rebates. If rebate reform was implemented, our modeling suggests that our largest price concessions to any one plan would become completely transparent to all other plans thereby putting downward pressure on our net prices.

Our modeling also shows that beneficiaries will pay less in out-of-pocket costs for their medicines. For Pfizer alone, we estimate that seniors taking Pfizer medicines could save $270 on average per year, and up to $574 per year for certain Pfizer medicines, through lower cost sharing. Notably, research also shows that sharing discounts at the pharmacy counter could reduce total health care spending, not just drug spending.

In contrast to rebates, point of sale discounts in Medicare Part D will be transparent. As such, plans and PBMs will have additional information enabling them to negotiate for lower net prices in any contract going forward. Nonetheless, despite the potential negative financial risk to the company, the move to point of sale discounts will be good for patients and the broader health care system. In fact, Pfizer believes that rebate reform should apply to all parts of Medicare, Medicaid, as well as to the products that fall within the pharmacy and medical benefits in the commercial market. It is important to avoid a bifurcated market that would continue the misaligned incentives currently in place that drive high list prices.

Eliminating rebates in the commercial markets and replacing them with upfront discounts will provide those patients with reduced out-of-pocket costs, and will in turn improve access, adherence, and overall patient outcomes. In addition, applying the changes to the commercial market will increase the likelihood, in our view, that rebate reform will achieve the goal of reducing list prices. A bifurcated market in which we eliminate rebates in government programs but maintain rebates for commercial plans will make it difficult for manufacturers to reduce list prices because while a price reduction applies to all markets, manufacturers will need to compete in the commercial market based on the current rebating system which incentivizes higher list prices and bigger rebates.

To ensure we are working towards this goal, we hope Congress will consider legislation that encourages elimination of rebates and the de-linking of fees based on the list price of a medicine in the commercial markets. These policies will ensure that patients who take these medications benefit from the negotiated discounts at the pharmacy counter. Consistent transparency in discounting is expected to lead to increased competition among manufacturers as each manufacturer competes for formulary position.

The Administration's timeline to implement these system changes can be achieved. If finalized, successful implementation of rebate reform will require coordination among all stakeholders (manufacturers, PBMs, wholesalers, pharmacies, and HHS), and additional guidance from the Administration regarding certain operational aspects of implementation. For example, the Proposed Rule would require rebates to be processed through a chargeback mechanism at the point of sale, however the Rule does not specify which entities will be permitted, and will have the capability, to process the point-of-sale price reductions.

To ensure Pfizer is ready to implement the proposed changes in the Rule, we are taking steps to enhance our processes, systems, contracts and other administrative operations.

We will work with other leaders in the healthcare sector to advance these reforms, and we're committed to lowering list prices if Congress passes legislation to extend the rebate rule to the commercial market.

Second: Capping Seniors' Out-of-Pocket Medicine Costs

Thousands of patients today are benefiting from specialty medicines that are a result of significant scientific and clinical advances. Today's innovative medicines treat highly complex conditions, such as cancer and rare diseases. In fact, among new medicines currently in clinical development across the industry, 74 percent are potentially first-in-class, meaning they represent entirely new ways of treating disease and other health issues.

Specialty medicines can provide great value to some of the hardest-to-treat diseases and may offer a more targeted treatment, meaning they can be more effective than other available options. But no one can benefit from a medicine, or any other health care treatment, that they can't afford. In some ways our health care system has not kept up with these advances, and one key example is health insurance benefit design. The primary purpose of any insurance – and health insurance should be no exception – is to protect people from a loss or risk, and to spread the cost of that protection among a large group of people. Yet, patients are increasingly being required to take on a bigger share of their medicines' costs, and that is particularly true when it comes to innovative and expensive treatments.

The Medicare Part D program – that provides insurance benefits for outpatient pharmacy medicines for people with Medicare – is a prime example of the trend in shifting costs on to patients. Part D plans can charge between 25 percent and 33 percent coinsurance for specialty tier drugs before enrollees reach the coverage gap. In the gap, they now pay 25 percent co-insurance for all brands. Then once they hit the catastrophic threshold ($5,100 in total drug costs in 2019), they pay 5 percent coinsurance. There is no maximum out-of-pocket cap.

This makes the Medicare Part D program an outlier among most other insurance programs that provide coverage for medicines. Further, all other Medicare-covered services have some form of cap or other supplemental protection (like Medigap) available against out-of-pocket costs.

A recent analysis by the Kaiser Family Foundation examined expected annual 2019 out-of-pocket costs for more than 2 dozen specialty tier medicines and found that median annual out-of-pocket costs ranged from $2,622 for to $16,551. For many of those medicines, most of that spending occurred above the catastrophic threshold.[2]

This significant cost-sharing burden is taking a serious toll on their ability to access needed medicines. In fact, there is evidence that at least a quarter of new Medicare Part D prescriptions are abandoned at the pharmacy counter if beneficiaries are asked to pay $50 or more, which unfortunately is often the case. This number can exceed 50% for new prescriptions. This is bad not only for patients, but also for overall healthcare system cost.

I think most would agree that cost-sharing requirements should not be so large as to inappropriately restrict or interfere with the proper use of medications, which can lead to negative health outcomes and additional costs to the health care system. Multiple studies have repeatedly shown that higher cost-sharing leads to reduced or delayed initiation of treatment, and lower adherence rates, which, in turn, may result in worse outcomes for patients as well as higher overall Medicare spending. Examples of studies showing the impact of poor adherence on outcomes and spending include:

- Medicare patients with Parkinson's disease, adults with Crohn's disease, children with cystic fibrosis and patients with rheumatoid arthritis have all been shown to achieve health care savings through improved use of medicines. [3]
- Advanced melanoma patients with high adherence to immunotherapy experienced both lower all-cause and melanoma-related costs as compared to patients with low adherence.[4]

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[2] Henry J. Kaiser Family Foundation. Medicare Part D Enrollees with Serious Health Conditions Can Face Thousands of Dollars in Out-of-Pocket Costs Annually for Specialty Drugs. January 29, 2019. https://www.kff.org/medicare/press-release/medicare-part-d-enrollees-with-serious-health-conditions-can-face-thousands-of-dollars-in-out-of-pocket-costs-annually-for-specialty-drugs/

[3] YJ Wei et al. Antiparkinson Drug Adherence and Its Association with Health Care Utilization and Economic Outcomes in a Medicare Part D Population. Value in Health 2014 17(2), 196-204. BG Feagan et al. Healthcare Costs for Crohn's Disease Patients Treated with Infliximab: A propensity Weighted Comparison of the Effects of Treatment Adherence. J Med Econ. 2014;17(12):872-80. AL Quittner et al Pulmonary Medication Adherence and Health-Care Use in Cystic Fibrosis. CHEST Journal 2014, 146(1), 142-151. Grabner, et al. "Costs Associated with Failure to Respond to Treatment among patients with Rheumatoid Arthritis Initiating TNFi Therapy: a retrospective claims analysis." Arthritis Research & Therapy (2017) 19:92.

[4] K Gupte-Singh et al. Adherence to Cancer Therapies and the Impact on Healthcare Costs among Patients with Advanced melanoma in the USA. Proceedings of the 22nd Annual International Meeting International Society of Pharmacoeconomics and Outcomes Research; 2017 May; Boston, MA. Abstract available at: https://www.ispor.org/ScientificPresentationsDatabase/Presentation/70971?pdfid=49558

- For patients with multiple sclerosis, initiation of disease modifying therapy was associated with significant reductions in health care resource utilization (emergency room or urgent care visits, and hospital inpatient stays) and non-prescription medical costs (up to $5,700).[5]

In fact, in 2012 the Congressional Budget Office credits Medicare policies that increase use of medicines with savings on other Medicare costs, recognizing that a 1% increase in number of prescriptions filled results in a 0.20% reduction in spending on medical services. Since then, research has shown that offsets may be 3 to 6 times greater for beneficiaries with chronic conditions.

It is critically important, therefore, that we review cost-sharing burdens in the Medicare prescription drug program and take steps to modernize the benefit to ensure seniors don't have to make the difficult decision of forgoing their needed prescriptions.

We need to start by adding a reasonable out-of-pocket maximum to the Part D benefit. However, we can and should go further and fundamentally restructure the Part D benefit design so that it is simpler for beneficiaries and more sustainable for the government.

To help mitigate the additional cost to the government of modernizing the Part D benefit to relieve the significant cost sharing burden many Medicare enrollees face today, we support policies advocated by organizations across the ideological spectrum that would require both the health plan and the pharmaceutical industry to shoulder more of the expense of insuring seniors in the program. For example, one concept that holds promise is changing the benefit design by adding an out-of-pocket cap, removing the Medicare coverage gap, and restructuring the catastrophic benefit so that the costs of drug benefits would be paid by a combination of Part D plans, drug manufacturers, and federal government reinsurance.

We are confident that we can achieve these policy changes in such a way that impact to beneficiary premiums is minimal and are ready to work together with Congress to find ways to modernize the Part D benefit to provide much-needed relief for Medicare enrollees.

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[5] Nicholas J et al. Comparison of Disease-modifying Therapies for the Management of Multple Sclerosis: Analysis of Healthcare Resource Utilization and Relapse Rates from US Insurance Claims Data. PharmacoEconomics Open. 2017. Available at: https://link.springer.com/article/10.1007/s41669-017-0035-2

Third: Knocking Down Barriers to Lower-Cost Biosimilars:

Medicines are the only segment of the healthcare system with a built-in cost containment mechanism. When a medicine's patent expires, lower-cost generics are made available, often at just 5% of the cost of the original branded product.

This system is working well for generic drugs. In fact, 9 out of 10 drugs sold in the U.S. today are lower-cost generics. However, the system is not yet working in the biologics space where the adoption of biosimilars is facing resistance.

Building on the success of the generic market, establishing a robust biosimilars market can help to lower the overall healthcare costs in the United States, and Pfizer is committed to bringing these more affordable treatment options to patients.
With more than 10 years of global in-market experience and six approved products in major markets, Pfizer is proud to be a leader in biosimilars and at the forefront of this vital healthcare segment. Pfizer is the leading biosimilars company worldwide by revenue, and in the U.S., we are the industry leader with five FDA-approved biosimilars.

As a major producer of biosimilars, Pfizer appreciates the actions Congress took through the Biologics Price Competition and Innovation Act (BPCIA) of 2009 to provide an abbreviated pathway for biosimilars to gain FDA approval. And Biosimilars have the potential to save the U.S. billions in health care costs, providing a solution that will lower health care costs for both patients and American taxpayers, as well as improve public health. That's why we must incentivize the use of biosimilars, which today can be as much as 40% less expensive than the branded biologic for Medicare patients.

Unfortunately, adverse incentives that favor higher-cost originator biologics are keeping biosimilars from reaching patients. In many cases, payers decline to include lower-cost biosimilars or generics in their formularies because they would risk losing the rebates they can get by covering higher-cost medicines. I can't think of a more concerning example of a broken U.S. healthcare system that is directly impacting the pocketbooks of Americans.

For instance, Pfizer produces a biosimilar which have struggled to gain market share. The primary barrier to its uptake is an anticompetitive contracting scheme that relies on rebates. The centerpiece of the scheme is the "rebate trap" that uses pricing penalties (i.e., the loss of significant rebates) to coerce insurers to enter into exclusive deals that cover the reference product while effectively blocking the biosimilar from coverage.

In addition to exclusionary contracting, we have also witnessed misleading marketing practices that mischaracterize important elements of biosimilar criteria. This creates doubt and confusion among patients, and it must end. Interestingly, the rebate reform I referenced earlier would go a long way toward removing the perverse incentives that lead to such exclusionary contracts.

At Pfizer, we believe there are several solutions that could help incentivize patients and providers to adopt biosimilars and share in the savings associated with their use. We believe that increasing the adoption of biosimilars will reduce costs to the Medicare program. Let me touch on two:

A Shared Savings Biosimilars Model

Congress could direct the CMS Innovation Center (CMMI) to create a biosimilar "shared savings" approach in which Medicare savings associated with prescribing a biosimilar, as compared to a reference biological, would be shared with providers. Currently, providers in Medicare Part B are reimbursed for administering biosimilars at average sales price (ASP)+6% (less under sequestration), of which the federal government pays 80% and beneficiaries pay 20% coinsurance. To increase biosimilar utilization under the program, providers could share in the difference in total ASP between the biosimilar and its reference biologic, for each administration.

For example, in the first year of a biosimilar being on the market, providers would receive, as an additional payment, 100% of the difference between the ASP of the biosimilar and the ASP of its reference biologic. In the second year, providers would receive 75% of the difference and in the third year and through the budget window, providers would receive 50% of the difference.

Reduced Patient Cost Sharing for Biosimilars

Congress could direct CMS to establish $0 cost sharing for all beneficiaries who utilize biosimilars in Medicare Part B. These savings would go directly into the pockets of patients who use these medicines, as well as to taxpayers who will benefit from the lower costs. This reduction in cost sharing would apply to patients who have no supplemental coverage, and patients with supplemental coverage that have deductibles or other cost sharing and could be time-limited.

Fourth: Accelerate the Shift to Value Based Care

Pfizer supports the move to value-based healthcare and is prepared to stand behind the benefits that our medicines deliver to patients and to the United States healthcare system.

This will require thinking about the value of healthcare interventions, including medicines, in a more comprehensive way, and designing new approaches to reimbursing participants in the system with regard to that value. It will also require the evolution of insurance designs that remove barriers to high-value treatments.
Further, we believe that we can help our healthcare system operate more efficiently and deliver better value to patients and payers when we also think through ways to address the so-called social determinants of health.

The U.S federal government is already trying to create a healthcare system where hospitals are rewarded for keeping patients from being readmitted, and where physicians get paid more to prevent disease than they do to simply treat it.
We strive to create a system where companies like Pfizer get paid based on the number of strokes we prevent or the number of cancer patients who go into full remission, rather than the number of pills we sell.

In such a system, if our medicines do not produce all the results we expect, we would be paid less. And if they do produce those results, we would be paid more. If done correctly, these arrangements – focused 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.

To make this a reality, we need Congress' help to address impediments that are slowing down the facilitation of these arrangements in the current system for the good of patients. Congress should clarify the Anti-Kickback Statute, the government price reporting requirements, and other laws to encourage interactions between manufacturers, health plans, PBMs, providers (e.g. pharmacists) and beneficiaries that allow for value-based purchasing arrangements, more comprehensive medication adherence incentives, and medication synchronization programs.

For example, offering patients incentives can be an extremely effective mechanism in promoting medication adherence. Current law only allows incentives for a very limited selection of preventive clinical services, and only individuals who are asymptomatic and not currently suffering from an injury, illness, or medical condition qualify.

We believe that broadening this definition to include incentives for interventions that help those already suffering from illness—as well as adherence programs to improve a beneficiary's ability to obtain medical items and services—will promote industry innovation and lower costs to the healthcare system.

We also see the value in pharmacy programs that combine medication synchronization with medication reviews and counseling to help identify and address gaps in patient care and increase adherence and persistence. These programs ultimately help to drive savings to the health care system

The complexities inherent in value-based contracting arrangements and the lack of clarity with respect to the existing Anti-Kickback Statute (AKS) safe harbors cannot be overstated. There is currently no safe harbor to the AKS that specifically addresses value-based arrangements. Instead, manufacturers and health plans must evaluate such arrangements under existing safe harbors, such as the discount or personal services safe harbors, which were not written with value-based contracts in mind.

Manufacturers also must navigate complex government price reporting regulatory requirements that do not sufficiently provide guidance for the potential price fluctuations over time that are associated with value-based arrangements, where a rebate or refund might be paid years after the patient started their drug therapy. Finally, value-based arrangements present operational challenges, such as issues associated with: (1) the logistics of collecting patient outcomes data relevant for a drug; (2) adjudicating disputes over outcome metrics; and (3) developing agreements and procedures for how to handle cases in which patient adherence affects outcomes.

As much potential as value-based arrangements offer, they function within the constraints of health insurance designs that don't always serve patients as well as they could. As already discussed, high cost-sharing for medicines can have a negative impact on adherence and outcomes. Applying the principles of value-based insurance design which promote the use of high-value care through lower cost-sharing can serve both patients and payers well.

Consider that many employers now are utilizing high-deductible plans coupled with health savings accounts. While these plans typically have lower premiums, patients are required to spend thousands of dollars out of pocket before their insurance coverage kicks in for needed medicines, creating a major affordability challenge for some patients.

The law allows insurers to cover certain preventive medicines before patients hit their deductible, but many medications are not allowed to be covered on a pre-deductible basis, creating cost barriers to care for patients, especially those with chronic conditions like diabetes, asthma, and mental health disorders. We believe the law should be changed to allow insurers to exempt more preventive medicines (including those that prevent chronic conditions from worsening) from the deductible. Ensuring patients can access their medicines can lead to significant downstream cost savings to the system by reducing hospitalizations and emergency care.

Finally, there needs to be a greater recognition of the role that social factors play in determining health. We are encouraged by the steps that CMS has taken to allow Medicare Advantage plans to provide nonmedical benefits that address the social determinants of health for people with chronic disease. For example, beneficiaries can now receive expanded meal delivery, transportation for non-medical needs like grocery shopping, and in-home services such as safety modifications in order to improve their health and/or overall function. We think efforts like these should be expanded to benefit even more patients.

In closing, across Pfizer, we share a passion to significantly improve patients' lives. And for all of us, our work is personal. I joined Pfizer because I truly believe we are a science-based company focused on bringing the next wave of innovations to patients to make a difference in their lives. Our success is directly connected to how strong our science is.

Today, more than 784 million people around the world used a Pfizer medicine or vaccine to improve their health and, in many cases, save their lives. We estimate[i] that Pfizer vaccines protected more than 65 million babies and elderly patients; our medicines helped reduce the risk of heart attack or stroke for more than 48 million cardiovascular patients; and oncologists used our therapies to treat more than 1.2 million people battling cancer. These are humbling numbers. More important, they represent real people; real people who rely on our innovations. We also have a bold ambition to bring 15 breakthroughs to patients in the next 5 years.

That is why we come to work every day. It's why the researchers in our labs in California, Connecticut, Massachusetts and New York work day-in and day-out to discover the next treatment or cure. It's why our manufacturing colleagues, who make some of the most complex molecules in existence, in Georgia, Kansas, Michigan, Missouri, North Carolina, Ohio, Pennsylvania and Wisconsin – work to ensure the reliable supply and highest standards of quality of our products.

These potentially lifesaving medicines will not reach the people who need them the most if our patients, your constituents, cannot afford them. Our system needs to be simpler and more transparent, and it needs to incentivize innovation while simultaneously ensuring access.

We are actively working together across the healthcare sector to identify and implement solutions that relieve patient affordability burdens. Where we can, we all need to come together to find systemic solutions to these persistent problems.

We all want America to remain as the leader when it comes to innovative medicines, and to ensure that people have access to them at that moment when they need it the most.
No patient should have to wait.

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

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[1] Patient counts are estimates derived from multiple data sources.

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

Next, I would like to call on Mr. Niksefat. You are recognized for five 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 is 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:]

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TESTIMONY OF KAVE NIKSEFAT
VICE PRESIDENT, U.S. VALUE & ACCESS
AMGEN
BEFORE THE U.S. HOUSE COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH
MAY 9, 2019

Full Committee Chairman Pallone and Ranking Member Walden, Health Subcommittee Chairwoman Eshoo and Ranking Member Burgess, and Members of the Subcommittee, thank you for inviting me to participate in today's hearing. I am Kave Niksefat, Vice President and Head of U.S. Value and Access at Amgen.

I commend the Committee and Subcommittee for holding a second hearing on the drug supply chain, given the important role it plays in determining what patients pay for their medicines. And I appreciate the opportunity to provide Amgen's perspective.

Amgen was founded nearly 40 years ago by a handful of biotech entrepreneurs who set up shop in a small office park in Thousand Oaks, California. Our first medicine, Epogen®, was approved by the Food and Drug Administration (FDA) in 1989 and changed the lives of many thousands of dialysis patients suffering from chronic kidney disease. Today, Amgen is still based in Thousand Oaks, but we now employ more than 21,000 staff members, who do business in roughly 100 countries globally. Our portfolio includes 20 medicines that treat many of the world's most devastating and costly illnesses, including cancer, cardiovascular disease, migraine, and osteoporosis. We are committed to the discovery and development of new medicines, having invested $3.7 billion in research and development last year and nearly $19 billion over the last five years. We also operate one of the most reliable biologics manufacturing networks in the world, including facilities in California, Massachusetts, Rhode Island, Puerto Rico and Kentucky and we just broke ground on a new, next generation biomanufacturing plant in Rhode Island.

Tremendous advances in science and technology have put us on the cusp of what we hope will come to be seen as the "biocentury." Just as physics and engineering led to extraordinary advances in the 20th century, we are now at a true inflection point in terms of our understanding of biology and, with it, our ability to take on serious illness, such as Alzheimer's disease, and help people live longer, healthier lives. The promise of the biocentury comes at a critical juncture for our country, as an estimated 10,000 Americans will turn 65 every day for the next 20 years – leading to an inexorable rise in diseases associated with the aging process.

We recognize that patients are having difficulty affording their health care, including their prescription medicines and we want to help this Committee and others advance solutions to lower out-

of-pocket costs for patients. We acknowledge that rising drug costs are a burden to patients especially as co-payments and deductibles on medicines have increased and as high deductible health plans become more prevalent. All of these factors together mean more patients experience increased out-of-pocket costs for prescription medicines and they need our collective help to ensure they can access needed therapies.

We also recognize that the healthcare supply chain is complicated, but that each participant in it plays an important and valuable role in our market-based system which I firmly believe is and continues to be the best healthcare system in the world. Simply put, the biopharmaceutical industry discovers more innovative medicines in the United States (U.S.) than anywhere else in the world and the benefit is that patients in our country get broader and faster access. Competition is driving bigger rebates on medicines every year and last year list prices for brand-name medicines increased less than the overall rate of inflation.[1]

But we can still do better – much better. And that starts by ensuring that all patients benefit directly from the market-based competition and negotiations that exist today when they pick up their drugs from the pharmacy counter.

I would like to thank the Committee for bringing to light the complexity of the U.S. drug supply chain and trying to find bipartisan solutions to improve access to medicines. The truth is that without all of us on this panel and others in the marketplace working toward solutions such as health insurers, employers, drug distributors, hospitals and physicians, we can make little progress for patients. There is too often a singular and overly simplistic focus on the list price of medicines and pharmaceutical companies' role in drug pricing. While Amgen and all innovators seek to set the list price of our medicines appropriately based in part on their value to patients, all parts of the supply chain have a role in ensuring the affordability of medicines[2].

In my testimony today, you will not hear me blame any one actor in the supply chain or call to eliminate pharmacy benefit managers (PBMs). To the contrary, we believe that PBMs play an essential role in the supply chain and as a large employer, Amgen works with a PBM each year to manage our own pharmacy benefit for our employees. What you will hear from me, however, are my impressions of the embedded complexities in the system that exist in portions of the supply chain as well as some solutions Amgen supports for remedying these important issues for patients so they can start to access needed medicines at more affordable prices.

First, I will describe some of the actions Amgen is taking to address the affordability problems that face our patients. We take seriously our duty for pricing products responsibly and have put forward

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[1] IQVIA. The Global Use of Medicine in 2019 and Outlook to 2023. January 2019. Available at: https://www.iqvia.com/institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.

[2] Amgen establishes the list prices of 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, the unmet medical need, the size of the patient population, the investment and risk undertaken, and the need to fund continued scientific innovation.

several solutions to health plans, PBMs and patients that lower both the net and list price of many Amgen medicines.

Second, I will highlight areas of the drug supply chain that fail to drive the more than $150 billion dollars that the biopharmaceutical industry provides in price concessions[3] to the patient in the form of lower out-of-pocket costs at the point of sale.

Third, I will offer policy solutions that Amgen supports to improve access and affordability for our patients.

Part 1: Amgen Actions to be Part of the Solution

Amgen has taken a number of steps to proactively offer solutions to address affordability issues for our patients.

List Price Reduction for Repatha®

Amgen continues to work diligently to address affordability issues for our patients. Last year, Amgen took the unprecedented step of making our innovative therapy Repatha® available at a 60% reduced list price, with the hope of improving affordability for patients, while also supporting the growth of this product in a competitive marketplace. Repatha® is one of Amgen's growing new medicines. It is approved by the FDA to prevent heart attacks and strokes by substantially lowering critically high levels of cholesterol in a wide range of high-risk patients with established cardiovascular disease. In clinical trials, Repatha® reduced the risk of heart attack by 27%, the risk of stroke by 21%, and the risk of coronary revascularization by 22%.[4]

Cardiovascular disease is one of the nation's most significant health challenges, costing the U.S. more than $600 billion each year and expected to exceed $900 billion by 2030. It is estimated that 39 million adults could benefit from managing their cholesterol. Repatha® is part of the solution to reducing the overall cost of healthcare in the U.S.

Amgen estimates that approximately half of all potential Repatha® patients are Medicare beneficiaries. For Medicare patients in particular, the new lower list price should have immediately reduced patient out-of-pocket costs from approximately $280 - $370 per month to $25 - $150 per month.

As I will explain later in my testimony, despite this list price reduction, embedded issues in the supply chain in combination with marketplace competitive dynamics have stymied a rapid move to better affordability for our Medicare patients despite the dramatic reduction.

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[3] See https://www.drugchannels.net/2019/04/the-gross-to-net-bubble-reached-record.html. Gross to net includes rebates, off-invoice discounts, price concessions, as well as manufacturers' payments to drug channel participants such as administration fees, product returns, the 340B Drug Pricing Program, and other items.

[4] Sabatine MS, Giugliano RP, Keech AC, et al, for the FOURIER Steering Committee and Investigators. N Engl J Med. Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease. 2017; 376:1713-22.

Leveraging 21st Century CURES to Establish a Lower than Expected List Price for Aimovig™

In 2018, we launched Aimovig™, a novel treatment developed specifically for migraine prevention and the first FDA-approved treatment to block the calcitonin gene-related peptide receptor (CGRP-R). For patients with migraine, no new preventive options have been made available for many years and significant unmet need remains for these patients. Prior to approval, Amgen was able to use key new communication pathways provided by the 21st Century CURES Act and subsequent FDA guidance to have economic discussions with payers around this important innovation. This dialogue with payers was helpful in informing our decision on how to price Aimovig™ and was a key factor in us introducing Aimovig™ at a list price that was approximately 20% to 65% below initial expectations.[5] More than 200,000 patients have accessed Aimovig™ since its approval. We would like to thank the committee for their bipartisan work in enacting the 21st Century CURES Act and wanted to illustrate that your legislative actions have made a difference.

Within a few months of Aimovig™'s launch, two competitors entered the migraine market which has driven the net price of our product down. While this demonstrates that market-based competition is working to reduce costs in the system and manufacturers are offering lower net prices, most of today's migraine sufferers are not directly benefiting from negotiated discounts. As I articulate below, Amgen believes that there are policy solutions to ensure patients get access to the lower prices that are negotiated on the product they need and that they see this benefit in the form of lower out-of-pocket costs at the pharmacy.

Developing a Robust Portfolio of Biosimilars as a Means to Further Improve Patient Affordability

Another way that Amgen is paving the way on affordability is through our commitment to bringing U.S. consumers one of the largest portfolios of biosimilars. When Chairwoman Eshoo and Ranking Member Barton reached across the aisle and led development of the Biologics Price Competition and Innovation Act (BPCIA), which created the biosimilars approval pathway, we embraced the opportunity to bring more affordable biologics therapies to U.S. consumers. We recognized that biosimilars would become an important part of broadening patient and physician options for treatments and foresaw that our expertise in developing and manufacturing biologics also would apply to biosimilars. We currently have 10 biosimilars in our portfolio. As we launch our biosimilars over the coming years at the appropriate times, we continue to believe that they will bring meaningful cost savings to the healthcare system for patients, physicians, pharmacists, and payers.

As I will explain later in my testimony, we believe that the current U.S. biosimilar market is healthy and robust and that patients will benefit from fairly-based competition on a level playing field. Therefore, we are not supportive of policy changes that have been proposed which would create an unlevel playing field between innovator medicines and their biosimilar competitors that could drive up costs to patients and the government.

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[5] https://www.optum.com/resources/library/new-migraine-drugs.html

A Leader in Value-Based Partnerships

Amgen remains a leader in value-based partnerships with over 120+ value-based partnerships across 35 countries in 6 therapeutic areas and at least 20 value-based partnerships in the U.S. with at least 15 different commercial payors. A value-based partnership is a collaboration that allows partners to experiment with innovative approaches designed to improve the patient experience, quality and efficiency of care, or both. Examples of value-based arrangements that Amgen has sponsored include our Repatha® Outcomes Based Rebate in which drug costs will be refunded if patients experience a heart attack or stroke while on our drug; the Imlygic® Population Cost Cap where Amgen takes risk for any additional doses of a cancer chemotherapy drug beyond a set level; and Enbrel® Effectiveness constructs where Amgen takes risk on the outcomes, and provides higher discounts if patients do not obtain expected outcomes. These value-based arrangements are offered in addition to standard discount contracts and support mutually beneficial opportunities to reduce costs, improve care and enhance patient experiences. Such partnerships reflect the company's belief that managing disease through innovative medicine is key to containing healthcare costs and improving population health.

As I will explain later in my testimony, we believe there is still more that can be done here especially in Medicare, where the opportunities to offer value-based contracts is limited.

Competing Within the Marketplace to Lower Net Prices

In addition to the steps that I just mentioned, the average net price for our medicines has not increased above the rate of inflation since 2017. Further, the net selling price of our medicines declined in 2018 and we expect a mid-single-digit decline in 2019.

Additionally, it is important to highlight that patient out-of-pocket costs have continued to increase year over year even as our discounts in competitive marketplaces continue to increase and our net prices continue to decrease.

As I will explain later in my testimony, we are supportive of policies that would pass rebates on to patients at the point of sale or that would move from back end rebates to up front discounts so patients can directly benefit from these rebates.

Part 2: Removing Barriers to Patients Realizing the Savings Generated by Our Market Based System

Much of the public debate about the cost of medicines has focused on list prices. Pharmaceutical companies set the Wholesale Acquisition Cost (known as "WAC") which is often referred to as the "list price." While the WAC or list price for each of Amgen's products is in part anchored to a medicine's value driven price – the value a medicine is likely to deliver to patients, to payers, and to society – the price is frequently established against a backdrop of a competitive environment. List price is the price we charge to wholesalers and distributors who purchase our medicines, but it does not account for the rebates and discounts we negotiate with the complex web of wholesalers, distributors, hospitals, providers, pharmacies, PBMs, health plans and other entities. Increasingly, list price has also become the basis of patient out-of-pocket costs with the growth in high deductible health plans and coinsurance constructs. The problem is not that the market-based negotiations are not effective at generating savings, it is that the savings never make their way to patients in the form of reduced out-of-

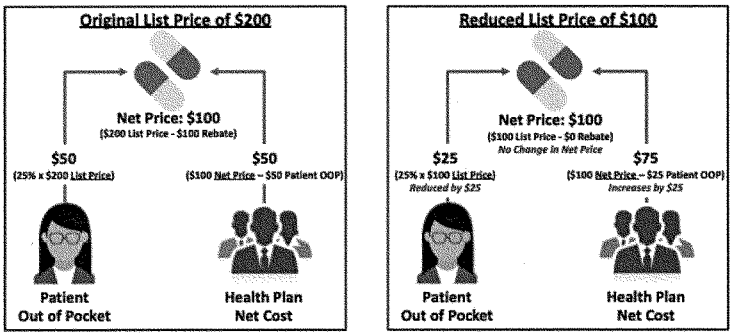
pocket cost at the pharmacy counter since patient out of pocket cost continues to be tied to list price rather than net price.

PBMs play an important role by handling the pharmacy benefit for health insurers and employer groups and facilitate access to drugs for millions of consumers who have medicines prescribed by their physicians. But due to marketplace consolidations which have occurred in recent years, three PBMs now control access to medications for over 80% of the market. PBMs exert great influence over terms for how much pharmacies are paid for dispensing the drug and use volume-buying leverage to negotiate deep discounts off the price of the drug. When competitor products are available, PBMs have the leverage to determine whether drugs are placed on formulary and which drug products are used most frequently. So, in competitive therapeutic classes if rebate concessions are not granted, PBMs often exclude a medicine from the formularies.

The pressure to increase rebates and price concessions in exchange for coverage under the health plan has grown immensely in recent years as prospective, multi-year, ever-increasing rebate guarantees have grown exponentially in the commercial market and competitive dynamics in the Medicare Part D marketplace have often driven plans to seek ever larger rebate pools. As a result, the current system sees drug manufacturers competing against each other not only on the lowest net price of a drug, but also the largest total rebate. This dual focus creates pressure on net prices and list prices, but in opposite directions: in a competitive environment, net prices are especially pressured to decrease but list prices are pressured to increase in order to provide greater rebates. The growing gap between list prices and net prices from price concessions (also known as the "gross-to-net bubble") has expanded to more than $150 billion in 2018.[6]

At the same time, the manner in which PBMs determine a health plan's "net cost" creates barriers to reducing list prices. PBMs calculate plan "net cost" by taking the net price of the drug (list price minus rebate) and reducing it further by the patient's out of pocket cost. So, the more the patient pays out of pocket, the lower the plan's "net cost". Since patient out of pocket cost is increasingly based on list price, higher list price drugs result in higher patient out of pocket costs and, therefore, lower plan "net cost". This means that PBMs can view list price reductions as increasing plan "net cost" for the sole reason that they decrease patient out of pocket cost. See below for an illustrated example in which a drug reduces its list price of $200 to its net price of $100.

[6] See https://www.drugchannels.net/2019/04/the-gross-to-net-bubble-reached-record.html. Gross to net includes rebates, off-invoice discounts, price concessions, as well as manufacturers' payments to drug channel participants such as administration fees, product returns, the 340B Drug Pricing Program, and other items.



As you can see in the illustration, without changing the net price to the healthcare system, the lower list price drug is viewed as increasing plan "net cost" because the patient pays less out of pocket at the pharmacy counter. In a better functioning system, list price reductions should be encouraged not discouraged. We believe the best way to get to this better functioning system is to pass along negotiated discounts to patients at the pharmacy counter, just like other negotiated discounts in the healthcare system are passed along to the patient at the provider's office. This system would incentivize list price reductions and reduce the pressure to lift list prices to generate ever increasing rebate demands.

We believe our experience with Repatha® is a good example to highlight these embedded complexities in the system.[7] As mentioned above, in October of 2018 we announced that Amgen made Repatha® available at a reduced list price of $450 per month, a 60% reduction from the medicine's original list price, with the hope of improving affordability for patients. Amgen made Repatha® available at a reduced list price by introducing new National Drug Codes (NDCs). The new lower list price option for Repatha® is identical to the original list price option of Repatha®. Amgen is preparing to discontinue the original list price option of Repatha® by the beginning of 2020. We chose this approach in consultation with multiple stakeholders in the supply chain, including health plans and PBMs, in an attempt to minimize the disruption to the drug supply chain during a transition period while PBMs adjust their agreements with their downstream employer and health plan clients. Absent such a transition period, we were concerned that commercial health plans and PBMs would immediately shut off access to Repatha® in favor of the other proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor option on the marketplace that offered a higher overall rebate based on a higher list price.

While we have seen some adoption of the lower list price option for Repatha®, thus far the uptake has been slower than you might imagine. This, despite the fact that Amgen has offered all PBMs and health plans contracts that ensure the net price after rebates of the lower list price option of Repatha® is always equal to or less than the contracted net price paid for the original list price option of

[7] The complexities here are exacerbated by the presence of a competitor who has admitted infringing our patents.

Repatha®. Unfortunately, even with the favorable net pricing of low list price Repatha®, some PBMs have determined that the lower list price option of Repatha® has a higher "net cost" because the patient's out of pocket cost is reduced with the lower list price.

In Medicare Part D, approximately 60% of patients have access to the lower list price option of Repatha® but the vast majority of Part D plans continue to classify Repatha® as a Specialty medication despite the fact that the list price of $450 per month is below the $670 per month Specialty threshold established by the Centers for Medicare and Medicaid Services (CMS). In fact, only 6% of Medicare beneficiaries can access Repatha® on a non-specialty, fixed co-pay of less than $50 per month commonly associated with similarly priced drugs. We understood that PBMs and plans found it challenging to change Repatha's tier when it did not make sense for them to do the same with respect to our competitor's higher priced product.

Likewise, outside of Medicare, only about half of commercially insured beneficiaries have access to Amgen's lower list price option of Repatha® and it remains excluded from coverage on a number of PBM formularies. While Amgen has offered equivalent or lower net prices on the low list price option of Repatha®, Amgen pays a lower nominal rebate to achieve that same net price. This lower rebate makes the lower list price option for Repatha® less attractive to PBMs, especially in a marketplace where the competition can offer a higher overall rebate when achieving the same net price. In fact, due to our multi-year agreement with a PBM, Amgen's own employees do not yet have access to the lower list price option of Repatha® through our PBM. Why? One word: Rebates.

It is important that policymakers understand the nuances of the market structure and problems inherent in the complex system in order to develop appropriate remedies to help fix the rising out-of-pocket costs for prescription drugs. PBMs often argue that these factors are used to keep health insurance premiums low, however it has become harder and harder to understand what proportion of rebate dollars help keep premiums affordable versus other uses. This essentially results in sick patients who take innovative medicines subsidizing the healthy patients, which is counter to the purpose of insurance.

Recently, there have been policy proposals and market shifts that would incentivize the market to move away from back end rebates and more toward up front discounts. We support ideas like these which will ensure that patients will benefit from the discounts secured by Medicare Part D plans. Actions like these will help to better align plan incentives with the interests of patients and help address rising out-of-pocket costs for prescription drugs for Medicare beneficiaries. We also support recent announcements of steps being taken in the commercial marketplace to allow patients to benefit from the net price at the pharmacy counter. Examples of such steps include UnitedHealthcare's decision to pass through rebates at the pharmacy counter in their fully insured plans in 2019; Optum Rx's similar announcement that new PBM commercial clients that sign contracts after January 1st, 2020 will be required to pass through rebates at the pharmacy counter; and Anthem's announcement that they will pass through rebates at the pharmacy counter in their Fully Insured plans in 2020. But until more plans make these kinds of changes, the majority of Americans still will not have access to lower priced medicine and the rebate dollar will continue to be the largest economic driver in the marketplace.

Part 3: Policy Solutions to Improve Affordability for Patients

We are supportive of the following policy solutions to improve affordability for patients:

- **Require Rebates to Be Passed on to Patients at the Pharmacy Counter:** We are supportive of policy changes that would ensure savings from rebates flow directly to patients. One approach would require that a portion of the rebate be passed through to patients at the pharmacy counter. We also support the Administration's proposal to move from backend rebates to up front discounts in order to lower out-of-pocket costs for patients. Even in the face of net price declines as we experienced last year, patients are not seeing the benefits of these net price declines. At the state level in 2019, five states considered requiring health plans to pass through at least a majority of rebates to patients; and last year, Louisiana became the first state requiring health plans to disclose to its insurance commissioner the percentage of rebates made available to enrollees at the pharmacy counter. The fact remains that at both the State and Federal level, we are supportive of lawmakers' efforts to look for ways to ensure patients can access these rebate dollars to improve affordability for patients. We strongly support these efforts and hope to continue to engage with the Committee on this topic going forward.

  As stated above, there have been recent announcements that health plans have started to provide offerings that give patients access to the rebates at the pharmacy counter. These are limited positive first steps in the commercial market and unfortunately do not extend to Part D. While we are encouraged to see these types of announcements that the PBM business model is beginning to evolve, the rebate dollar will continue to be the single largest economic driver in the drug supply chain. At Amgen, we continue to try to lead on these issues. For example, as a large employer, our benefits structure with a large PBM is set up such that if our employees are faced with paying the list price of a covered prescription at the pharmacy counter, the discounts are passed through to them at the point of sale.

  In terms of specific policy solutions to address the issue with Part D patients having difficulty accessing Repatha® at more affordable cost sharing levels, we think CMS can take immediate actions to help address this issue. Specifically, CMS can issue guidance highlighting that, in instances where manufacturers lower list price for medicines that puts them below the specialty tier threshold of $670, plans should move the lower list price drug from the specialty tier to a tier with better (or no worse) cost sharing (e.g., preferred brand). We hope to work with the Committee on this specific policy solution since it is a way to quickly reduce out of pocket costs for patients taking Repatha®.

- **Embrace a Robust and Competitive Level Playing Field Between Innovators and Biosimilar Manufacturers:** When the BPCIA was enacted, creating the biosimilars approval pathway, we embraced the opportunity to extend our mission to serve patients and leverage our biotechnology expertise by deciding to invest in manufacturing high-quality biosimilars. We recognized that biosimilars would become an important part of broadening patient and physician options for biologic treatments and have committed to be a part of a biosimilars market that will ensure innovation, quality, and reliable supply of biosimilars and originator biologics, as well as bring meaningful cost savings to the healthcare system for patients,

physicians, pharmacists, and payers. However, for this market to have continued success and long-term viability depends on a level playing field for competition and scientifically accurate information that establishes the confidence of patients, physicians, pharmacists, and payers – all of which are essential to achieving meaningful cost savings and multiple public health benefits. With this in mind, Congress should not adopt policies that provide for preferential reimbursement of a biosimilar over innovator medicines – especially those that add costs to patients and the government. As a manufacturer of both innovator and biosimilar medicines, we do not believe biosimilars need special reimbursement advantages to successfully compete given that this new marketplace is already succeeding at driving savings to consumers.

There have been some concerns raised that the biosimilar market is somehow "not working" or that we, in the U.S., are lagging behind Europe in this area. I would like to take this opportunity to correct these misperceptions based on our real time experiences from the U.S. marketplace. Amgen has faced biosimilar market competition in the U.S. since 2015, and now faces competition from multiple biosimilars for three of our medicines. For example, biosimilars that compete against our originator product Neupogen® have achieved majority market share and meaningful cost reductions (e.g., Zarxio® has a 43 percent market share and the majority of market share among short acting granulocyte colony-stimulating factors (G-CSFs) in the U.S.) and represents the clearest example of how biosimilar competition is working. With respect to comparisons to Europe, the U.S. is not behind. The European Union (EU) biosimilar pathway was established in 2005. During the first eight years of the EU pathway, five biosimilars were approved. The U.S. biosimilar pathway was implemented in 2010. During the first nine years of the U.S. pathway, FDA has approved 18 biosimilars, with seven currently on the market. As of January 2019, there were 70 biosimilar candidates enrolled in FDA's biosimilar product development program. This demonstrates the level of interest and commitment by manufacturers in the growth and development of the U.S. biosimilars market.

Biosimilars have an important place in the evolving U.S. market, and the competition promoted by biosimilars will result in cost savings that create budgetary space for new innovations that will also be valued in the healthcare system. Robust and fairly-based biosimilar competition on a level playing field is the best way to achieve meaningful cost savings for the healthcare system, including patients, physicians, pharmacists, and payers, in a way that builds market stability that can be realized over the long term.

- **Address Regulatory Impediments to Value-Based Contracts:** Amgen has strong interest in entering into additional value-based contracting arrangements however regulatory barriers are preventing our ability to drive more creative agreements. For example, if we enter into a value-based contract which results in a large payment because a patient did not achieve the expected clinical outcome, it could trigger Medicaid best price implications for our medicine in all 50 states. Similarly, we would like to see safe harbors created that would give the market confidence that these types of arrangements do not run afoul of the anti-kickback statute. Therefore, we are supportive of regulatory or legislative approaches that would exempt value-based arrangements from Medicaid "best price" while at the same time creating a new anti-

kickback statute 'safe harbor.' This could be done in manner that requires such arrangements to entail at least a minimal amount of risk assumed by both parties to the agreement to qualify for such exemptions. These changes would meaningfully improve the ability of manufacturers to enter into more creative value-based agreements with payers which in turn could yield savings and better deliver downstream quality of care.

- **Create a Maximum Out-of-Pocket Cap in Medicare Part D:** As benefit designs have evolved since passage of the Medicare prescription drug benefit in 2003, more and more patients are encountering affordability challenges in the Part D program. For example, patients on biologics are often put on a 'specialty tier' where cost sharing can range between 25% and 33% of the list price of a drug. While the catastrophic phase of the current benefit reduces beneficiary cost-sharing to 5%, that amount can still be a significant burden for beneficiaries, particularly as beneficiary liability rarely is reflective of the rebates and discounts provided to Part D sponsors. One study found that in 2015, one million Medicare beneficiaries who were not receiving low-income subsidies reached the catastrophic phase and had average out-of-pocket spending of $1,215 per person above the catastrophic threshold.[8] Given that many seniors struggle with the affordability of their medicines in Part D at all phases of the benefit – deductible phase, initial coverage phase, donut hole, and catastrophic — Amgen is supportive of capping on an annual basis the level of spending a patient has in Medicare Part D.
- **Requiring 340B Hospitals to Pass Discounts onto Patients:** Consistent with what we have stated previously, we are interested in improving affordability in both the retail market and hospital market. 340B hospitals often purchase medicines at a heavily discounted price. 340B hospitals, however, are not required to make low-income patients aware of the discounts they receive and are under no obligation to pass along 340B savings to uninsured or low-income patients. Hospitals can charge uninsured patients the full list price for 340B discounted medicines. Moreover, hospitals often mark up the cost of our medicines purchased through the 340B program by hundreds of a percent. We are keenly aware of significant price mark-ups applied to drugs purchased through 340B. Last year one employee that works on our oncology team was diagnosed with cancer. This person received his/her cancer care at a premier research hospital which is also a participating 340B hospital. The hospital charged the employee multiple times the list price for the Amgen cancer product although the product was purchased by the hospital for less than half the list price. Because of this type of dynamic, where hospitals are marking up the price of our medicines at high levels, Amgen is supportive of policy changes that would require 340B hospitals to pass discounts onto a 340B patient. We would support the requirement that hospitals have a sliding fee scale, similar to grantees, that requires hospitals to share the 340B discounts with low-income patients.

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[8] Juliette Cubanski et. al., No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Costs Without a Hard Cap on Spending, Kaiser Family Foundation (Nov. 7, 2017), *available at* https://www.kff.org/medicare/issue-brief/no-limit-medicare-part-d-enrollees-exposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending/.

Conclusion

In closing, we are encouraged by forums like this and appreciate the opportunity to participate. As I hope my testimony has made clear, there is no doubt that the rebate dollar will continue to be the single largest economic driver in the drug supply chain.

We know more needs to be done to improve patient access and affordability. And so, I pledge Amgen's continued commitment to working with the Committee, Subcommittee, Congress and the Administration to advance market-based reforms that will promote fair competition and improve access to new therapies without stifling innovation and crippling one of the true crown jewels of the U.S. economy.

This is not something that a single company – or even an entire industry – can make happen on its own. And, just like our work in research and development, we know that some of the efforts we undertake may not yield the results we hope for.

But, as the examples of our own medicines demonstrate, we can lower health care costs and improve population health and productivity if we create the conditions needed to drive more innovation and greater access in the health care system.

The patients in our country deserve better. We must work together to bring about needed change for them and for the future of our health care system.

Thank you.

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 five 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 four 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 nine 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 two 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 healthcare 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:]

Statement of Jeffrey J. Hessekiel, J.D.
Executive Vice President and General Counsel
Exelixis, Inc.

Before the
Subcommittee on Health
Committee on Energy & Commerce
U.S. House of Representatives

Hearing on "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"
May 9, 2019

Chairwoman Eshoo, Ranking Member Burgess, and Members of the Subcommittee, thank you for the opportunity to appear before the House Energy & Commerce Subcommittee on Health to discuss issues related to the prescription drug supply chain in the United States.

I am Jeff Hessekiel, Executive Vice President and General Counsel at Exelixis, an innovative, research-focused, biotechnology company that is on a mission to help cancer patients recover stronger and live longer. At Exelixis, we focus exclusively on the most difficult-to-treat cancers, and we have established a broad drug discovery and development platform that has helped bring new cancer therapies to patients in need. As befitting our name, which is the Greek word for evolution, after a long, almost 25-year journey, we are proud to have grown into a stable company with just over 500 employees, based in Alameda, California.

Like the other company representatives on this panel, I am here today to have a frank and open discussion with you and the members of the Subcommittee about the root causes of high prescription drug costs and how drug prices are set in the U.S. health care system. It is possible for us to work together to promote the affordability of new and innovative therapies for patients without undermining the development of the next generation of medicines upon which we, and our children, will rely in the future.

I am also here today for another important reason – to highlight the important role that emerging biopharmaceutical companies, like my employer Exelixis, play in the drug development ecosystem. The voices of small and medium-sized innovative biotech companies are rarely heard in the national debate over prescription drug pricing, yet emerging biotech companies like Exelixis are playing an increasingly larger role in discovering innovative medicines. They are the engines of discovery in the fast growing areas of oncology and orphan drugs. According to a recent report by the IQVIA Institute, of the 59 new drug launches in 2018, 38 were patented by emerging biopharma companies, and 74 percent of those were also registered for FDA approval by these companies.[1] Emerging commercial biotechs like Exelixis account for the greatest share of late-stage pipeline activity; in 2018, emerging biopharma companies accounted for 72 percent of all late-stage clinical pipeline activity, up from 61 percent one decade ago.[2]

Before considering fundamental changes to an innovation system that has so often placed medical miracles in a bottle or pill, it is critical to understand the overwhelming challenges and the inherent risks of failure at each step of the discovery, development, regulatory and commercialization process. Please consider how future changes may impact America's most productive sources of medical innovation – small and medium-sized research-focused biotech businesses. In most cases, these innovations have only emerged thanks to the willingness of entrepreneurial scientists and investors to risk billions of dollars on medical long-shots. Sometimes those bets pay off to the benefit of public health, but far more often, the process is marked by repeated failures and "near-death" business experiences. For Exelixis, this is not a

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[1] The Changing Landscape of Research and Development: Innovation, Drivers of Change, and Evolution of Clinical Productivity, IQVIA Institute for Human Data Science (April 23, 2019) (Landscape Report), *available at* https://www.iqvia.com/institute/reports/the-changing-landscape-of-research-and-development (accessed May 7, 2019).

[2] *Id.* at 15.

theoretical matter. Since the inception of our company, investors have risked more than $3 billion supporting our R&D efforts, with over $2.1 billion of that investment spent before the company ever sold a single dose of medicine. At one point, less than 5 years ago, negative clinical results from two pivotal trials drove our share price down to just over $1, and our debt liabilities were several magnitudes larger than our existing cash position. As of today, however, the bet that long-term investors made in Exelixis has paid-off. More importantly, that boom and bust cycle eventually put important new medical therapies in the hands of American oncologists.

Small and mid-sized biotechs, like Exelixis, are very concerned that, unless we speak up – and are heard – well-intended, but narrowly-considered, law and policy changes could do permanent harm to the prolific American system of pharmaceutical discovery and innovation, which is increasingly driven by companies like ours.

Our Commitment to Fighting Cancer

Cancer continues to be one of the most challenging diseases for researchers around the world. In the United States in 2010, care for cancer survivors cost an estimated $137.4 billion.[3] In 2019, there will be an estimated 1,762,450 new cancer cases diagnosed and 606,880 cancer deaths in the United States.[4]

Simply put, Exelixis fights cancer. Our flagship molecule, cabozantinib (the active ingredient in our products CABOMETYX® and COMETRIQ®) has been approved by the FDA to treat patients with forms of liver, kidney and thyroid cancer.[5] Moreover, it has shown the potential to treat over 20 other forms of solid cancer tumors and so is the subject of more than 80 clinical trials, including at cancer centers and academic institutions across the country, including in Massachusetts; North Carolina; Connecticut; New York; Pennsylvania; California; and in other states and countries. CABOMETYX® and COMETRIQ® are taken daily by patients who are prescribed the treatment. Our drugs are covered by Part D for Medicare patients.

Our success in bringing cabozantinib to market for patients and achieving financial stability is only recent. For most of the company's 24-year history, Exelixis operated without product revenue, taking significant risks to sustain formidable research facilities and clinical trials. Along

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[3] National Cancer Institute, National Cancer Trends Progress (2019), Financial Burden of Cancer Care, *available at* https://progressreport.cancer.gov/after/economic_burden (accessed May 7, 2019).

[4] The American Cancer Society (ACS) Cancer Facts & Figures 2019, *available at* https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2019.html. (accessed May 7, 2019). ACS expects that 74,000 new cases of kidney cancer will be diagnosed in 2019, and 15,000 people will die from this cancer this year. The ACS also estimates that 42,000 new cases of liver cancer will be diagnosed, and 32,000 people will die from this cancer in 2019. For thyroid cancer, there will be 52,000 new cases diagnosed, and 2,000 people will die in 2019.These statistics evidence the urgent need for biotechnology companies like Exelixis to continue their work so that patients battling these devastating diseases can remain at home and with their families as they receive the treatment they need.

[5] Cabozantinib was first approved by the FDA as COMETRIQ® to treat a rare form of medullary thyroid cancer (MTC) in late 2012. After conducting additional clinical trials, Exelixis submitted a separate New Drug Application for approval of cabozantinib as CABOMETYX® to treat advanced renal cell carcinoma (RCC or kidney cancer).

the way, Exelixis accumulated a nearly $2 billion deficit, although the company's dedication to battling cancer never waned.

We began our work in the late 1990s and early 2000s, focusing on early stage scientific research. The first goal was to study human genes and gain biological insights that could inform better, safer drug development. Over the next decade, we shifted our strategy to focus on the discovery and investigation of discrete drug candidates, alone and with partners, to diversify risk and pursue a "multiple shots on goal" approach. By 2002, we had decided to focus our internal operations exclusively on cancer. We used unique, industry-leading high throughput drug discovery processes to identify compounds with therapeutic potential and then advance them rapidly through preclinical and early clinical development. As is typical, the large majority of those drug candidates failed. But some succeeded, of which the most promising was cabozantinib.

Our history demonstrates the tough financial reality of the biopharma business. Clinical research is much more expensive than lab research, so Exelixis' notable success identifying and advancing promising drug candidates in its labs then resulted in unsustainable clinical research costs. In 2008, Exelixis' R&D spending grew to $257.4 million, nearly twice the $132.1 million the company spent in the labs in 2002. Nearly everything Exelixis had was poured into research and development, as we spent between 73 percent and 87 percent of operating expenses on R&D (nearly $2.3 billion). Even though we were a public company, it was becoming increasingly difficult to secure the additional capital necessary to fund our extensive research and development budgets.

Although FDA approved cabozantinib as COMETRIQ® in 2012 for a small number of patients with a rare thyroid cancer, this product revenue stream was not nearly significant enough to fund our operations and debt service. Then, the company suffered a catastrophic event in late 2014 after two phase 3 registrational cabozantinib clinical trials failed in prostate cancer. That turn of events forced us immediately to restrict spending, reduce our workforce by more than 70 percent, and focus our limited resources and financial reserves on two important and difficult-to-treat indications – kidney and liver cancer. It was our last shot goal. Fortunately for seriously ill cancer patients and our company, cabozantinib demonstrated positive results in two large global pivotal trials in these indications. It is the only drug of its kind to improve overall survival in a statistically significant manner for both kidney and liver cancer.

Today, Exelixis is financially secure thanks to revenues generated as a result of the value and promise of cabozantinib. This enabled us to pay off all our debt in 2017; in 2018 our annual net income was $690 million and our revenue was $854 million. In the United States, we commercialize cabozantinib ourselves. Outside of the U.S., we have licensed cabozantinib to global pharmaceutical companies.

However, our recent financial success has in no way dulled our ambition. We are reinvesting the cabozantinib revenue stream to grow the company and deliver the next generation of Exelixis medicines to help patients recover stronger and live longer.

In 2018, we moved our headquarters to Alameda, California. We are building a research campus equipped with new, state-of-the-art research laboratories, and we intend to invest increasingly substantial amounts on research and development in the years to come. We are proud to be "home-grown" in the United States, a part of the Alameda community, and able to bring new, high-quality jobs to the vibrant community we have adopted as our new home.

Policy Proposals

I appreciate that this Subcommittee has invited me here today for more than a great business success story. Before I speak to drug pricing specifically, I would like to comment on the important topic of transparency. I hope that my presence here, and the information that I am sharing, demonstrates Exelixis' commitment to candor. Ours is not the only company that feels this way. As Congress considers various legislative proposals that would mandate additional transparency in pharmaceutical pricing, we urge you to consider the following:

- First, transparency and reporting requirements should not be limited to a single stakeholder in the supply chain, but should be required for all participants, including drug and device manufacturers, pharmacy benefit managers (PBMs), insurers, hospitals, and physicians. We believe that transparency is a prerequisite for good policymaking; but transparency should be required in all corners so that lawmakers, regulators and, most importantly the patients served by the healthcare system, have the information necessary to make informed decisions.

- Second, reporting requirements should mandate disclosure of objective data and metrics, including what portion of a company's overall spend is dedicated to research and development, as opposed to other expenses, such as sales and marketing. Similarly, companies should have to disclose prices. However, companies should NOT be forced to provide notice to purchasers ahead of price increases. That requirement can enable drug purchasers to game the system, and it does nothing to help patients.

- And, finally, as you consider new drug manufacturer reporting and transparency requirements, we urge you to consider provisions that explicitly preempt the increasing number of state laws covering the same subject matter. It is significantly burdensome and expensive for small businesses, like ours, to comply with a patchwork of inconsistent state reporting laws.

The Subcommittee has asked for input to better understand: (1) the root causes of prescription drug costs; (2) how prices are set; and (3) how each stakeholder in the supply chain can lower prices so that Americans can afford the care that they need. I will do my best to address each of these issues from Exelixis' perspective.

(1) Factors to Consider In Addressing the Cost of Innovative Prescription Drugs

As related above, drug discovery and development imposes significant serial risks and requires tremendous capital investment. This is particularly the case for oncology research. As Exelixis' experience illustrates, R&D at cancer drug companies can exceed hundreds of millions annually

and can total billions of dollars cumulatively before a drug may even be brought to market. Failure and attrition is more common than success.

The factors that most influence the high cost of innovative prescription drugs in the United States are: (1) the tremendous cost of investment in drug discovery research and the clinical trial testing and, perhaps even more importantly, (2) the aggregate cost of all the failed experiments and trials along the way that, while unsuccessful themselves, were a necessary and unavoidable part of the scientific journey that eventually produced an innovative medical product fit for sale. In 2018, the median time from a patent was first filed to its FDA approval was 13.6 years[6] and, when one includes the cost of necessary failures, the R&D cost of transforming the breakthrough to an actual medicine was approximately $2.6 billion.[7] Those facts are directly relevant to the price charged for that medicine once it finally makes it to market.

I respectfully request that when you consider the issue of high drug prices, you permit me to explain why, at least as the system in our country is currently structured, it is essential to look deeper than list price. The list price of Exelixis' flagship product CABOMETYX® is $18,365 per month. However, to understand our business, please do not stop your analysis there. This is not the net price that Exelixis realizes for its medicine. Exelixis has a firm voluntary commitment that NO patient prescribed an Exelixis medicine will go without it due to lack of insurance coverage or inability to pay. If a patient with a prescription does not have insurance or cannot afford our product, we will provide financial assistance, if permitted, or will provide the patient with the drug for free. Exelixis also provides mandatory and voluntary discounts and rebates to public and private insurers and safety net providers, which affect the net price that Exelixis actually recoups on product sales. On a net basis, Exelixis realizes only approximately 73 percent of the list price.

Some may argue that, when a drug company successfully commercializes a medicine, it has already paid for the research and development costs that led to that medicine's discovery and approval, so those costs should not be taken into consideration and need not be passed on. Putting aside the critical concerns of recouping those costs to pay debt or return shareholder equity, Exelixis believes that the revenue collected through sale of approved products should be applied predominantly to the R&D that will lead to the next generation of medicines. In the case of Exelixis, this has meant that, since our inception, we have committed at least 73 percent or more of our operating expenses to developing new medicines. During the launch phase of our newly approved drugs, our sales, general and administrative expenses have increased; however, we plan to have our R&D investment grow again substantially in 2019 to an even greater portion of our overall spend and into the foreseeable future as our more recently discovered drug candidates advance into clinical development.

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[6] Landscape Report, p. 9.

[7] DiMasi JA, Grabowski HG, Hansen RA, "Innovation in the pharmaceutical industry: new estimates of R&D costs," *Journal of Health Economics* 2016; 47:20-33, summary *available at* https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub (accessed May 7, 2019). Full article on file with Exelixis.

This cycle of high at-risk investment, return of capital, and reinvestment, is often referred to as the biopharmaceutical innovation cycle. As Congress considers policies that could substantially interfere with this innovation cycle, I strongly urge you to consider the effect that these policies would have on small, innovative businesses, like Exelixis, that are driving the lion's share of medical innovation. Rather than diminishing resources available to small businesses, we should be encouraging such businesses to invest further in the next generation of lifesaving cancer treatments, including potential cures.

(2) How Are Prices Set?

Turning to how prices for drug products are set, at Exelixis, like other commercial-stage drug manufacturers, before we set the launch price of a medicine, and also when we consider increasing the price of a medicine after its launch, we rely on extensive blinded market research with physicians in the therapeutic areas for which the drug may be indicated. We also conduct similar research with formulary managers, and with government and private payers. Our goal is to determine how compelling these stakeholders find the clinical data for the product and the product's safety profile, especially as compared to the competitive approved products already on the market and late-stage investigational products in the same therapeutic category that may soon be approved for sale. The results of that market research permit us to understand the product's relative value proposition as perceived by the stakeholders who may ultimately prescribe or make decisions concerning coverage or reimbursement of the product.

In addition, we consider the market's current commercial context – what are the existing price points for the products with which our product will likely compete? And also, what net price for the product is Exelixis likely to realize after discounts and rebates?

Finally, we consider Exelixis' research and development costs related to the product to date, and the future anticipated costs that are likely to be incurred to fully investigate the therapeutic promise of the product for patient health. We evaluate the remaining period of market exclusivity that Exelixis can likely rely upon, during which the company will have its opportunity to recoup the investments that were necessary to transform the product from a scientific breakthrough to a medicine offered for the benefit of cancer patients.

We believe that our approach to product pricing is responsible and appropriately considers both the specific value of our product relative to its competitors, as well the realities of the necessary risks and rewards that drive the discovery of new, lifesaving medicines.

(3) Making Drugs Affordable to Patients in Need

Lastly, I turn to the most important question – how can drug prices be brought down? As to this point, I hope my remarks have offered some insights, at least regarding why innovative medicines to treat the most serious, life-threatening diseases in the United States – like cancer – cost so much to payors. My goal is to convince you to pause before forcing fundamental changes that would disrupt, or even destroy, the biopharmaceutical innovation cycle. Yes, other countries have implemented price controls or government-mandated pricing to keep drug prices artificially low. However, those countries are not, nor have they ever been the source of humanity's most

critical medicines and medical advances; that has been the United States. And Americans – each and every one of us and our loved ones – have benefitted immeasurably from that innovation. This Committee's landmark 21st Century Cures Act legislation reflected that uniquely American vision. Setting price controls or requiring manufacturers to lower list prices in the U.S. or forfeit their intellectual property is not a viable solution if we expect medical innovation to continue in the future. Taking such steps would weaken incentives for companies to invest in discovering lifesaving new medicines, in the end slowing the innovation cycle and access to vital medicines for patients. This would be acutely felt by small drug makers, like Exelixis, that do not have an established suite of commercialized products or capital structure needed to continue investing in R&D.

At least when it comes to the most critical medicines, we have a serious patient affordability problem. We agree with Chairwoman Eshoo's statement at this Subcommittee's last hearing on the drug supply chain, on December 13, 2017, that "the system is crying out for reform." Manufacturers like Exelixis already assist financially qualified patients with commercial insurance to access their prescribed medicines and we are ready to contribute financially to solving this problem for Medicare Part D patients as well. I believe that other stakeholders in the supply chain, such as payors and PBMs, would also step up, given the opportunity to help ensure that Americans with the most serious illnesses can access treatments without delay.

The National Cancer Institute has recognized the increased burden on cancer patients and their families resulting from the "financial toxicity" experienced by patients with health insurance paying higher premiums than in the past, along with higher copayments, deductibles, and coinsurance,[8] all of which exacerbate the stress that comes with a medical diagnosis that can devastate a cancer patient and his or her family and can "diminish the quality of life and impede delivery of the highest quality care."[9] The financial distress faced by cancer patients is disproportionately higher based on age, race and income, and patients face an even greater risk of financial toxicity when they have an advanced-stage cancer.[10]

And THAT problem is absolutely solvable. At Exelixis, we are doing everything that we can, and support further changes to the law, to ensure that our products are affordable for patients in need. Patients prescribed Exelixis' medicines are fighting the most threatening and debilitating cancers, and require personalized treatment options. Even when prescribers have access to the full array of cancer treatments,[11] we recognize that out-of-pocket costs represent a significant

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[8] Financial Toxicity (Financial Distress) and Cancer Treatment, National Cancer Institute, *available at* https://www.cancer.gov/about-cancer/managing-care/track-care-costs/financial-toxicity-pdq. (accessed May 7, 2019).

[9] Zafar, et al., Financial Toxicity, Part 1: A new Name for a Growing Problem, Oncology (February 2013), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4523887/ (accessed May 7, 2019).

[10] *Id.*

[11] Given that there may be limited – or in some cases, only one – clinically appropriate treatment for a patient available, we strongly support maintaining CMS' current policies regarding the Part D protected classes, as this structure recognizes that physicians must be able to access the full array of available innovative therapies to determine the optimal cancer treatment for a patient. We oppose any proposals that would impose utilization management or formulary restrictions on protected class drugs, particularly those treating cancer.

burden for patients who are diagnosed with cancer and their caregivers. The bulk of out-of-pocket costs usually occur within 1-2 months of a cancer diagnosis,[12] and patients can face the additional burden of loss of work or productivity and insurance coverage that imposes added costs on a patient battling a deadly disease.

Very soon after receiving the emotionally crippling diagnosis of cancer or cancer progression, Part D patients learn that the Medicare Part D coverage model imposes burdensome financial challenges as well. These patients usually find themselves subject to the Part D specialty tier, cost-sharing in the donut hole, and continued 5 percent out-of-pocket (OOP) cost-sharing the catastrophic portion of their coverage benefit. For cancer patients, these costs create almost immediate financial stress for patients and their families and caregivers.[13] One study of lower-income cancer patients taking oral oncology drugs found that proactive financial assistance programs helped achieve greater medication adherence: financial assistance was associated with an 8 percent increase in adherence over the course of the 2014-15 measurement period.[14] Even for patients and their families living well above the federal poverty level, annual OOP costs regularly total more than a third of their annual income.[15]

Especially for patients facing life-threatening diseases, including cancer, high out-of-pocket costs are concerning because as a patients' out-of-pocket costs increase, the likelihood that they will abandon or delay initiation of an appropriate treatment increases dramatically.[16] Studies demonstrate that the rate of prescription abandonment specifically for oral anti-cancer agents, are as high as 60 percent for individuals with Part D, compared to 40 percent for commercially insured patients.[17] At Exelixis, we want to ensure no patient who can benefit from our medicines is forced to abandon it. Through our patient assistance programs, we provide free drug to financially needy uninsured and underinsured patients, as well as copayment assistance to commercially-insured patients. We do all that we can, within the constraints of the U.S. system, to mitigate the impact of cost-shifting insurance benefit design on the patients we serve.

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[12] ACS, The Costs of Cancer: Addressing Patient Costs (April 11, 2017), *available at* https://www.fightcancer.org/policy-resources/costs-cancer (accessed May 7, 2019).

[13] *Id.*

[14] Express Scripts, "Financial Assistance programs Increase Adherence to Oral Oncology Drugs" (Jan. 12, 2016), *available at* http://lab.express-scripts.com/lab/insights/adherence/patient-assistance-programs-increase-adherence-to-oral-oncology-drugs. Accessed May 2019.

[15] Doshi *et al.*, Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents, Journal of Clinical Oncology (Nov. 2017); *see also* Starner, *et al.*, Specialty Drug Coupons Lower Out-Of-Pocket Costs and May Improve Adherence at the Risk of Increasing Premiums, 33 Health Affairs 1761, 1762 (Oct. 2014) (finding in a survey of literature focused on biologic anti-inflammatory drugs and multiple sclerosis drugs that when monthly out-of-pocket costs for prescription drugs exceeded $150-$200, rates of new therapy abandonment approximately doubled, the odds of being adherent were reduced 39 percent, and the risk of discontinuation increased 27 to 58 percent.

[16] Doshi *et al.*, Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents, Journal of Clinical Oncology (Nov. 2017).

[17] *Id.* at 47, Chart 1.

Current Office of Inspector General (OIG) guidance, however, prevents Exelixis from offering copayment assistance to Medicare beneficiaries, leaving some of the most vulnerable cancer patients unable to access the specific therapy prescribed by their physician, which can lead to them becoming non-adherent to their needed therapy solely due to financial reasons. For patients diagnosed with advanced cancer, there is no merit to the policy argument that Medicare beneficiaries should have financial "skin in the game" with respect to their medications. These patients may have only one appropriate treatment, which does not have a generic or biosimilar alternative. Patient advocacy groups have stated that in these cases, "copayment cards cannot influence the choice of drug because there is no choice available."[18] While we recognize that there are products or drug classes as to which the co-payment assistance prohibition makes sense, we believe there is an urgent need for, at a minimum, an oncology exception (if not a catastrophic disease exception) to the policy.

The amounts that cancer patients pay at the pharmacy are at the heart of the affordability problem. Exelixis strongly urges Congress to allow Medicare Part D cancer patients to obtain the same cost-sharing assistance from manufacturers as commercial patients by eliminating the prohibition on allowing manufacturer copayment assistance for Part D beneficiaries. Congress should develop a new or revised anti-kickback statute (AKS) and beneficiary inducement civil monetary penalty (CMP) safe harbor that would permit manufacturer copay assistance to Part D beneficiaries for "clinically unique medications."[19] Alternatively, at a minimum, Congress should direct the U.S. Department of Health and Human Services (HHS) to create a Center for Medicare & Medicaid Innovation (CMMI) demonstration, under which AKS and beneficiary inducement CMP requirements could be waived and the benefits of cost sharing assistance for the Medicare Part D population could be evaluated.

At least for cancer patients, we can and should improve affordability in these ways. We also believe this Committee should continue to promote market-based reforms that will improve affordability through stronger competition for today's patients, while ensuring we continue to spur the next generation of treatments for tomorrow's patients. We appreciate this Committee's work to promote more robust generic and biosimilar entry once patents and exclusivities for innovator drugs have expired, and your efforts to move toward a health care payment system – including a drug payment system – that is based on value rather than volume. We believe this work, along with more transparency and data to empower patients and providers on cost and value from all sectors of the supply and payment chain, are essential and responsible approaches to improving access and affordability for American patients.

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[18] Susan G. Komen response to Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, 83 Fed. Reg. 22692, p. 3.

[19] A "*clinically unique medication*" is a treatment: (1) for a disease -- such as cancer-- where available treatment options are clinically differentiated, such that lack of access to a particular therapy could severely undermine a patient's quality of care and put the patient at risk of adverse clinical outcomes; (2) for which payor prior authorization is required; and (3) that does not have any therapeutically equivalent generic alternatives. Exelixis Response Letter - OIG-0803-N RFI re Anti-Kickback Statute & Beneficiary Inducements CMP (10-25-18), *available at* https://www.regulations.gov/document?D=HHSIG-2018-0002-0157.

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We hope this information is helpful to you as you frame new approaches to drug pricing and payment in the United States. As you proceed, it is critical to ensure that America's most innovative companies, like Exelixis, are permitted to continue driving innovation forward for patients with cancer and helping those patients access our medications when they require financial assistance so they can realize the full benefit of their prescribed therapies.

Thank you for the invitation to speak with you today. I look forward to your questions.

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

I now would like to recognize Ms. Bricker. You are recognized for five 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:]

"Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"

by

Amy Bricker, R.Ph.
Senior Vice President, Supply Chain
Express Scripts

Before the

House Committee on Energy and Commerce
Subcommittee on Health

May 9, 2019

Chairwoman Eshoo, Ranking Member Burgess, and members of the Subcommittee, thank you for inviting me to testify at this hearing. I am Amy Bricker, R.Ph., Senior Vice President, Supply Chain for Express Scripts.

I have had the privilege of working in the healthcare industry for most of my career. As a registered pharmacist working in the retail pharmacy setting, I have seen first-hand the opportunities we have to improve pharmacy care. Prior to joining Express Scripts, I served as Regional Vice President of Account Management for Walgreens Health Services. During my ten years at Express Scripts, I have held leadership roles in pharmacy network management, supply chain economics, and retail contracting and strategy. As Senior Vice President, Supply Chain, I am responsible for key relationships and strategic initiatives across the pharmaceutical supply chain, including working with drug manufacturers and retail pharmacies to create value for Express Scripts' clients and keep medicine within reach for patients. My team also has responsibility for developing value-based contracts to improve affordability, access, and care for the complex and costly conditions many people face. Until recently, I had the honor of serving on the Medicare Payment Advisory Commission (MedPAC).

I appreciate the opportunity to testify on the role Express Scripts plays in the supply chain and on improving affordability and access to prescription drugs. Express Scripts helps more than 80 million Americans achieve better care at a lower cost, including those in health plans, union-sponsored plans, state employee health plans, and public programs, including Medicare Part D and Medicaid. We are proud to serve TRICARE, the health program for 9.4 million uniformed service members, retirees, and their families, for more than 10 years. Express Scripts' tools include an innovative specialty pharmacy care model for costly and complex drugs; clinically-based drug utilization reviews; clinically-based formulary management; medical and drug data analysis; and specialized Therapeutic Resource Centers, with pharmacists specially trained to serve patients with a range of conditions.

In December 2018, Cigna completed its combination with Express Scripts. Together, our companies have industry-leading cost trend capabilities that are uniquely positioned to deliver better care, expanded choice, and greater affordability. Our combined company's 74,000 employees come to work every day to enhance the health, well-being, and peace of mind of the more than 160 million customer relationships we serve globally.

Cigna is a global health services company; our subsidiaries are major providers of medical, pharmacy, dental, disability, and related products and services in more than 30 countries and jurisdictions around the world, including South Korea, China, India, the Middle East, and Europe. Cigna is also the largest provider of expatriate benefits in the world. In the United States, Cigna is one of the largest health services providers. We emphasize whole-person health and clinical quality to deliver choice, affordability, and enhanced quality of life for our customers and clients. Key enablers of our success are collaborative relationships with providers, an emphasis on outcomes- and value-based reimbursement, robust patient support services, and transparency tools for customers and clients to make informed decisions that address their specific needs.

We appreciate the opportunity to be a constructive participant in public policy discussions and to contribute workable solutions to societal challenges in all of the countries, markets, and jurisdictions in which we operate. The United States drives the most innovation in health services. While innovation can yield life-changing new therapies and treatments, it often comes with a high price tag, especially in the pharmaceutical sector.

At Cigna and Express Scripts, we strive to achieve better health, with greater choice, affordability, and predictability. We do this by supporting our customers in maintaining their health and partnering with physicians and other providers to provide coordinated, connected care that is focused on delivering value aligned to clinical quality and evidence-based guidelines. We challenge ourselves every day to accelerate solutions that enable access to new innovations and price stability. We are already making good progress.

Pharmacy is the most frequently consumed aspect of health care for Americans. On average, people use their pharmacy benefit 11 times a year, making it the most widely used benefit employers and health plans offer. For some illnesses that once required surgery, prescription drugs have emerged as an effective front-line option. However, prescription drug spending is forecast to grow at 5.5 percent per year, on average, between 2018 and 2027.[1] Over the past 10 years, the Consumer Price Index (CPI) has increased 15 percent.[2] During that same period, the prices for generic drugs have dropped by an average of 60 percent; conversely, these savings have been subsumed by an astonishing 208 percent increase in the cost of branded drugs.[3]

Express Scripts' solutions for driving lower drug spending and fostering the use of lower net cost treatments are making medications more accessible for Americans. In 2018, Express Scripts' clinical first approach returned $45 billion in savings to our clients – employers, health plans, government programs, unions, and others.[4] Because of our innovative solutions and approach to pharmacy care, our clients achieved the lowest drug trend in 25 years, just 0.4 percent across employer-sponsored plans. The average 30-day prescription cost our patients only 6 pennies more than in 2017. Further, we delivered an unprecedented 0.3 percent decline in drug spending across Medicare plans. All of this was accomplished in an environment where manufacturers raised list prices by an average of 7.3 percent for traditional brand drugs and 7.1 percent for specialty brand drugs. We secure discounts from manufacturers and pharmacies and guide patients to effective, lower-cost therapies to achieve these results.

We deliver these results because we take a holistic approach to pharmacy care. We know there is a lot that happens from the moment a person goes to their physician with a health issue, to when a diagnosis is made, to when a prescription is written, and then ultimately filled. We are there, every step of the way, to make sure patients get the care they need at a cost they, and their employers and health plans, can afford. Our focus is clear: better care, greater choice, and lower costs.

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[1] https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/downloads/forecastsummary.pdf
[2] https://www.statbureau.org/en/united-states/inflation
[3] http://lab.express-scripts.com/lab/drug-trend-report/~/media/29f13dee4e7842d6881b7e034fc0916a.ashx
[4] http://lab.express-scripts.com/lab/drug-trend-report/2018-drug-trend-report

With that context as background, our statement today focuses on the following topics:

- Our efforts to drive improved affordability, predictability, and accelerate value-based care for patients;
- The role of rebates in the prescription drug supply chain; and,
- Legislative and regulatory solutions to lower drug costs for patients.

Our Efforts to Drive Improved Affordability, Predictability, and Accelerate Value-Based Care for Patients

We are at our best when there is competition in the marketplace. When there are multiple therapies for a disease with similar clinical efficacy, we are able to leverage competition to drive discounts for our clients and customers. Our approach begins by having independent panels of healthcare professionals evaluate medicines (Pharmacy and Therapeutics Committee, or P&T Committee), and once they have determined which are necessary for our members, we can then negotiate with drug manufacturers to achieve lower net costs.

Express Scripts uses clinical expertise and scale to negotiate lower drug costs with drug manufacturers, leveraging competition to help drive savings for clients, which include employers, labor unions, health plans, the federal government, and states. These negotiations serve to create competition in the market for prescription drugs, and the savings ultimately benefit patients through lower premiums and reduced out-of-pocket costs. Additional savings are realized when clients take advantage of Express Scripts' clinical support services, which enable individuals to lead healthier and more productive lives.

When it comes to prescription drugs, our goal is to achieve improved clinical outcomes at lower costs. Express Scripts offers several innovative programs to help us achieve that goal:

- Our **SafeGuardRx℠** programs help our clients closely manage high-cost drug classes through a holistic approach that combines clinical care with advanced analytics, and patient engagement supported by technology. Through SafeGuardRx Solutions, we have leveraged value-based arrangements to expand access and lower costs in some of the most challenging therapy classes, including hepatitis C, high cholesterol, cancer, inflammatory conditions, pulmonary conditions, and multiple sclerosis.
- One of our SafeGuardRx programs – The **Diabetes Care Value Program** – improves pharmacy care while controlling plan costs for individuals with diabetes. Developed with drug makers and launched in 2017, the program has reduced diabetes drug spending by 19 percent – a total savings of $42.6 million. The program combines specialized diabetes pharmacy care with benefit strategies, such as utilization management and quality pharmacy networks, and improved compliance with recommended treatment guidelines.
- Our **National Preferred Flex Formulary** is a unique approach that provides employers and health plans with the flexibility to take advantage of the possibility of a drug manufacturer choosing to lower the price of a drug by offering an authorized generic

alternative. Should the manufacturer offer an authorized generic, that product can be added to the formulary. In the end, we care most about the lowest net cost of a drug, not the rebate. We welcome manufacturers lowering their list prices so that patients can have greater access to medications.

- **SmartShareRx℠** offers employers and plan sponsors more flexibility in how they use rebate savings. The program was established to share estimated rebate savings on eligible medications to combat patients' primary pain point: cost-sharing in the deductible phase. However, the program has evolved to apply estimated rebate value to eligible medications filled in all phases of the pharmacy benefit to reduce patients' out-of-pocket costs at the pharmacy counter. Despite the availability of point-of-sale rebate benefit designs in the commercial market for years, we have had few employers and plan sponsors take up this option. For more than 10 years, we have offered the option to clients to provide rebate value at the point-of-sale.

- **Inside Rx℠** is a prescription savings program launched in partnership with manufacturers and retail pharmacies to expand affordable access to brand and generic medications for patients with no insurance, high deductibles, or high out-of-pocket costs, by offering discounts to these patients at the point-of-sale. Since the launch of the program in May 2017, we have helped patients save an estimated $400 million.

Express Scripts builds solutions that are as unique as the clients and patients we serve, working to partner across the health care ecosystem to uncover opportunities, take action, and deliver better outcomes. Real-time clinical alerts that reach physicians through electronic prescribing systems can turn data into actionable patient intelligence, helping people stay on their therapy regimen and avoid dangerous drug-drug interactions. Express Scripts' Real Time Prescription Benefit, launched last November, helps to simplify the patient's experience with his or her prescriber and improve transparency of drug costs. We provide patient-specific information and pricing information directly into the physician's Electronic Health Record (EHR) within seconds. Physicians using electronic prescribing can see the following information to inform prescribing decisions:

- Alternative drugs and associated details, such as generic versus brand pricing;

- Coverage information, including electronic prior authorization requirements, step therapy requirements, or quantity limits; and,

- The patient's cost through each pharmacy dispensing channel: retail, home delivery or specialty pharmacy.

By providing drug cost information and reconciling coverage issues at the point of prescribing, we are mitigating confusion and pain points for patients at the pharmacy counter. These systems are delivering measurable savings to patients at the pharmacy counter, while encouraging providers and patients to communicate to make better-informed medication choices. Electronic prior authorization capabilities are improving as well, eliminating hours of potential wait time for prescribers and patients.

Cigna and Express Scripts also directly provide patients real-time pricing information, customized to their individual plans, via our websites and mobile apps, so patients can choose the pharmacy that provides the most affordable dispensing option. Our innovations help better inform patients of their cost sharing and treatment options, improving affordability and predictability for patients.

As we look ahead to gene therapies, a growing category of high cost drugs, we are actively developing new value-based payment models. For example, we have periodic payment agreements with manufacturers that are structured as value-based contracts to reward efficacy. Simply put, if a drug is working, the company gets a payment. If not, the payment stops. Similarly, we have worked to develop "discontinuation" payment arrangements that require payment to be returned if a patient does not see a benefit from the drug.

Express Scripts' innovative pharmaceutical and pharmacy solutions position Cigna to offer even greater value to our clients, public program partners, and patients. The combined company integrates Express Scripts' pharmacy benefit management with Cigna's health care products and services.

For example, over seven million Americans diagnosed with diabetes use insulin. For some patients, the increasing price of insulin limits access and adherence. When Cigna and Express Scripts announced the combination, we clearly stated we would improve choice, affordability, and predictability. As discussed at the April 10th Oversight and Investigations Subcommittee hearing on insulin, within the first 100 days of our combination we were able to launch a new **Patient Assurance Program** which will bring additional affordability and predictability to customers who rely on insulin to manage their diabetes. Furthering Cigna and Express Scripts' respective historical efforts in diabetes disease management, the Patient Assurance Program establishes a lower, fixed out-of-pocket cost for covered insulins, ensuring customers will pay no more than $25 out-of-pocket when filling a 30-day insulin prescription at a retail pharmacy or through home delivery. This is an early example of the accelerated change and innovation our new company is positioned to drive in the financing and delivery of care.

The Role of Rebates in the Prescription Drug Supply Chain

As drug pricing strategies have evolved over time, drug makers have elected to offer discounts, or rebates, rather than lower the price of their medicines in an effort to improve affordability. Part of our job is to negotiate discounts, and then pass along the value so plans can offer lower premiums and provide robust benefits.

Not all drugs are discounted. In fact, drug makers offer rebates on a relatively small number of medicines. Approximately 90 percent of all prescriptions filled are generics. The remaining 10 percent are branded drugs, which represent 70 percent of the spending on prescription drugs. We believe there are targeted solutions to address this 70 percent. We work to do this through sophisticated, evidence-based negotiations for clinically equivalent therapies.

Solutions for driving lower drug spending and fostering the use of lower net cost treatments often include negotiating discounts or rebates. The role of rebates in prescription drug pricing

has been mischaracterized. Rebates are not the cause of increasing drug prices. Rebates are discounts paid by drug manufacturers after a patient receives a manufacturer's drug. In the system today, rebates are used to reduce overall health care costs for consumers. Today, employers and others use the value of discounts to help keep premiums affordable and lower out-of-pocket costs.

Most drugs do not involve a rebate structure. For example, rebates are not typically offered for generic medications, for drugs without market competition (*i.e.,* sole-source brand drugs), or for drugs administered by a physician. According to a study of drugs covered under Medicare Part D by the actuarial firm Milliman, 81 percent of all drugs analyzed do not offer rebates and 64 percent of brand drugs analyzed do not offer rebates.[5] Many sole-source, highly expensive specialty drugs, like drugs to treat cancer, do not offer rebates and continue to be priced higher and higher:

- In 2017, non-rebated drugs treating depression, high-cholesterol, infertility, and other conditions all registered price increases of more than 15 percent.[6] This means beneficiaries who take these drugs will not benefit under the Department of Health and Human Services' (HHS) recently proposed rule reforming rebates in Medicare Part D and Medicaid.
- List prices for oral oncology medications, which are not rebated or discounted to any significant extent, doubled between 2011 and 2016, from $20 per unit to $40 per unit.[7].
- The Milliman study found that on average, the highest cost drugs have the lowest manufacturer rebates (as a percentage of gross drug cost), for brand drugs with rebates.
- Looking at the 39 oral oncology medications on the market in 2010, six experienced 100-200 percent inflation between 2010 and 2016; one was greater than 300 percent and another one was greater than 800 percent.[8] Rebates are not available on these drugs, but the manufacturers continue to increase list prices. Under HHS's proposed rebate rule, beneficiaries using non-preferred and specialty drugs would therefore see premiums increase, and will not see a reduction in cost at the pharmacy counter.

Restricting or eliminating rebates does not assure improved affordability for patients or taxpayers:

- A study by the actuarial firm Oliver Wyman found that rebates reduced overall costs in Medicare Part D by $34.9 billion from 2014 to 2018, and eliminating rebates would have driven Part D premiums higher by 52 percent in 2018 alone.[9] From 2014 to 2018, the

[5] Milliman, Prescription Drug Rebates and Part D Drug Costs. July 16, 2018. The Milliman analysis focused on approximately 1,300 drug and therapeutic class combinations, reflecting 97 percent of 2016 Part D gross drug spending.
[6] Express Scripts, Let's Talk About Rebates, May 15, 2018. http://lab.express-scripts.com/lab/insights/industry-updates/lets-talk-about-rebates
[7] Express Scripts, The Cost of Hope: 5 Things to Know about the Cost of Cancer Drugs. May 30, 2017. http://lab.express-scripts.com/lab/insights/industry-updates/the-cost-of-hope-5-things-to-know-about-the-cost-of-cancer-drugs
[8] http://lab.express-scripts.com/lab/insights/industry-updates/sharing-smarter
[9] Oliver Wyman, Premium Impact of Removing Manufacturer Rebates From the Part D Program. July 2018. https://www.pcmanet.org/wp-content/uploads/2018/07/OW-Part-D-Manufacturer-Rebate-Premium-Impact-FINAL.pdf

national average Part D premium increased less than two percent per year. Manufacturer rebates are one of the major contributors to holding premiums relatively flat over the last five years.

- The Centers for Medicare and Medicaid Services' (CMS) Office of the Actuary (OACT), in reviewing HHS's' proposed rule addressing rebates estimates that Part D premiums will increase by as much as 25 percent and that federal spending will increase by $196 billion over ten years.[10]
- The Congressional Budget Office (CBO) analysis of the proposed rule confirms these estimates. The analysis finds that implementing the proposed rule will increase federal spending by about $177 billion over ten years while increasing premiums for seniors. The CBO also does not expect manufacturers to reduce list prices following implementation of the rule.[11]
- Data released by CMS for 2019 Part D premiums, and national average plan bids, show a negative trend for the first time in more than a decade.[12] CMS cites drug manufacturer and pharmacy price concessions as a factor driving lower costs.
- A *Health Affairs* analysis of the most recent National Health Expenditures prescription drug forecast for 2017-2026 concluded that increased rebates "contributed to lower net prices for many prescription drugs in recent years and are expected to have dampened prescription drug spending growth in 2017."[13]

In the Medicare Part D program, rebate savings are passed to Part D plan sponsors and are responsible for saving enrollees and taxpayers billions of dollars each year since the Part D program began. CMS requires Part D plan sponsors to show how they are using rebates to deliver coverage to their members. All Part D plan sponsors must submit to CMS detailed annual reporting of rebate amounts by drug and Part D plan. In addition to reporting individual drug rebates, plan sponsors must also report to CMS how much of the rebate amounts were retained by the pharmacy benefit manager (PBM) rather than being shared with the sponsor, rebate guarantee amounts, rebate amounts reflected at the point-of-sale, third-party payer claim rebate amounts, and any other rebate amounts not already reported. Not only are plan sponsors required to report these rebate amounts to CMS, but they must also report what the rebates are for, such as formulary or tier placement, market share targets, volume targets, inflation rebates, or rebate guarantees. Finally, plan sponsors must report any administrative fees charged to manufacturers.[14]

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[10] https://aspe.hhs.gov/system/files/pdf/260591/OACTProposedSafeHarborRegulationImpacts.pdf

[11] https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf

[12] 2019 Medicare Advantage ratebook and Prescription Drug rate information. https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data-Items/2019Rates.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending

[13] *Health Affairs*, National Health Expenditure Projections, 2017–26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth. February 14, 2018. https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1655

[14] Final Medicare Part D DIR Reporting Requirements for 2017. Accessed 3/4/19 at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly-Items/SysHPMS-Memo-2018-May-30th.html

In the commercial market, rebates are an effective tool that employers and health plans use to generate more savings for prescription drugs. Employers and other plan sponsors that work with Express Scripts choose how rebates are used. Some plan sponsors use them to lower premiums and cost sharing, others choose to expand access, or provide discounts to consumers at the point-of-sale. Nearly half of Express Scripts' clients have opted for 100 percent pass-through of rebates. Express Scripts passes approximately 95 percent of rebates, discounts, and price reductions back to its core PBM commercial and health plan clients and their customers.

Express Scripts welcomes the opportunity to work with policymakers to bring down drug costs for patients at the pharmacy counter. There are a number of opportunities to address high list prices and patient exposure at the pharmacy counter that address competition, access to generics, and benefit designs. However, legislative or regulatory efforts to eliminate or restrict the ability of plan sponsors or PBMs to negotiate lower overall costs will lead to higher drug prices not only for Medicare beneficiaries and taxpayers, but also for millions of individuals who access health benefits through their employers.

We believe there are more direct and effective ways to deliver relief to patients most in need without disrupting coverage for millions. For example, in addition to the policy opportunities discussed later, we believe a better way to address patient out-of-pocket costs is to allow payers and their PBMs to use the power of benefit designs to limit beneficiary exposure while ensuring payers continue to have all of the tools at their disposal to negotiate lower costs. For individuals in high-deductible health plans, this could include changes to the tax code to allow coverage of chronic care treatments and other services pre-deductible, for example. Additionally, many have discussed possible changes to the Medicare Part D benefit design to achieve lower patient out-of-pocket costs, and Cigna and Express Scripts welcome the opportunity to be a constructive participant in those efforts for both Medicare Part D beneficiaries and patients in the commercial market.

Legislative and Regulatory Solutions to Lower Drug Costs for Patients

We support efforts by Congress and the Administration to use market-based solutions that put downward pressure on prescription drug prices through competition, consumer choice, and open and responsible drug pricing. For example, last year we endorsed legislation championed by Rep. Buddy Carter and others to ensure patients are told the lowest cost option available to them at the pharmacy counter. We were pleased the legislation became law, and included a provision authored by Rep. John Sarbanes and Rep. Bill Johnson to provide more transparency into so-called "pay-for-delay" agreements that prevent biosimilar drugs from entering the marketplace.

Looking to the future, we believe efforts to address out-of-control drug pricing through legislative and regulatory actions should include:

- **Prioritizing reforms to lower costs and protect patient access in Medicare:**
    - Public programs must have the ability to leverage the commercial market's successful utilization management tools that lower costs while protecting patient access. We support efforts to modify the six protected "classes of clinical

concern" in Part D, where all or substantially all drugs in a class must be covered, allowing drug manufacturers to name their price with little opportunity to negotiate. CMS's plan to only moderate the effect of protected classes—not eliminate them—would save $2 billion over 10 years.

- There are also clear opportunities to achieve savings in the Medicare Part B program, including introducing Part D utilization management tools into Part B and potentially shifting some Part B drugs to Part D. Because of the complexity involved with identifying the "candidate" drugs for moving into Part D, along with assessing the consequences and impacts of doing so for both programs, we strongly recommend CMS engage stakeholders through a work group-type process where sample, de-identified data could be shared for mutual evaluation.
- We support efforts to ensure the MedPAC and the Medicaid and CHIP Payment Advisory Commission (MACPAC) have access to aggregate, de-identified information submitted currently by PBMs, Part D sponsors, and Medicare Advantage plans to CMS. Legislation to address this issue was recently introduced by several members of this Committee, including Rep. Buddy Carter, Rep. Tom O'Halleran, Rep. Greg Gianforte, and Rep. Peter Welch. We applaud the Committee for its recent passage.

- **Advancing value-based arrangements in public programs:**
  - It is essential to bring the benefit of value-based payment to spending in public programs. Such arrangements may involve outcomes-based payments that cannot be determined until well after the plan year concludes. Changes to existing laws and/or regulations would allow for such arrangements in all settings and help improve the overall value of national spending for pharmaceuticals. The specific changes Cigna and Express Scripts believe are needed include:
    - Modifying Medicaid Best Price (MBP) rules to exclude outcomes-based pharmaceutical contracts from inclusion in MBP calculations in certain situations where failure to achieve a desired outcome leads a manufacturer to refund the full (or majority) cost of the drug, or where payment is contingent on the health outcomes of individual patients;
    - Creating additional flexibility under the Anti-Kickback Statute (AKS) to support value-based contracts and other innovative programs; and,
    - Revising Part D regulations to explicitly permit and provide guidance for how outcomes-based contracting should be accounted for in plan bids or between plan sponsors when the outcome measurement period spans plan years, or when outcomes can only be measured at the end of a plan year.

- **Advancing price transparency for patients and providers in public programs:**
  - We strongly support the concept of providing information about the price of drugs, therapies, and the cost of care to beneficiaries and their providers as a means of improving price transparency, educating consumers, and incentivizing the efficient use of care throughout the health care system. We support efforts by CMS to move toward a system in which Part D enrollees and their providers have access to real-time benefit check and electronic prior authorization tools, while ensuring an appropriate standardization and timeframes for implementation.
- **Speeding generics and biosimilars to market**:
  - Enacting the Creating and Restoring Access to Equivalent Samples (CREATES) Act, introduced by Rep. Peter Welch and Rep. David McKinley, among others, which aims to lower drug prices by ending restricted access to samples by manufacturers of brand-name drugs, and help to speed generics to market. We applaud the Committee for its recent passage. According to the Congressional Budget Office, its enactment would save $3.9 billion over 10 years. [15]
  - Prohibiting patent settlements that include so-called "pay-for-delay" arrangements, which delay the availability of lower-cost generics and biosimilars. Legislation to address these arrangements was recently introduced by Rep. Bobby Rush, and we applaud the Committee for its recent passage. We hope Congress will enact authority to block these anti-competitive agreements, removing barriers to competition and expanding the availability of lower-cost generics and biosimilars. According to a Federal Trade Commission (FTC) study, these anticompetitive deals cost consumers and taxpayers $3.5 billion in higher drug costs every year.[16]
  - Encouraging the FDA to finalize guidance on biosimilar naming standards, improve the efficiency of the biosimilar product development and approval process, and develop effective communications tools to educate providers and patients about the safety and efficacy of biosimilars.
  - Preserving the ability of the Inter Partes Review (IPR) process at the U.S. Patent and Trademark Office to invalidate patents that do not represent true innovation. Legislative and regulatory efforts to weaken this process will extend patent monopolies for pharmaceutical and biological products, resulting in higher prices for patients.
  - Considering changes to provisions included in the United States-Mexico-Canada Agreement (USMCA) that would extend exclusivity for biological products in

[15] https://www.cbo.gov/publication/55181
[16] https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay

Mexico and Canada for ten years. These provisions will limit the ability of Congress to address the 12-year exclusivity period for brand-name biologics.

- **Stopping Orphan Drug Act abuses**:
    - Pharmaceutical manufacturers have been accused of abusing the Orphan Drug Act, which was introduced to incentivize drug manufacturers to prioritize the development of "orphan drugs," drugs used to treat an illness or disease that affects fewer than 200,000 people. We support efforts to ensure that this pathway is used only for true orphan designation, and not, as some observers say, as a legal cover to seek specious orphan drug designations.[17]

Thank you for the opportunity to be here today, and for the consideration of our views. We look forward to working with you and others to improve the affordability and accessibility of prescription drugs for all Americans. Many of the proposals highlighted in my testimony are achievable if we work collaboratively, throughout the system, to overcome the challenges facing public and private stakeholders, and the health of our nation.

I welcome the opportunity to discuss these issues with you and look forward to your questions.

[17] https://khn.org/news/drugmakers-manipulate-orphan-drug-rules-to-create-prized-monopolies/

Ms. ESHOO. Thank you for your testimony.

I now would like to call on Mr. Eberle. And you are recognized for five 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 six 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 opti-

mize 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 healthcare, 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:]

Prepared Testimony: **Brent Eberle, R.Ph, MBA**
Chief Pharmacy Officer, Navitus Health Solutions

Submitted to the United States House of Representatives, Energy and Commerce Committee Subcommittee on Health

May 9, 2019

Chairwoman Eshoo, Ranking Member Burgess and members of the Health Subcommittee, thank you for the opportunity to come before you and share with you how Navitus Health Solutions ("Navitus") — a 100% pass through and fully transparent pharmacy benefit manager (PBM) — provides value to its customers and lowers the overall cost of care.

My name is Brent Eberle, and I am the Senior Vice President and Chief Pharmacy Officer at Navitus, where I have worked since 2004, shortly after Navitus was formed. Navitus was formed in response to frustration at the State of Wisconsin's Employee Trust Fund related to the lack of transparency in the existing, traditional PBM models. Most PBMs use a traditional or "spread" PBM model, where the PBM retains some of the payments from manufacturers and they charge their clients additional margin or "spread" above the amounts that they pay pharmacies. Two Wisconsin health plans, Dean Health Plan and Touchpoint Health Plan worked together to form Navitus as a fully transparent, 100% pass through PBM as an alternative to the traditional model, and that has been Navitus' business model ever since.

Navitus' mission, which we live by every day, reads:

> ***Navitus Health Solutions is a 100% pass-through pharmacy benefit company committed to lowering drug costs, improving health and providing superior customer service in a manner that instills trust and confidence.***

Navitus is headquartered in Madison, Wisconsin, and we have approximately 820 employees located in offices in Wisconsin, Texas and Arizona. Since the founding of our company in 2003, Navitus has relentlessly worked to reduce the overall drug costs paid by our clients, while improving member health, providing superior customer service, and ensuring regulatory compliance. Navitus administers pharmacy benefits for over six million members across our commercial, ACA/Exchange, Medicaid, Medicare Part D, and discount card lines of business. As a pass-through, transparent PBM, Navitus has a different business model than most PBMs.

The term pass-through means that we pass-through to our clients all of the payments that we receive from drug manufacturers in the form of rebates, incentives, administrative fees, data fees, and any other amounts that we receive from drug manufacturers. We also pass-through to our clients all of the discounts that we negotiate with pharmacies and any other amounts that Navitus may receive from pharmacies, such as audit recoveries. We believe that this ensures that there is no conflict of interest or confusion about who we are working for. Navitus is always working on behalf of the benefit plans that are our clients and their members, and never working on behalf of

drug manufacturers or pharmacies. Instead of taking money from drug manufacturers, Navitus charges our clients a reasonable, fully disclosed administrative fee, usually on a per member per month basis.

Navitus believes that it is critical for benefit plan sponsors to have all relevant information so that they can make good decisions related to the plans. As a transparent PBM, we provide our clients with information about all amounts that we receive from drug manufacturers and the discounts we receive from pharmacies, so that they have all of the relevant information that they may need when making decisions about the benefits that they provide and the costs that they pay.

In today's complex and costly health care system, plan sponsors are seeking greater transparency, accountability and affordability. Many do not believe they are getting it from their PBM. In fact, 63% of employers stated in a recent survey that their PBMs aren't transparent, especially when it comes to revenue streams.[1] However, plan sponsors aren't alone. Patients are looking for greater transparency and affordability, too, which is understandable when one in four people can't afford their medications.[2] With an outcry from plan sponsors and patients, calls for reforms have become louder.

The Role of PBMs

In spite of the negative attention that PBMs have been getting recently, PBMs perform several critical functions in getting people the medications that they need at prices that they can afford. PBMs act as consolidators of market power for health benefit plans, acting as a counter balance to the massive market power of drug manufacturers and pharmacy chains. By representing all of the benefit plans that are their clients, PBMs are able to combine the buying power of many individual plans and negotiate with manufacturers and pharmacies to obtain lower prices than any individual plan could obtain on their own. This helps to lower the overall costs of health care.

PBMs also perform numerous other important tasks, like providing population health programs to improve the quality of care and developing systems for the standardized processing of claims and coordination of benefits that has drastically improved the speed and ease that patients can get medications. In addition, PBMs process and maintain eligibility, develop and manage formularies, develop and recommend plan designs, perform retrospective and prospective drug utilization review, monitor quality and implement quality and improvement programs, as well as auditing and investigating fraud, waste and abuse to reduce unnecessarily expenses, improve quality of care and help law enforcement prosecute fraudulent activities.

One of the most critical and unique functions that we perform for our clients is negotiating pass-through arrangements to reduce their pharmacy costs. When negotiating with pharmacies, we obtain market competitive prices to ensure our clients receive the lowest net costs. In these negotiations, we develop both broad and limited networks for our clients and their members depending on their needs. Broader networks provide access to a larger range of pharmacy choices and limited networks provide adequate access, but also result in lower prices when implemented. When negotiating with drug manufacturers, we determine the overall product value by evaluating

clinical efficacy and the net cost. We then prefer the products with the best overall value resulting in a lowest net cost formulary. We fully leverage our pass-through model in these negotiations, so the manufacturers and pharmacies know that all of the benefits go to our clients to help lower their overall pharmacy benefit cost.

Part of my role at Navitus is to oversee the clinical aspect 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 to ensure medications are used appropriately and according to current practice guidelines, increase medication adherence through patient education and engagement, and prevent the overuse or misuse of medications through our opioid management efforts. Our clinical teams are passionate about improving patient care, and our business model based in financial and operational transparency helps to ensure the programs we develop provide value and optimize the dollars our clients make available for pharmacy. We play an active role in being stewards of the pharmacy benefit for our clients and their members.

In addition to our population health programs, our clinical teams are charged with developing formularies that appropriately balance clinical quality and the lowest overall net cost. This is core to what we have done from day one. As part of our commitment to the approach, we have strategically aligned the Formulary and Drug Information teams alongside the Industry Relations (or Rebates) team to ensure our goals and objectives around quality and lowest net cost are aligned across the organization. Through this approach and our overall business model, we have been able to remove any incentive to add a product to the formulary simply to garner rebate discounts.

Our lowest net cost approach combined with a full pass-through of all rebate dollars and zero spread has consistently delivered industry-leading drug trend management. While PBMs are often evaluated by those in the industry on specific pricing metrics that can be difficult to compare and often result in higher costs, we direct our focus on managing our client's per member per month net drug spend. In 2018, our net drug spend was nearly flat and nearly 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 also saw a 2% decrease in their out of pocket pharmacy costs. Additionally, this approach can be applied across all lines of business including commercial, Medicare Part D, and Managed Medicaid.

The continued evolution of our business model is to extend transparency to our providers and members through innovative technology that is focused on 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's members see where the lowest cost pharmacy is in their area. Additionally, the growth of the Internet of Things (IoT) 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 in 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 drug costs.

Recommendations for First Steps

As with all parts of healthcare, transparency and aligned incentives can play a significant role in improving quality and reducing cost. We strongly believe in these principles and that is why we have created a full pass-through PBM so that every dollar in rebates and incentives from the manufacturers are passed through to our clients to reduce the cost of healthcare premiums. Every year we have a third party audit our books and validate our process and we invite every client to look at our books to see what we are doing. Our model works and our clients appreciate how we are able to reduce the cost of healthcare.

As the Administration, Congress and even state legislatures undertake efforts to reduce the cost of pharmaceuticals through regulation of PBMs, we advise caution to avoid inadvertently increasing the cost of prescription drugs to the consumers. Even though our fully transparent pass-through model gives all of the rebates back to our clients, we believe that removing rebates may take away a useful tool for reducing costs for our clients.

Any effort to reform the PBM industry should start with increasing transparency so that the decision-makers in benefit plans, and in governmental entities for government-sponsored plans, have all of the information that they need to make the best decisions they can. In the current system, too many of the decisions being made, including proposed regulation, are based on partial information. By making the necessary information available to the individuals and entities making decisions, with enough detail to support those decisions, the entire system can be made more efficient and much better decisions could be made, improving care and lowering costs.

In addition to transparency, we recommend taking out the conflicts of interest plaguing the PBM industry. Most PBMs accept money from drug manufacturers in the form of rebates, administrative fees, data fees, and other financial incentives with numerous designations. We believe that when PBMs retain payments from drug manufacturers, it creates misaligned incentives, where the PBM is actually working for the drug manufacturers, and not just for the benefit plans and their members. To avoid such a conflict of interest, at a minimum PBMs should be required to fully disclose to their clients all amounts retained from drug manufacturers, in detail, so that the true costs of medications are known to the plans paying for them.

Similarly, we believe that the actual amount paid to pharmacies by each PBM, along with any claw backs, claim recoveries, or other amounts paid to the PBM by the pharmacy, should be disclosed to the PBMs' benefit plan clients. If such amounts are not fully disclosed (or passed through) to the PBMs' clients, then the PBM has an incentive to maximize the financial incentives received from drug manufacturers and the "spread" added to pharmacy to maximize the PBMs' profits at the expense of their clients.

CMS Proposed Change in Safe Harbor Rule for Rebates

As you know, CMS proposed a new rule for the Medicare Part D and Medicaid managed care programs, on January 31, 2019, that would "remove the safe harbor exemption for rebates applied

after the point-of-sale and establish a new safe harbor that would enable a pharmaceutical manufacturer to offer reduced prices on a prescription pharmaceutical product (referred to as chargeback discounts) when they are applied at the point-of-sale."[3] At Navitus, we agree with the Department of Health and Human Service's stated goal of trying to lower prescription drug costs for the millions of Americans who desperately need medications and trying to increase transparency in drug pricing, as these goals have been part of our corporate mission from the start of our company. We also agree that traditional PBM business models may drive up drug expenses by promoting higher cost agents in their quest to secure higher rebates from drug manufacturers because traditional PBMs often keep a portion of the rebates that they negotiate. In contrast, however, Navitus discloses the amount of all rebates it receives from manufacturers and passes 100% of all these rebates back to our clients.

While we understand and admire CMS' intent to reduce the cost of prescription drugs, we believe it is essential to understand that not all PBMs are alike. Reforms meant to impact spread pricing and non-pass-through rebate models will impact PBMs like Navitus and its clients. We also do not believe that the proposed rule will solve the issue of increasing drug prices. Additionally, we are concerned that the proposed rule will have unanticipated negative consequences for beneficiaries and health plans.

Navitus agrees that rebates from drug manufacturers warp the incentives that PBMs are operating under, creating a market dysfunction where the goals of CMS and the Part D plans are not aligned with those of the PBMs providing services to the plans. For PBMs, the amount of rebates that are paid to Part D plans are often used as a rough measure of performance by the plans and their consultants. However, higher rebates are not necessarily a good proxy for lower costs. When PBMs choose drugs with higher rebates, but also higher overall costs, then the total costs can be significantly higher for the plans and CMS in spite of the higher rebates.

The proposed rule appears to assume that all PBMs use traditional "spread" pricing, where a percentage of rebates is retained by the PBM, and assign blame for high drug prices to all PBMs and rebates provided by drug manufacturers. However, transparent, pass-through PBM models that align to the best interest of payers that purchase their services are already being employed in the industry.

As noted above, Navitus uses a transparent, pass-through model and passes all rebates it receives back to its clients. As a transparent PBM, Navitus also provides its clients with all of the information they need to make benefit decisions necessary to achieve the lowest possible overall costs. Our model removes the incentives to make decisions that result in higher drug costs. When combined with our focus on delivering the lowest-net-cost medications, our clients experience lower year-over-year drug trend, decreased per-member-per-month (PMPM) drug expenses, and reduced overall pharmacy costs. We believe that this model already achieves what the proposed rule intends to make happen and propose that if both (a) transparency and (b) the passing through of all drug manufacturer payments to Part D plans or CMS were required, that would solve most of the issues that result from the current rebate structure in drug pricing.

Conclusion

Thank you for the opportunity to share with you our pass-through PBM model and our recommendations for moving forward. Even though the pass-through PBM model covers a small portion of overall lives across the country, Navitus and its smaller peers such as Independent Health (Buffalo, NY) and SelectHealth (Murray, UT) have played an important role in driving down the overall cost of prescription drugs for our clients.

As this Committee looks at ways to reduce the overall cost of prescription drugs, we believe that transparency in the market is the most important first step that can be made to truly understand the cost of drugs. Transparency is what our clients want and transparency is what we provide. We firmly believe that transparency should be the norm, not the exception.

Thank you again for this opportunity.

Brent J. Eberle, RPh MBA
Senior Vice President, Chief Pharmacy Officer

Navitus Health Solutions, LLC is a wholly owned subsidiary of SSM Health, an integrated health system headquartered in St. Louis, Missouri that is a not-for-profit entity originally founded by Catholic nuns in 1872. SSM Health currently has over 40,000 employees in Missouri, Wisconsin, Illinois and Oklahoma. SSM Health also operates Dean Health Plan, a provider sponsored health plan in Wisconsin, which serves the individual, commercial, Medicaid and Medicare market. SSM Health is also one of the founding members of Civica Rx, a non-profit drug manufacturer whose mission is to reduce drug shortages and ensures that essential generic drugs are available and affordable to everyone. Dean Health Plan is also a member of the Alliance of Community Health Plans, which also includes PBMs with similar models to Navitus, including SelectHealth and Independent Health.

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Appendix: Background on Different PBM Models

Given that the PBM industry is not well known to individuals outside the industry, we believe it may be helpful to understand the three PBM models generally in use—traditional, hybrid and pass-through.

Traditional PBMs

Traditional models earn "spread" or revenue through various pharmacy dispensing channels such as retail, mail, and specialty. Spread occurs when the pharmacy is paid one price and the plan sponsor is charged a different—most often higher—price. The difference is often referred to as "spread."

Traditional pricing models also generate spread by retaining a portion of the negotiated rebates from pharmaceutical manufacturers. This incentivizes the PBM to create more spread revenue by driving up costs through formulary product selection. In turn, this leads PBMs to promote products that have higher rebates, creating an incentive for manufacturers to price products higher and deeply rebate the products back to the PBMs. As a result, plan sponsors and members end up paying more than they need to. This might be why 69% of employers in a recent survey stated that they would welcome an alternative to rebate-driven approaches to managing pharmacy costs.[4]

To earn more revenue, traditional PBMs agree to dollar-for-dollar-guarantees that are locked into the contract with the plan sponsor. Over the course of a typical three-year agreement, the PBM may negotiate better contracts with pharmacy networks and pharmaceutical manufacturers. Any improvements in those contracts become additional revenue for the PBM.

Because PBMs operating under this model produce significant margin on spread pricing of drugs, they typically charge a significantly reduced administrative fee for services rendered as the majority of their revenue comes from the non-disclosed fees. Visibility into actual market prices and the actual true-net cost (net of rebates) are significantly obscured, if not invisible to plan sponsors.

The traditional model is the most popular of the PBM approaches and accounts for about 94% of overall PBM business and transactions across the industry.[5] Although the other models may seem less popular, fewer plan sponsors choose these because they are unaware other options exist. However, these alternative models are gaining traction.

Hybrid PBMs

Hybrid pricing models offer some combination of the traditional and pass-through models for a slightly more transparent option, allowing visibility into some pricing and revenue practices. A hybrid model may disclose the portion of rebates it retains and takes spread in only one or two channels such as mail and specialty. However, transparency is limited, leaving little visibility into how much the PBM retains. Hybrid PBMs may charge a minimal administrative fee or none at all.

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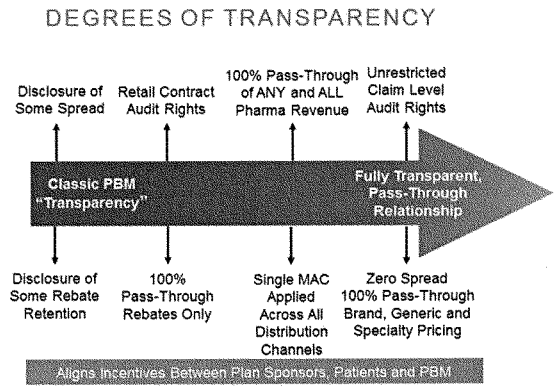
Pass-Through PBMs

On the other hand, pass-through pricing models offer the most transparency. As the result of a pass-through PBM's transparent financial and operational processes, 100% of rebates and discounts are passed back to the plan sponsor. Because spread is not involved from any distribution channel, the plan sponsor is billed the same amount the pharmacy is paid. This takes the unnecessary costs out of pharmacy benefits, making prescriptions more affordable for plan sponsors and their members. A pass-through PBM's only revenue source is an administrative fee for services agreed to by the plan and PBM up front. This model offers visibility down to the claim and invoice level for complete transparency and full disclosure. Ultimately, the plan sponsor has complete visibility into the true claims cost and knows what it is paying for PBM services.

It is important to note that some traditional PBMs are claiming to offer a "pass-through" model. However, plan sponsors should be aware that this might be their version of a pass through. A 100% pass-through PBM does not retain any dollars from pharmacies or pharmaceutical manufacturers.



Impact of the Proposed Changes Related to Rebates in each PBM Model

Most of the traditional model PBMs are publicly traded companies and must answer to shareholders. Historically, they have performed well and delivered a high gross profit per claim. Without revenue from rebates, these organizations will likely have to find other revenue streams, from both new and existing sources. This may occur as higher administrative fees or increased pharmacy network spread, negatively impacting plan sponsors.

Hybrid PBMs may follow suit as well. Although some of these organizations may not be publicly traded, they will still need to replace lost revenue.

Pass-through PBMs tend to be smaller, privately held organizations so they likely will not be negatively impacted by the removal of rebates. They operate with full financial disclosure and transparency and charge an administrative fee to earn revenue. Since revenue streams are not impacted under the pass-through model, this may provide plan sponsors with an option that is more predictable from a cost standpoint and can continue to deliver the desired savings for greater affordability. [6]

Specialty Pharmacies

Like many PBMs, Navitus owns a specialty pharmacy, Lumicera Health Services, which employs an industry-unique, transparent, cost-plus model. In a typical specialty pharmacy model, the pharmacy is paid on a percentage basis for each prescription dispensed. This percentage can range from 6 to 15 percent, which can amount to substantial additional cost due to the high acquisition price of specialty medications. In contrast, Lumicera's transparent, 100% pass-through business model operates by charging clients the actual drug-acquisition cost, cost of shipping, and a fixed patient management fee to cover dispensing and patient care, based on the handling and clinical counseling needs of the drug and its disease state.

Sources:

[1] Toward Better Value: Employer perspectives on what's wrong with the management of prescription drug benefits and how to fix it, National Pharmaceutical Council, 2017, page 8, https://www.npcnow.org/system/files/research/download/npc-employer-pbm-survey-final.pdf

[2] Kaiser Family Foundation Health Tracking Poll – February 2019: Prescription Drugs, March 1, 2019, https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/

[3] https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/RxSafeHarbor.html

[4] Toward Better Value: Employer perspectives on what's wrong with the management of prescription drug benefits and how to fix it, National Pharmaceutical Council, 2017, page 8, https://www.npcnow.org/system/files/research/download/npc-employer-pbm-survey-final.pdf

[5] Navitus analysis, 2014-2017 and SEC filing from traditional PBMs, 2014-2017.

[6] See *The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Manager*, Drug Channels Institute, 2018.

Ms. ESHOO. Thank you very much.

We have concluded the opening statements. We are going to move to member questions. Each Member concerning the value of cabozantinib based on the data from our clinical trials and the drug's safety profile. Member will have five minutes to ask questions of our witnesses and I will start by recognizing myself for five 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 payors 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. OK, 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. Yes.

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 five 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, but 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 an OIG rule that views that as a form of kickback, and so it is seen as an inducement to try and get patients on drugs.

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

Mr. BURGESS. Correct.

Mr. HESSEKIEL [continuing]. Elimination of that restriction across public health plans. We are saying that for cancer patients and patients with catastrophic disease——

Mr. BURGESS. It makes sense.

Mr. HESSEKIEL [continuing]. 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 five 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 untangle 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. OK.

Mr. HESSEKIEL. Absolutely.

Ms. MATSUI. OK, 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 healthcare 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 healthcare 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 healthcare 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. OK, 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. OK. 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. OK. 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? OK.

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 five 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' 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 healthcare 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 focus 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 really 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 whatever 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 five 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 healthcare.

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 reform 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 three or four 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 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 information 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 five minutes of questioning.

Mr. PALLONE. 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 improved 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.

Mr. PALLONE. 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.

Mr. PALLONE. 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.

Mr. PALLONE. Do you want to add to that or, if not, do you agree?

Mr. EBERLE. I agree.

Mr. PALLONE. 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.

Mr. PALLONE. OK. 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.

Mr. PALLONE. OK, 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——

Mr. PALLONE. 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——

Mr. PALLONE. 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.

Mr. PALLONE. 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.

Mr. PALLONE. 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 five 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 Oversight&Investigation 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 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 Oversight&Investigation, 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 brand product that offer a discount and then determine 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 authorization protocol to ensure the lowest cost product is used first.

Mr. GUTHRIE. OK. 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 failing 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. OK, I only have eight 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 five 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. OK, 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. OK, 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. OK. Well, please do, on Amgen's position, because we are all concerned about the market effects of these type of agreements. I mean nine 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 five 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 3-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. OK. 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, are able to offer affordability for all patients with diabetes, and are 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. OK. 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. OK. 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. OK. 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 five 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. OK. 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 it 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. OK.

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

Mr. BUCSHON. OK, fair enough.

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

Mr. BUCSHON. OK. 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. OK. 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 are certainly competitive pressures to raise rebates, or discounts, as the chairwoman would like me to use the term.

Mr. BUCSHON. Discounts, OK.

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. OK. 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. OK, 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. OK, 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 a 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. Luján, for his five minutes of questions.

Mr. LUJÁN. 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 look like. You say, "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."

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. LUJÁN. Very similar, actually, answers the question.

Mr. MCCARTHY. Yes, very similar. Yes.

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

Mr. MCCARTHY. Oh, OK.

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

Mr. MCCARTHY. Yes.

Mr. LUJÁN. OK.

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. LUJÁN. Can you get me a dollar amount of how much money——

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

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

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

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

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

Mr. LUJÁN. 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. LUJÁN. 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. LUJÁN. 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 payors.

Mr. LUJÁN. 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. LUJÁN. Mr. Niksefat?

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

Mr. LUJÁN. 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. LUJÁN. Mr. Niksefat?

Mr. NIKSEFAT. Yes, that is correct.

Mr. LUJÁN. Mr. Hessekiel?

Mr. HESSEKIEL. That is correct.

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

Ms. BRICKER. Yes.

Mr. EBERLE. Correct.

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

Mr. NIKSEFAT. Yes.

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

Mr. NIKSEFAT. That would represent a public disclosure.

Mr. LUJÁN. Are you willing to disclose them publicly——

Mr. NIKSEFAT. Yes.

Mr. LUJÁN [continuing]. 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. LUJÁN. Mr. McCarthy?

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

Mr. LUJÁN. 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 [continuing]. 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. OK 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. OK.

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. OK. 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 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 five 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. OK.

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, five 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 has 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 the 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. OK, 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 be placed on the formulary?

Ms. Bricker.

Ms. BRICKER. We do not.

Mr. SCHRADER. OK.

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 five 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 onto 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 of the 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. Luján 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 only 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.

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.

Where's the solution? Help us help you. Give us 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 peel, 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 him. You are recognized for five 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 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 are 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 OK 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 at 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 two 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 are 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. OK, 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 five 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 needed to give them seven 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, have experienced difficulty getting our biosimilars on formularies.

Mr. CARTER. OK, 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. OK. 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. OK 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 five months and has recently matched our move 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. OK, 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. OK, 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. OK, 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. Eberle.

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 copay, 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. OK, 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 five 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, or 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. OK, 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. OK, and you?

Mr. EBERLE. Yes, we utilize 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. OK, 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. OK, so I get a sense that they are not consistent throughout the industry.

Mr. EBERLE. I would—each PBM, each health plan——

Mr. RUIZ. OK, 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 got 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. OK 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. OK.

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. OK, 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 are 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. OK. 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 five 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, "Amgen establishes a list price for our medicines in the context of an established set of pric-

ing 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-ones, 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, eight 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 nearly three times as high in 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 countries that was free and a competitive market for drugs, not a country that engages in price controls. I am not sure 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. OK. 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 eight 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 I 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 five 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 prescribers.

Mr. BILIRAKIS. OK, 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. OK.

Ms. BRICKER. And then it makes its way to the beneficiary through lower premiums and lower coinsurances or copays.

Mr. BILIRAKIS. OK 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. OK. 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. OK.

Ms. BRICKER [continuing]. Or out-of-pocket costs at the point-of-sale.

Mr. BILIRAKIS. OK 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 for them 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 one day, depending on how busy they are or other factors.

Mr. BILIRAKIS. OK. 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. OK, I would like to—OK, yes, please. Anyone from—anyone else want to add something to that?

OK, 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. OK, very good.

I guess I yield back. You are right, those five 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 as, 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. OK, 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 three 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 don't 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 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.

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 on 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. OK, 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. 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. OK 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 five 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 six 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, so 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. OK, 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 pressured 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. OK. 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, if it is on the deductible or on the coinsurance basis.

Ms. KUSTER. Yes, OK.

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. OK, 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 five 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 copay, it really makes it ridiculous. Other developed nations are able to achieve savings because they are not afraid to leverage the purchasing power of the 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 are 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, OK. 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. OK, 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 the 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 five 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 [continuing]. Repatha, is unavailable to your company's own 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 [continuing]. 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 three 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 five 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, phar-

macy 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. OK.

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 antiparasitic 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. OK, 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.]

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. OK, 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. OK, away we go.

Dr. Greene, you are now recognized for your five 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. OK? 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, PHAR.D., VICE PRESIDENT, PHARMACY SERVICES, BLUE CROSS BLUE SHIELD OF NORTH CAROLINA; LYNN ESCHENBACHER, PHAR.D., CHIEF PHARMACY OFFICER, ASCENSION; JACK RESNECK, M.D., CHAIR, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION; RICHARD ASHWORTH, PHAR.D., PRESIDENT OF PHARMACY, WALGREENS; AND LEIGH PURVIS, DIRECTOR, HEALTH SERVICES RESEARCH, AARP

STATEMENT OF ESTAY GREENE, PHAR.D.

Dr. 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 healthcare 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 three 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 Dr. Greene follows:]

Testimony on

Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain

By

Estay Greene, Pharm.D., M.B.A.

Vice President, Pharmacy Services

Blue Cross and Blue Shield North Carolina

Before the

House Energy and Commerce Committee

Subcommittee on Health

May 9, 2019

Introduction

My name is Estay Greene and I am the Vice President of Pharmacy Services with Blue Cross and Blue Shield of North Carolina (Blue Cross NC).

Since 1933, Blue Cross NC 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.

Blue Cross of NC is a member of the Blue Cross Blue Shield Association (BCBSA), a national federation of 36 independent, community-based, and locally operated Blue Cross and Blue Shield companies that collectively provide healthcare coverage for one in three Americans. Blue Cross and Blue Shield companies offer quality healthcare coverage in all markets across America and participate in all federal insurance programs, including the Federal Employee Health Benefits Program (FEHBP), Medicare Advantage, Part D, CHIP and Medicaid managed care programs. BCBS companies also serve individuals and employers in the small and large group markets. We are committed to high quality, affordable coverage for all regardless of pre-existing conditions. Blue Cross of NC has offered coverage in the Affordable Care Act Exchanges in every county in North Carolina since 2014.

For nearly a century, BCBS companies have provided secure and stable healthcare coverage to people in communities across the country, allowing them to live free of worry, free of fear. Serving one-in-three Americans nationwide (over 106 million), BCBS companies, their foundations, and their employees stand committed to their local communities – where they live and work. They do this by creating and supporting programs that drive positive health outcomes addressing some of the most pressing issues affecting the country today: community health disparities, the opioid epidemic and social determinants of health.

I would like to thank Chairwoman Eshoo (D-CA) and Ranking Member Burgess (R-TX) for their leadership in holding today's hearing and providing the opportunity to discuss key ways to improve patient access to affordable prescription drugs. In my remarks today, I will address:

I. How Blue Cross NC engages with drug supply chain entities
II. Blue Cross NC activities to help patients afford prescription medicines
III. Policy solutions to address rising drug prices

Blue Cross NC Engagement with Drug Supply Chain Entities

PBMs Provide Services for Blue Cross NC and its Members

Blue Cross NC 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 NC 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.

The primary form of drug discounts by PBMs has evolved into manufacturer rebates on some brand and specialty drug products. Today, PBMs negotiate with manufacturers for the rebates to secure the lowest net prices for their health plan and employer clients. In the commercial market, PBMs pass along the vast majority of rebate dollars to their health plan clients, who, in turn, use those savings to decrease premiums or reduce out-of-pocket costs for prescription drugs for all of their insured customers. All Prime Therapeutics owner clients receive a pass through of 100 percent of manufacturer rebates (see the *Blue Cross NC activities to help patients afford prescription medicines* section below for how Blue Cross NC shares rebates with members).

In the Part D and MA-PD markets, PBMs are required to pass on rebates to plan sponsors, and plan sponsors, with few exceptions, then use those rebate dollars to keep premiums low for all of their Medicare beneficiaries. Low Part D premiums ensure access to Part D coverage. CMS noted that higher rebates and other price concessions lead "to lower bids and, therefore, puts downward pressure on beneficiary premiums."[1] In the Medicaid markets, either states or a contracted entity (e.g., Medicaid MCO or its PBM) negotiate with manufacturers to secure supplemental rebates for state Medicaid programs.

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[1] Centers for Medicare & Medicaid Services. Fact Sheet. "Medicare Part D – Direct and Indirect Remuneration (DIR)." 19 January 2017.

Health plans and their PBM partners have had some success in holding drug manufacturers' monopoly pricing power in check. In PBM drug trend reports for 2017, several PBMs cited negative or low, single-digit spending growth for commercial, Medicare and Medicaid clients even when the specialty drug spending trend was in the double digits.[2] This demonstrates the value of PBMs negotiating manufacturer rebates on behalf of health plans and their enrollees, while highlighting the growing concern of specialty drug pricing and utilization.

The Role of Pharmaceutical & Therapeutic (P&T) Committees: Informing Decisions with Supply Chain Entities and on Pharmacy Benefits

A PBM will leverage its purchasing power when negotiating with drug manufacturers for the lowest possible net price, but there are other conditions and programs in use to drive prices lower for enrollees. PBMs and/or their health plan clients determine:

- Whether a drug will be a covered drug on a formulary
- A drug's formulary tier placement and the corresponding cost-sharing amount
- Whether a drug is subject to safety protocols or utilization management programs that encourage consumers to select drugs based on safety, clinical effectiveness and cost effectiveness

PBMs use drug formulary and coverage status (e.g., tier and extent of utilization management requirements such as step therapy) for a given drug relative to competitive products to negotiate

[2] For examples, see CVSHealth Drug Trend Report 2017, https://payorsolutions.cvshealth.com/sites/default/files/cvs-health-payor-solutions-2017-drug-trend-report-feature-april-2017.pdf; Prime Therapeutics trend reports 2017, https://www.primetherapeutics.com/en/news/pressreleases/2018/drugtrend-2017-release.html; Express Scripts trend report, http://lab.express-scripts.com/lab/insights/industry-updates/record-low-increase-in-rx-spending-in-2017.

discounts in the form of rebates from manufacturers. The PBM and its plan client in turn agree to cover drugs and offer enrollees incentives to use particular medications (such as lower cost-sharing through tier placement).

These decisions are made with input from a pharmacy and therapeutics (P&T) committee, a multidisciplinary expert group that is usually comprised of *external* doctors, pharmacists and other health care professionals, along with some plan medical professionals. This committee reviews medications and related products throughout the year based on current evidence-based medicine and makes recommendations on which drugs to include on the plan formulary. In making the decision to add a drug to the formulary, the evidence would have to show clinical benefit to have the drug available for use by a plan's members. When recommending to not add a drug, the clinical evidence generally must be insufficient to meet the standard of adequate scientific rigor to prove efficacy or safety.

P&T committees may determine that some drugs are simply as good as what is currently available. In those cases, the drugs in question will not be given as high a priority for inclusion in the formulary unless their side effect profile represents an improvement from the alternative. It also may replace the current drug if it provides an equal or superior alternative but is more cost effective. If a drug is excluded from a formulary, plans will cover at least one alternative treatment that is both as effective and safe in treating a disease or condition.

Cost considerations do not enter into the P&T decision-making process as to whether a given drug meets the scientific evidence hurdle to support that it is both safe and effective for the

conditions that it is designed to treat. However, once a P&T committee determines that a drug falls into the "may add" category[3], a plan takes into consideration the cost of similar drugs. That generally is operationalized by favoring the most cost-effective drug(s) in a category for inclusion in the formulary, or by choosing to differentiate competing products through benefit design, e.g., through tiered formularies where a similar drug of higher cost sits in a tier that requires a higher member contribution. This is an example of the importance of distinguishing pharmacy policy from pharmacy benefits. P&T committees rarely are involved in creating pharmacy benefits, unless they are asked to render an opinion about the potential advantages or harm to a patient of a benefit design.

Blue Cross NC Activities to Help Patients Afford Prescription Medicines

Blue Cross NC shares the Committee's goals to ensure patients have access to safe, effective and affordable prescription medicines. Here are three specific policies or tools we are using:

First, we made the decision starting January 1, 2019, to pass back drug rebates directly to customers when they buy rebated drugs. In the first quarter of 2019, we passed back $3.13M to members in rebates, decreasing our members' cost share by 19 percent. This change applies to all of our fully insured customers and is an option for large employers whose claims we manage but are paid by their employer.

[3] Here we use drugs in the "may add" category to mean a drug that may or may not be added as a covered drug under the pharmacy benefit for reason that therapeutically equivalent drugs, with similar efficacy and risk profiles, are available.

Blue Cross NC negotiates prescription rebates with drug manufacturers to help offset the high costs of their products. We have always passed back these rebates to our customers, and we will continue to do so. In the past, we have spread the rebates across our entire customer base to offset premium increases. Now, as costs at the pharmacy counter continue to soar, we are going to target this benefit specifically to our members taking high cost, rebated prescription drugs.

This is especially important for members with high deductible health plans who could potentially bare a much larger out-of-pocket cost for high-priced rebated drugs. High deductible plans were introduced as a way to hold down premiums in response to continually rising health care and pharmaceutical costs. They have grown in enrollment: among our fully insured population, members with high deductible health plans increased by 600 percent since the end of 2006 – or from 16,000 members in 2006 to more than 110,000 at the end of 2018.[4]

Here is how passing back rebates will 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.

While our policy change will help, much more must be done. In just the last three years, drug manufacturers have increased costs for our customers by $360 million, but only increased rebates by $130 million – pocketing $230 million of their cost increases[5].

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[4] Blue Cross NC internal data, accessed May 7, 2019
[5] Blue Cross NC internal data, accessed Dec. 8, 2018

A study released this week from Johns Hopkins found that drug prices were 3.2 to 4.1 times higher in the U.S. on average than in comparison countries, even with rebates taken into account.[6]

And even with passing back more than $3 million in the first quarter, Blue Cross NC and those same members still paid more than $33 million for rebated drugs in that same timespan.[7]

To significantly address high costs, we have to address the main driver: expensive prescription drugs. We believe that proposals that increase competition in the pharmaceutical industry are necessary to bring lower-cost, equally effective medicines to patients.

Second, BCBS companies are committed to providing access to prescription medicines and educating members about formulary changes in a clear and effective matter. Consumers need actionable information about their pharmacy benefits and cost-sharing amounts. Blue Cross NC educates our members on how their pharmacy benefits work to access prescription drugs and provide a variety of interactive tools to help members choose the most effective, most affordable medicine.

Specifically, we recently launched a transparency tool around Rx pricing where we send information to members about the 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

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[6] Johns Hopkins University Bloomberg School of Public Health, May 6, 2019
[7] Blue Cross NC internal data, accessed May 7, 2019

Solutions, has generated $10 million in member drug savings, and has an average savings of $153 per fill.[8]

Third, to help members with high-deductible health plans save on drug costs, we waive the deductible on the purchase of preventive care medications. Currently, we waive the deductible on medications that prevent drug use, cancer, cardiovascular events, osteoporosis, and asthma.

Policy Solutions to Address Rising Drug Prices

Blue Cross NC applauds the committee for holding this hearing and seeking this opportunity to address the high cost of prescription drugs. We support policies to ensure that people have timely access to safe, effective and affordable cutting-edge prescription medicines when they need them. BCBS companies across the United States have been working to move to value-based and outcomes-based arrangements for prescription medicines to achieve improved quality at lower cost.

Based on these experiences as well as BCBS companies' generations of healthcare experience and commitment to ensuring their customers' health needs are met, BCBSA has identified four key strategies to address escalating prescription drug costs and ensure that people have timely access to safe, effective, cutting-edge prescription medicines and their generic equivalents at the most affordable price, and in the right setting. These include:

[8] RxSS 2018 Book of Business results over the last 2–3 years.

1) *Reducing barriers that limit competition and consumer choice*. Currently, significant barriers hinder patients' timely access to affordable and safe generic drugs and biosimilars. Promoting competition and consumer choice will make prescription medicines more affordable. To that end, we support passage of the CREATES Act, bills that prohibit anticompetitive pay-for-delay arrangements, and bills banning patent abuses that unduly delay generic and biosimilar entry.

2) *Promoting greater transparency and sharing of information regarding the pricing of prescription medicines*. Understanding how drug prices are currently established is a necessary step in discussing any policy options that are meant to address the unsustainable rate of rising prices. There should be transparency regarding the pricing of prescription medicines, a drug's effectiveness relative to other treatments and an assessment of the therapeutic value of the product. It is also important that health insurers know which new drugs are coming into the pipeline. This allows health insurers to work with doctors and pharmacists in planning and working to ensure there are ways to get prescription medicines to patients at the most affordable cost.

3) *Providing medical and healthcare professionals with the tools they need to support patient education and adherence*. BCBS companies support policies that give medical professionals the tools they need to educate and support patients in taking their prescription medications as directed. Unfortunately, nearly three out of four people report that they do not always take their prescription medicine as directed. Addressing this problem would improve patients' health and safety, prevent adverse side effects and unnecessary hospitalizations, and, as a result, help to rein in costs.

4) *Promoting additional regulatory changes that help patients get the right medicines for them, at the most affordable prices.* BCBS companies believe that a number of regulatory adjustments can be made to increase competition and improve patient access to affordable prescription medicines. These include: (a) removing the "protected class" status in Part D for certain medications to allow for better drug price negotiations and increased use of tools to help patients get the right medicines at the most affordable prices; (b) ensuring FDA regulation of prescription drugs off-label use ; and (c) modifying drug marketing guidelines to include transparency on pricing and improved information on clinical effectiveness.

More information on these recommendations can be found in BCBSA's white paper, "Ensuring Patient Access to Safe, Effective and Affordable Prescription Medicines."[9]

Again, we commend the committee for taking on these important issues as it is critical that all stakeholders work together to ensure the affordability of prescription drugs for all Americans. Achieving this important goal will require the public and private sectors to collaborate to develop solutions that benefit patients and the entire health system.

Thank you for the opportunity to testify today and your leadership in seeking opportunities to improve healthcare.

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[9] "Ensuring Patient Access to Safe, Effective and Affordable Prescription Medicines," https://www.bcbs.com/sites/default/files/file-attachments/page/DrugPricing_WhitePaper_110317.pdf

Ms. ESHOO. Thank you very much, Dr. Greene.

The clock shows that you have three 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?

Dr. GREENE. I agree.

Ms. ESHOO. Wonderful. Thank you for your testimony.

Now it is a pleasure to welcome Dr. Eschenbacher and you have five minutes to present your testimony.

STATEMENT OF LYNN ESCHENBACHER, PHAR.D.

Dr. 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 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 four 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 payors 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 prices 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 Dr. Eschenbacher follows:]

TESTIMONY OF
LYNN ESCHENBACHER, PHARMD, MBA, FASHP
CHIEF PHARMACY OFFICER AND
VICE PRESIDENT OF MEDICATION MANAGEMENT

Ascension

Before the
UNITED STATES CONGRESS
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Health Subcommittee

Hearing on
Lowering Prescription Drug Prices:
Deconstructing the Drug Supply Chain

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I. Introduction

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 currently serve as Chief Pharmacy Officer and Vice President of Medication Management at Ascension. I want to start by thanking the full Committee and this Subcommittee for your ongoing, bipartisan, and thoughtful work to address the important issue of high and rising drug prices. I appreciate you calling today's hearing to look more closely at and better understand how the drug supply chain works, particularly the role it plays within the broader context of the drug pricing debate. Ascension appreciates these efforts and we are honored to be here today testifying before the Subcommittee.

II. Background

Ascension is a faith-based healthcare organization dedicated to transformation through innovation across the continuum of care. As one of the leading non-profit and Catholic health systems in the U.S., Ascension is committed to delivering compassionate, personalized care to all, with special attention to persons living in poverty and those most vulnerable. In FY2018, Ascension provided nearly $2 billion in care of persons living in poverty and other community benefit programs. Ascension includes approximately 156,000 associates and 34,000 aligned providers. The national health system operates more than 2,600 sites of care – including 151 hospitals and more than 50 senior living facilities – in 21 states and the District of Columbia, while providing a variety of services including physician practice management, venture capital investing, investment management, biomedical engineering, facilities management, clinical care management, information services, risk management, and contracting through Ascension's own group purchasing organization.

In my current role, I am responsible for developing and implementing pharmacy services that positively impact patient safety and quality. I am also responsible for improving operational efficiencies through the standardization and optimization of pharmacy services while demonstrating the value of pharmacy. I spend the vast majority of my time thinking about, developing, and rolling out new programs and processes that allow Ascension to be a better steward of patient, public, and system finances, while improving the health and wellness of our patients and communities.

Before coming to Ascension, I worked in a wide array of settings – including academic medical centers, community hospitals, and county hospitals, as well as with systems that run physician practices and infusion centers. I have also worked in a variety of roles – including medication safety, clinical services, operations, and process improvement. Immediately prior to joining Ascension, I served as Assistant Director of Clinical Services for Pharmacy for WakeMed Health & Hospitals in Raleigh, NC. Before that, I was the Medication Safety Officer for Duke University Hospital in Durham, NC. I completed a pharmacy practice residency at Parkland Health & Hospitals in Dallas, TX, and hold a bachelor's degree in biology from Indiana University in Bloomington, a doctorate of pharmacy from The University of Texas at Austin, and a master's of business administration from The Fuqua School of Business at Duke University with a focus in Health Sector Management. I am currently a fellow of the American Society of Health-System Pharmacists (ASHP) and was awarded the national Distinguished Service Award by ASHP.

These positions and experiences total almost 20 years in this field and have provided me with substantial knowledge about how the medication supply chain works, where it delivers significant value for patients, and where there are opportunities for improvement. I am honored to be asked to testify, and I am pleased to share some of my insights with you. In particular, I want to highlight some potential opportunities that Congress, the Administration, and industry can leverage to improve the functioning of the supply chain and pharmaceutical market.

III. Overview: Price Increases and Supply Chain Abuses Have a Meaningful Impact on Providers

The Committee has asked me to provide input regarding the impact of rising drug prices on the supply chain. To that end, my testimony will address in three ways how high and rising drug prices reorient how we deliver the best quality of care and how we operate as a system: first, I will outline how, in the context of varying reimbursement structures, escalating costs are directly and indirectly impacting patients and the providers who care for them; then, I will discuss the efforts we undertake to mitigate the impact of these additional costs on patients, both immediately through care process adjustments and over the longer term through various targeted assistance programs – all focused on the ultimate goal of ensuring patients do not experience gaps in access to therapies as a result of price escalations; and finally, I will offer some observations from the hospital supply chain perspective on where we see market failures driving inappropriate price increases, as well as recommended solutions that we believe will have meaningful impacts, such that our ability to invest the maximum amount of resources into delivering high quality care and community benefit becomes less encumbered by the very real implications of unforeseeable and excessive cost increases.

First and foremost, the most critical goal for Ascension is providing the highest quality care for the patients we are privileged to serve, while having a special focus on caring for the poor and vulnerable. This is our Mission and it shapes everything we do. As healthcare providers, Ascension and our counterparts in healthcare delivery cannot provide the quality care that our patients deserve and need without the partnership of the pharmaceutical industry. We wholeheartedly believe it is important to maintain protections for intellectual property and reward innovation. At the same time, however, we need to balance these innovations with access.

We understand that in certain, very specific circumstances the price of a drug may be justified by the research and development investment, manufacturing cost, and true clinical value of the treatment; however, most price increases are not predicated on this creation of value. While we understand there may be rational increases in prices that reflect market dynamics, we are nevertheless concerned about

the sudden, unfounded, unpredictable, and cumulatively burdensome price spikes and launch prices that divert our finite resources away from our ability to care for patients both in and out of the hospital. While pharmaceutical price inflation is nothing new, the increases that we have seen over the last several years are unprecedented. These price increases are among the largest and most unpredictable drivers of increased hospital costs. Not only do price increases create significant financial burden, they also place serious constraints on our ability to carry out an essential part of our Mission through special focus on serving the poor and vulnerable.

A. Drug Pricing Increases and Impacts as Experienced by Ascension

Recent Aggregate Price Inflation Has Been Significant

To navigate the vast and complex health care supply chain, Ascension has established our own group purchasing organization (GPO) – The Resource Group. In general, The Resource Group helps our hospitals and other providers realize savings and efficiencies by aggregating purchasing volume and negotiating discounts with manufacturers, distributors, and other vendors. The Resource Group does not purchase or procure products, nor do they determine which products the GPO participants can or should buy – they ingest input from participants about their clinical needs and preferences, then negotiate contracts that those providers can use when making *their own* purchases in line with *their own* decision-making process.

Establishing a GPO through Ascension has allowed us to better control our systemwide approach to procurement. Through both The Resource Group and other direct contract negotiations, we have gained unique insights into the functioning of the hospital supply chain. From this perspective, we have seen the positive impact that competition and appropriate negotiating leverage can have on prices in similar product areas, such as the implantable device market. In that market, we have seen a steady decline in prices over time, as competitive products come to market.

In the prescription drug market, however, the lack of meaningful competition driven by an overabundance of sole-source branded products, patent and Food & Drug Administration (FDA) exclusivity abuses, and other factors, means manufacturers have almost no incentive to offer negotiated price concessions or other contracting accommodations to providers. **As a result, in the span of only four years, Ascension alone has had to mitigate against a 34% increase in drug costs, totaling $564 million in additional costs for providing care to the patients we serve.**

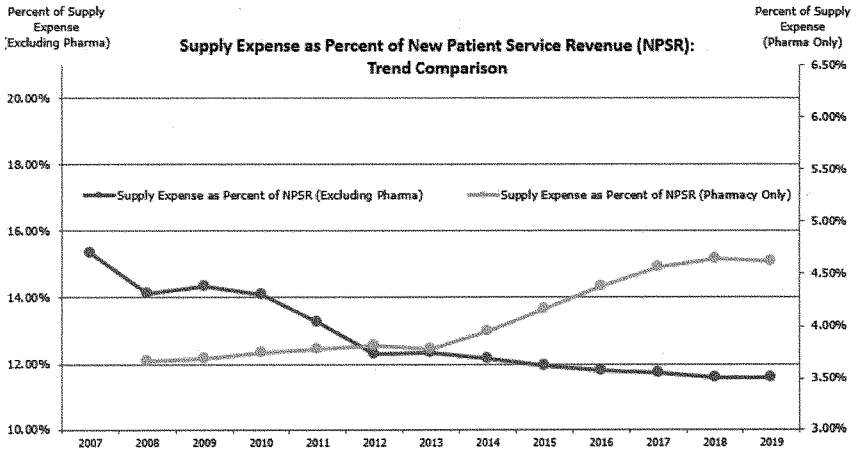
Price Increases Are Frequent, Unpredictable, and Difficult to Protect Against

Contrary to popular belief, very few manufacturers are willing to enter into a contract for their product(s) or offer volume-related discounts or accommodations for even the largest of health systems, like ours. Just over half of our pharmaceutical spending comprises products that are "on contract". Across those contracts, only 18.6% provide for a full year of firm – or steady – pricing, and only 4.8% provide for two years of firm pricing. As a result, **we typically experience up to 40 new price increases each week**, with the greatest number of increases experienced during the weeks of January 1 and July 1 each year – when we can see upwards of several hundred product price increases. In January 2019, the number of drug price increases reached the thousands. While we fervently seek to mitigate the impacts of these increases, the frequency at which price increases occur and the unwillingness of many manufacturers to negotiate consistent, long-term contracts with providers collectively create significant uncertainty and administrative burden.

Contracting Practices and Price Trends for Drugs are Distinct from Other Segments

These practices are not the norm for other areas of procurement across healthcare providers. In the implantable device space, we have entered into contracts under which hip and knee supply pricing is set for up to three years. This kind of certainty and stability allows us to accurately predict and manage budgets, which creates efficiency across the system.

Furthermore, it remains unclear what distinct and measurable value the additional revenues derived from higher pricing adds to the system. Our top 10 pharmaceutical companies show an average research and development (R&D) expense of 16.7% of total revenue as of 2017; reported selling, general, and administrative expense (SG&A) during that year was 25.2% of total revenue. On the supply side, our hip implant costs have *decreased* by 37.0% and knee implant costs have *decreased* 51.8% from 2009 to 2018. At the same time, our top three (public) hip and knee companies with which we contract show an average R&D expense of 15.7% of revenue in 2017 and an average SG&A expense of 41.1%. Thus, despite similar research and development costs generally borne by manufacturers in both sectors, and higher manufacturing and sales costs often associated with implantable devices, there is a marked divergence in our observed price trends – many drug prices have grown at rapid, unpredictable, and unsustainable rates over time, as overall implantable device prices have declined.



High and Rising Drug Prices Directly Impact Patients and Providers

As I discuss in greater detail here, the frequent, unexplained, and unpredictable price increases have proven extremely difficult to prevent in the normal course of business. They are the result of market imbalances and supply chain abuses that I will highlight below and, in turn, suggest corresponding proposed solutions. However, as they exist today and in the context of provider reimbursement and care delivery structures, these practices have a direct impact on our ability to direct finite resources towards patient care, charitable services, and community benefit. At best, we are able to mitigate the impacts to

our system and our patients through a variety of operational modifications and charitable programs. For these reasons, I would again applaud you for the work this Committee and Congress has undertaken to promote competition and create a more robust and balanced market for pharmaceuticals.

Drug Pricing Implications Vary Across Care Settings and Payment Systems

a. Acute Care

In the inpatient setting, insured patients are substantially shielded from the direct financial impact of high drug costs as hospitals are typically paid a bundled payment covering most, if not all, of a hospital stay. This is true across most payers – from Medicare to commercial insurance. The result of this structure, however, is that the cost of drugs used during a hospital stay is built into that bundled payment. These bundles are generally recalibrated on an annual basis to adjust for increases in the market basket of items and services covered in an inpatient stay. As a result, payment for the inpatient stay eventually increases to reflect the higher drug cost. As a general rule, however, within Medicare and with commercial payers, this bundled payment amount is set and remains unchanged throughout the year. So, generally, when the price of a drug goes up in a given week or month, that newly added cost must be immediately absorbed by the hospital. At the same time, hospitals also treat patients who are self-pay (or uninsured) or underinsured through charity or uncompensated care. Within Ascension, we cover the out-of-pocket costs for patients with incomes below 250 percent of the federal poverty level (FPL) and cover the out-of-pocket costs on a sliding scale for patients with incomes from 250 percent to 400 percent of FPL. Any time the cost of delivering care to these patients goes up, we bear the vast majority of that cost directly.

So while patients may not feel the immediate impact of higher drug costs during an inpatient stay, these cost increases nonetheless have a real and measurable impact on the patient. In the longer term, an increase in pricing will be felt by all patients as increased costs will eventually contribute to higher insurance premiums or higher out-of-pocket costs for patients as the bundles are recalibrated. More immediately, and discussed further below, the diversion of our resources to cover these added costs affects our ability to provide other patient-centered services that we deliver as part of our Mission.

b. Outpatient and Physician Offices

Unlike the inpatient setting, most drugs that are administered by practitioners in the outpatient setting or in a physician's office are reimbursed on a standalone basis. By way of example, the Medicare program typically pays providers directly for these drugs (*i.e.*, Part B drugs) at a fixed rate of Average Sales Price (ASP) plus six percent (or 106% of ASP)[1] to cover acquisition and carrying costs associated with procuring product and maintaining a necessary level of supply. A manufacturer's ASP must be calculated by the manufacturer every calendar quarter and submitted to the Centers for Medicare & Medicaid Services (CMS) within 30 days of the close of the quarter.

This system presents its own set of unique challenges: ASP is based on self-reported pricing information that incorporates a wide swath of purchasers, so that each provider's reimbursement might vary in terms of the degree to which the payment covers the provider's costs; the validity of ASP reporting has been called into question by federal government watchdogs[2], raising uncertainty about the accuracy of the

[1] This rate of payment is established in statute, but in practice the rate of reimbursement is actually 104.3% of ASP as a result of sequestration.
[2] https://www.gao.gov/assets/680/678175.pdf

resulting payments; and there is a built-in lag between a manufacturer's implementation of a price increase and the reflection of that new data in the ASP. As a result, providers might be underpaid for a given drug (depending on the price at which they are able to purchase a product (relative to ASP)), as well as for any changes in that price not immediately accounted for in the ASP and any additional associated costs. And because beneficiaries are generally responsible for 20 percent of the payment rate for these Part B drugs, they are likely to experience an increase in out of pocket costs more immediately than they do with respect to drugs administered in the inpatient setting.

Here too, many Medicare beneficiaries are shielded from this out of pocket cost because they have also purchased a Medicare supplemental policy that covers coinsurance and copayment expenses, while lower income patients may qualify for assistance with these out-of-pocket costs through Medicaid or other Medicare assistance programs. But many beneficiaries nevertheless see these increased costs – and those who are not eligible for or able to afford additional assistance will experience these rising costs and struggle to afford those medications. **If medications are not properly managed due to unaffordability or lack of access, the risks increase for diminished health and even hospital admissions**. In the long run, these outcomes are costlier to patients and the program overall – to say nothing of the impact they can have on quality of life.

c. Retail

In the retail setting (or, for drugs covered under Medicare Part D), the patient feels the immediate impact of any increase in price for a product in the form of higher coinsurance. The patient is also directly impacted when his or her plan's Pharmacy Benefit Manager (PBM) plays a role in excluding a particular product (or pharmacy) from coverage. We have seen this example play out recently in the biosimilar space, where innovator biopharmaceutical manufacturers often offer steep rebates to PBMs that incent the exclusion of competitor biosimilars from a formulary. This practice is costly for patients: "patients usually pay a coinsurance percentage (for example, 20%) for high-cost brand-name and specialty drugs; however, because the coinsurance percentage is calculated based on the price of the prescription drug before the application of rebates, patients often pay a greater share of the true cost to the health insurer than the listed coinsurance percentage."[3]

However, retail exclusions and price increases do not divorce providers. When patients' out of pocket costs for retail pharmaceuticals go up, our pharmacists and physicians are on the front line of helping patients mitigate the impact of such added costs, to ensure there are no downstream health consequences from a patient going off their medications, changing doses inappropriately, or sacrificing other aspects of their health and well-being to afford their prescriptions.

Legacy Reimbursement Structures Evidence the Need for Health System Transformation

Ascension is committed to a long-term vision of a sustainable, high-quality health system that serves individuals as whole persons throughout the course of their lifetime. Accordingly, we strongly support the movement towards innovative, value-based care and payment models that support population health. Today's highly complex system of billing and reimbursement for drugs under Medicare, which represents only a fragment of the delivery system, has helped to perpetuate the persistence of a siloed and outdated

[3] Milliman, *A primer on prescription drug rebates: Insights into why rebates are a target for reducing prices*, May 2018. Available at: http://www.milliman.com/insight/2018/A-primer-on-prescription-drug-rebates-Insights-into-why-rebates-are-a-target-for-reducing-prices/

fee-for-service reimbursement system. The complexity of the structures described above is exacerbated by the specialty supply chain, which changes how certain drugs are reimbursed – regardless of the site of administration. For infusion services, some medications are reimbursed through PBMs, while some are reimbursed through the applicable medical specialty, causing fragmentation and administrative burden.

These and other legacy reimbursement structures – such as cost-to-charge ratios used by some commercial payers and Medicaid programs – undermine the move to value-based care models. They also create distortions in perceived behavior that can appear, without diving under the surface, unfounded. For example, reports released last year by the pharmaceutical industry suggested that some hospitals may be marking up charges to private payers for certain separately billable drugs at a rate of nearly five hundred percent. While briefly noting that "Hospitals are generally not paid 100% of charges," the report fails to examine the actual payment percentages provided to hospitals. If a hospital "charges" 500% of the acquisition cost for a given drug, but a contract pays only 20% of the amount charged, that hospital would break even against acquisition cost – without addressing costs related to storage, waste, dispensing, and administration.

When reimbursement is paid as a percentage of charge, and charge is the **only** known piece of information, actual reimbursement cannot be deduced. Because they are the result of proprietary negotiations, other factors remain privately held, including: actual acquisition costs, percent(s) of charges paid, and additional discounts negotiated. Just as list prices are not a true measure of what a manufacturer is ultimately paid for a drug, hospital charges are merely a single factor among many that are used in the complicated process of establishing any final payment. And for uninsured patients, Ascension – like many other non-profit and safety net hospitals – offers charity care programs and discounts, to help ensure patients are able to access care, regardless of their ability to pay.

To better promote integrated care, decrease complexity, and reduce administrative burdens and expenses, it is essential that the healthcare delivery system quickly move away from these kinds of reality-distorting legacy reimbursement structures toward value-based models that drive us toward whole-person care across populations.

B. Existing Options to Mitigate the Impact of Price Increases on Our Patients and System

When price increases begin to prove overly burdensome to either our hospitals or our patients, there are a variety of protocols and programs we rely on to mitigate the impact, always with the overarching goal of protecting patient safety and ensuring the best possible health outcomes.

Immediate Mitigation: Substitution, Education, and System Updates

As noted above, pharmaceutical price increases are not limited to only a few drugs. Ascension tracks cost changes on a weekly basis, and we are currently budgeting a six percent year–over-year rate of inflation for fiscal year 2020.

In an effort to mitigate such increases in cost, Ascension turns to a national Therapeutic Affinity Group (TAG). This group consists of pharmaceutical leaders and physicians from across our system. In addition to medication safety initiatives that improve outcomes and increase patient safety, these leaders feel it is imperative in instances of drug shortages or significant drug price increases to also look for alternate therapies that provide effective care and also steward our system resources and achieve savings for those who ultimately pay for healthcare. The TAG's primary objective is first and foremost to conduct clinical

evaluations that ensure quality of care and patient outcomes are not compromised. This work is not easy. It takes much time and effort to gather the data, create potential alternatives, socialize the potential options, move through an approval process and then implement. We will not compromise patient safety and will not recommend switching to a therapeutic equivalent – regardless of costs borne by our system – unless we are convinced that the switch is evidence-based and will not have an adverse impact on patients. But to accomplish any appropriate switching requires at a bare minimum: physician engagement, negotiation and contracting efforts with a new manufacturer or supplier, purchase and procurement of product, physical stocking of product in the appropriate locations across facilities, modifications to electronic medical records processes, and education and information dissemination to protect against medication errors as new therapies are rolled out. Each of these discrete steps in the process represents significant time, personnel resources, and additional expenses for any impacted facility – when scaled up across a whole system, one significant price increase can effectively mobilize a small revolution in our care delivery processes.

Ongoing Patient Impact Mitigation: 340B Drug Pricing

The growth in pharmaceutical spending highlighted above – a 34% net increase, totaling an additional $564 million in costs over four years – is calculated *after* taking into account the 340B discounts that a number of our safety net facilities qualify for. **The 340B program is a vital tool with which hospitals are able to stretch our scarce resources to provide care to the poor and vulnerable by mitigating against the immediate and long-term impacts of high and rising drug prices.** The program is critically important because the pharmaceutical market and supply chain are not collectively incentivized to set and maintain drug prices at levels that ensure sustained and meaningful access to medications for hospitals and their patients. Instead, year-over-year growth in prices becomes embedded into *today's* pharmaceutical costs; the ongoing price increases effectively compound onto themselves. In other words, last year's price increase will continue to impact the cost of delivering care this year and next – and will continue to divert and consume additional resources going forward, as compared to years prior. The 340B program allows our qualifying safety net facilities to obtain pharmaceutical products at more predictable and manageable prices. Absent this program, our patients and qualifying hospitals would feel more of the brunt of myriad price increases. The 340B program instead allows qualifying Ascension hospitals and other covered entities to implement and maintain investments in community- and patient-tailored programs that offer patients access not only to affordable medications, but to health care and community services that are critical to the poor and vulnerable. And while low government payer reimbursement rates coupled with rising drug prices can constrain the ability of Ascension safety net hospitals to carry out our Mission to provide compassionate and personalized care to the communities we serve, 340B discounts help address this shortfall so that we are able to continue to serve the poor and vulnerable in these communities and invest in programs to improve their health.

Across Ascension, 50 of our hospitals participate in the 340B Drug Discount Program. Of these, 21 are critical access hospitals (CAHs), 23 are disproportionate share hospitals (DSHs), and the remaining hospitals fall into a variety of other categories, including sole community hospitals, children's hospitals, and rural referral centers. Ascension's 340B hospitals were able to invest roughly $200 million last year in charity care and community benefit programs as a result of the current 340B program. Our 340B savings allow us to stretch scarce resources, allowing us to invest in a multitude of programs designed to increase access to prescription medicines and other health services for low-income patients. These include the following, among others: providing medications at low or no cost; operating primary and specialty care clinics in urban and rural communities; providing clinical and ambulatory pharmacy services and oncology services; providing free medical care; embedding nurse services in local school districts; and operating

Medical Missions at Home, as discussed further below. Our 340B savings also fund programs to address a wide variety of healthcare conditions among our most vulnerable populations, including diabetes, cancer, and behavioral health conditions.

There are many examples throughout Ascension of how the reduced drug costs resulting from the 340B program enable us to stretch our resources to expand services for the poor and vulnerable, several of which are outlined in detail in Appendix A. In sum, the 340B program – when leveraged as intended – enables safety net providers to not only mitigate against high and rising drug prices, but to be good stewards of finite patient, program, and provider resources. To that end, Ascension has signed on to the American Hospital Association's 340B Stewardship Principles.[4] We strongly believe in the value of transparency and rigorous internal oversight, to ensure that the program meets the Congressional objective: "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

Ongoing Patient Impact Mitigation: Ascension Medical Missions at Home

As noted above, Ascension has undertaken a national commitment to running Medical Missions at Home, which deliver healthcare and social and support services in places of worship, schools, community centers, homeless shelters, and food pantries at no cost to those who might not otherwise have access to these services. The program was launched in 2008 in Davidson County, TN, which had approximately 87,000 uninsured at that time. Medical Mission at Home day-long events now provide free services such as primary care, dental care, no-cost prescriptions, eye exams and eyeglasses, social services referrals, flu shots and follow-up to those who need it most.

One of the most in-demand services provided through this program is access to medications. Prescriptions dispensed at our Medical Missions at Home are provided through the Dispensary of Hope, which is discussed further below. With each Medical Mission at Home, processes have improved, more services have been added, and more patients have benefitted from these events.

In 2019 alone, we have been able to assist hundreds of patients with access to no-cost medications. The data we have seen includes the following examples, though these are just a small sample of the Missions carried out[5]:

- Our 2019 Florida Medical Mission at Home in one day dispensed 304 prescriptions, serving 177 patients. In the year prior, Florida's Medical Mission at Home dispensed 294 prescriptions, serving 173 patients.
- Our 2019 Oklahoma Medical Mission at Home on a single day served 180 patients, filling 76 prescriptions at no cost. Attendees who did not require medical treatment received donated items such as diapers, wipes, shoes, socks, formula, and fresh fruits and vegetables.
- The 2019 Rutherford County, Tennessee Medical Mission at Home filled 123 prescriptions and served 370 patients.
- The 2019 Davidson County, Tennessee Medical Mission at Home filled 327 prescriptions and served 667 patients.

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[4] https://www.aha.org/press-releases/2018-09-18-aha-hospital-leaders-announce-340b-good-stewardship-principles-0

[5] Additional Medical Missions at Home for 2018 – 2019: https://www.medicalmissionathome.org/get-involved

Ongoing Patient Impact Mitigation: Dispensary of Hope

Dispensary of Hope started in 2003 as a collaborative effort – today hosted and funded by Ascension – with the collaborative comprised of medication manufacturers, health systems, free clinics, and charity pharmacies. Dispensary of Hope distributes medications through more than 180 partnering sites across the country. During fiscal year 2018, the Dispensary of Hope network of about 50 Ascension locations filled 137,245 (30-day) prescriptions. The Dispensary of Hope works with community programs that are licensed to dispense medication by supplying inventories of the most needed medications. Patients are given medication free of charge and may return for unlimited medication fills as long as their prescription remains valid and the patients continue to qualify for the program. To be eligible for Dispensary of Hope medication, patients must have a valid prescription, must be self-identified as uninsured, and must be earning 200 percent or less of FPL.

All medication at the Dispensary of Hope is donated through the generosity of prescription drug manufacturers and distributors, and no medication is purchased. Currently, more than two dozen pharmaceutical manufacturers – including 24 generic manufacturers and one branded manufacturer – donate medication to the program each month.

The national program is unique in its goal to create a stable medication list, pre-positioned in clinics and pharmacies close to the uninsured low-income U.S. residents. One of the most exciting recent developments has been the addition of insulin to this medication list.[6] There are currently 16 Dispensary of Hope sites ordering insulin with 1090 vials distributed. As of March 30, 2019, 155 vials have been dispensed to patients in need. By 2024, the Dispensary of Hope expects to distribute 2.7 million scripts annually.

Patient Impact Mitigation: Leveraging Pharmaceutical Patient Assistance Programs

In addition to Ascension-sponsored programs, providers across our system will work with patients in-need to help navigate and secure discounted or free medications through pharmaceutical patient assistance programs (PAPs). We often find that these programs are imperfect and the market distortions that they create are well-documented – including delays in access due to eligibility processing, the brand-adherence (rather than generic substitution) that they promote, and resulting increased insurance premiums and overall costs to the healthcare system.[7] Regardless of these downsides, the reality is that PAPs are an existing mechanism that can sometimes help patients access life-sustaining medications – and we do our best to help patients maintain adherence to their therapies however possible.

IV. Market Failures and Supply Chain Abuses That Are Driving Price Increases and Proposed Corresponding Solutions

The implications of frequent, unexplained, and unpredictable price increases are vast, as I hope has become evident. Our efforts to mitigate against them can often present their own challenges in terms of how we are able to best use finite resources to care for patients in fulfilment of our Mission. As noted above, however, we at Ascension believe this current reality is largely the result of market failures and

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[6] *See* https://www.dispensaryofhope.org/news/posts/eli-lilly-partners-with-the-dispensary-of-hope

[7] *See*, e.g., Catherine Starner et al., "Specialty Drug Coupons Lower Out-Of-Pocket Costs And May Improve Adherence At The Risk Of Increasing Premiums," Health Affairs, vol. 33, no. 10 (October 2014), pp. 1761-1769.

supply chain abuses that persist unchecked. We believe the following represent some of the most significant supply chain issues and corresponding proposed options to address them.

A. Market Failures and Supply Chain Abuses

Market Failures: Insufficient Competition, Patent Abuses

As the generic marketplace has largely demonstrated, and as we've seen in other supply chains, competition for prescription drugs should generally result in increased options for lower cost therapies, particularly through the introduction of one or more generic or biosimilar competitors. Manufacturers understand this and have long manipulated patent and exclusivity protections in creative ways to maintain monopolies where they exist, or to otherwise delay, hinder, or limit competition. As more entrants are introduced to the market, increased pressures flow through the system putting downward pressure on manufacturer list prices, incentivizing PBMs to cover more product options, and providing alternative therapeutic options for providers to utilize when necessary.

Potential Solutions to Increase Competition

Given the current realities of the branded drug market, which is plagued by a lack of competition and a resulting imbalance of negotiating leverage, hospitals and other purchasers can undoubtedly stand to benefit from Federal efforts that incent against market abuses and failures in order to create a more appropriately level playing field. These potential solutions include:

- **Promoting faster FDA approval of generic and life-saving drugs.** We recognize and applaud the efforts that the FDA has taken to reduce the backlog of generic drug applications. Nevertheless, the FDA still faces a backlog of nearly 4,000 generic drug applications, and approval times can be three or more years. We would urge Congress to provide FDA the necessary resources to clear this backlog and prioritize generic drug approval applications. Several FDA programs have been implemented to date with the goal of expediting review of new drugs that address unmet medical needs for serious or life-threatening conditions. Incentives should drive competition for expensive treatments where no competitors exist and should encourage second or third market entrants to truly spur price competition and access. Again, we applaud the FDA's efforts in this area and would encourage Congress to provide this needed funding for approval of generic drugs on an expedited basis.
- **Creating and Restoring Access to Equivalent Samples (*i.e.*, the CREATES Act).** Currently, FDA requires manufacturers to submit detailed Risk Evaluation and Mitigation Strategies (REMS) to weigh a drug's risks and benefits. While this type of information can create additional safety information for patients and safeguards for providers, manufacturers often manipulate REMS to block generic manufacturers from obtaining samples of brand drugs under the guise of addressing patient safety concerns. This practice can stifle the introduction of generic competition, thus preventing lower price options from being available. We applaud the Committee's action on this legislation to date and urge Congress to move it forward.
- **Promoting the uptake of biosimilars.** Statutory and regulatory policies should encourage both market entry and the uptake of biosimilars, which have significant potential to expand treatment options and reduce costs of expensive biologics through increased competition. Today, we see payors and PBMs hesitating to put biosimilars on their formularies, which may be the result of rebate-driven incentives. Policies that promote the uptake of biosimilars should consider the impacts of such rebate structures and address them as necessary, including through increased

transparency where appropriate. In addition, as biosimilars become more available, it is critical for the FDA to educate drug manufacturers and physicians on the availability of interchangeability designations in order to effectively increase competition.

- **Limiting application of exclusivity protections to truly innovative products.** Pharmaceutical manufacturers are currently able to extend market exclusivity protections by seeking approval for a "new" product that is essentially the same as the initial innovator product. Prohibiting these tactics will allow more competitors to come to market faster.

Market Failures: Year-over-year Price Increases and High Launch Prices

The steady weekly, monthly, and annual increases in prices for products that have often been on the market for extended periods of time may not have the same immediate and notable impact as a high one-time spike or an extremely high launch price, but they nonetheless consume significant resources when evaluated cumulatively. These year-over-year price inflations often occur without any added demonstration of quality or value. On the other end of the spectrum, shockingly high launch prices continue to threaten the financial stability of the safety net and public programs. While new blockbuster drugs may in fact offer demonstrably improved outcomes, our current system lacks or prevents the use of innovative financing mechanisms to support the availability of such next generation pharmaceuticals.

Potential Solutions to Incent Appropriate Launch Prices and Prevent Unwarranted, Year-Over-Year Price Increases

Policy options to incent appropriate launch prices and prevent unwarranted, year-over-year price increases and exceedingly high launch prices that divert resources away from direct patient care and community benefits include:

- **Increase funding for public and private research on drug pricing and value**. Increase funding for private and public research efforts like the Institute for Clinical and Economic Review (ICER), a non-profit organization that evaluates evidence on the value of medical tests and treatments. Investments in objective information is critical for physicians, patients, and payers as more high-priced and potentially high-value drugs are launched.
- **Require manufacturers to demonstrate alignment of increased costs with improved outcomes across new versus existing drugs**. Through comparative effectiveness research (CER) studies, manufacturers should be required to demonstrate how their product is better than others, so that physicians and patients can make informed decisions about the value of different therapies. This will be particularly important for those new products with very high costs.
- **Expand value-based pricing in public programs**. Federal programs like Medicare and Medicaid are not currently well-positioned to accommodate value-based payment models for pharmaceuticals. Steps should be taken to ensure these programs can leverage recent developments in value-based purchasing to ensure all segments of the healthcare system can benefit from market-based efforts to lower drug prices.
- **Pursue the International Pricing Index (IPI) Model Only with Adequate Safety Net Protections**. Given the persistence of price increases in the current market, we think it would be worthwhile to test – through an appropriately sized and scoped demonstration model – an approach to U.S. drug pricing that provides new tools to enhance providers' negotiating leverage. However, any model should include adequate protections to ensure no safety net providers, including 340B entities, are inadvertently harmed (*e.g.*, exclude 340B covered entities).

Supply Chain Abuses: Coverage Design Limitations and Fragmentation of Care

We have increasingly observed that payors and PBMs are denying claims based on the site of care, rather than for want of medical necessity. Claims denials and site-specific coverage limitations can have serious consequences for patients, especially those with limited mobility or access to transportation, including diminished continuity of care. Continuity of care and whole person treatment is particularly critical for patients with multiple chronic illnesses. Similarly, payors and PBMs have been hesitant to include biosimilars on their formularies, thereby limiting access to branded biopharmaceuticals that may offer rebate incentives or other arrangements. While some of these design limitations and practices have the effect of limiting competition, they also diminish patient access to the full array of therapies and sites of care that may be necessary to provide appropriately comprehensive and innovative care.

This also results in increased burden and confusion for the patient, as some patients might have to seek out care in different settings to ensure coverage. For example, a patient may need to obtain their prednisone from a retail pharmacy, go to an infusion center for infusion therapy, and then get a specialty medication from an entirely separate specialty pharmacy. This approach to coverage creates a lack of continuity of care and fragmentation, as well as burden for the patient who must navigate this complex system. In addition, the medications might fall under differing reimbursement streams (*e.g.*, coverage through a plan/PBM or medical specialty benefit), creating more confusion and complexity. This kind of fragmentation can also act as a barrier to population health and whole-person care.

Potential Solutions to Promote Appropriate Coverage

Policies to promote appropriate coverage of competitive innovators and ensure care continuity that best manages a patient's health outcomes could include:

- **Promoting the expansion of any willing provider requirements**. Allow providers or facilities to provide or dispense medications to their own patients, regardless of the site of service, to ensure adherence, compliance, and improved outcomes for those patients for whom we are care.
- **Promoting the uptake of biosimilars.** As noted above, statutory and regulatory policies should encourage both market entry and the uptake of biosimilars, which have significant potential to expand treatment options and reduce costs of expensive biologics through increased competition. Today, we see payors and PBMs hesitating to put biosimilars on their formularies, which may be the result of rebate-driven incentives. Policies that promote the uptake of biosimilars should consider the impacts of such rebate structures and address them as necessary, including through increased transparency where appropriate.

Supply Chain Abuses: Hidden, Unpredictable Fees

Our pharmacies have seen a marked increase in the use of direct and indirect remuneration (DIR), a term used as a catch all for many types of fees applied by plan sponsors and their pharmacy benefit managers to pharmacies participating in Medicare Part D networks. DIR fees can include the following:

- Fees for network participation, also called "pay to play fees." These can be a flat fee per claim or a percentage of each claim.
- The "true-up" between the Maximum Allowable Cost (MAC)/adjudicated rate and the contract rate. This is a reconciliation process that results in the difference between those rates being assessed to the pharmacy. This generally occurs quarterly or annually.

- Reconciliation for the lower reimbursement rates from pharmacies that don't score well on PBM-established quality measures or "Performance Metrics."

These fees are assessed after the point of sale transaction, sometimes several months after. This makes it extremely difficult for the pharmacy to determine if they are receiving the correct reimbursement. As a result, recent research suggests that patients are likely to pay more out of pocket costs, as many PBMs will charge a co-pay that is higher than the drug's price without insurance. PBMs will subsequently 'clawback' the difference from the pharmacy, but there is no evidence that the clawback obtained from the pharmacy is ever credited back to the patient.

Potential Solutions to Prevent Hidden, Unpredictable Fees

Policy options to prevent the use of hidden, unpredictable, and retroactive fees that increase overall costs to providers and patients could include:

- **Requiring all DIR fees to be accounted for upfront.** This proposal would effectively eliminate retroactive pharmacy DIR fees by requiring all price concessions be accounted for at the pharmacy counter.

V. Conclusion

Thank you again for the opportunity to testify before the Committee. Ascension appreciates the Committee's continued bipartisan efforts to fully assess and address these important issues and we are honored to serve as a resource to you, both today and in the future.

Appendix A

Examples of 340B-enabled Patient Services and Assistance Programs

There are many examples throughout Ascension of how the reduced drug costs resulting from the 340B program enables us to stretch our resources to expand services for the poor and vulnerable. One example is Ascension's Our Lady of Lourdes Memorial Hospital in Binghamton, New York. Lourdes Hospital has provided compassionate care to those in need since 1925 and has participated in the 340B program since April 2016. In 2017, Lourdes provided approximately $79.6 million in uncompensated care to the community. The hospital's 340B savings support programs to help uninsured and underinsured patients receive needed care and medications, including Lourdes' Patient Financial Assistance Program (PFAP). This program helps patients who meet income guidelines with payment of bills for services provided by and billed by Lourdes. In 2014, Lourdes expanded the PFAP to include prescription medications. This prescription component of the program is especially important in efforts to help the working poor. These patients are unable to afford the care they need because they are faced with high deductibles or co-pays but may not be eligible for other programs. In 2017, Lourdes enrolled 13,018 individuals in the PFAP, an increase of 24 percent from the year before. Pharmaceutical access impacted more than 80,000 prescriptions, which accounted for $1.2 million in co-pay assistance to vulnerable patients. If the 340B program was scaled back or eliminated, Lourdes' ability to provide care and assistance to these needy patients would be in jeopardy.

Another example of how the 340B program enables us to expand services to the poor and vulnerable is at Ascension Indiana. St. Vincent Health in Indiana relies on 340B to provide medications to its rural, poor and vulnerable patients. Without the program, the hospital's Joshua Max Simon Primary Care Center (PCC) would not be able to provide its patients with the prescription medications they need at a cost they can afford. Patients served at the Center are charged on a sliding scale for drugs based on their income. Most of those served pay only 20 percent of the 340B discounted price; the remainder of the cost is covered by St. Vincent. In 2017, the PCC served more than 101,000 patients and filled more than 41,000 prescriptions that were all eligible for 340B pricing.

In Tennessee, Ascension's Saint Thomas Hickman Hospital, a 25-bed CAH, has provided personalized care to those in Centerville and Hickman County since 1964. The hospital was the first in Tennessee to qualify as a CAH, serving roughly 10,000 people each year. Nearly 20 percent of the hospital's patients do not have health insurance, and the next closest hospital is about 30 miles away. Without the 340B program, Hickman Hospital would not be able to provide patients the prescription medications they need at a price they can afford. In FY17, Hickman saved $476,035 through 340B discounts, which was used to improve patient care through the provision of vital medications and services to the poor and vulnerable. In high-poverty, rural areas such as Hickman County, which has one of the highest suicide rates in the state, many patients face several obstacles to receiving the care they need. The 340B program allows Saint Thomas Hickman to improve access to care for the most vulnerable members of the community by: sponsoring a Medical Mission at Home health event that provides mental health, medical, vision, and dental services; creating both an Alzheimer Caregiver and a Diabetic Education Support Group that meets monthly; offering a Behavioral Health Screening Day; expanding the campus clinic to provide expanded behavioral health services and hiring a behavioral health nurse practitioner and a clinical therapist; and opening a charity pharmacy.

Ascension Kansas provides yet another example. Via Christi Health in Kansas has participated in the 340B program since 2012. In FY2016, Via Christi received $4.3 million in 340B benefit and provided $77.8 million in community benefit, which included $44.5 million in charity care, and $7.9 million in unpaid costs of Medicaid services. Among other programs offered, Via Christi uses its 340B savings to offset the cost of patients' prescription drugs, annually providing more than 5,500 prescriptions to 2,000 patients at no cost.

Ms. ESHOO. Thank you very much, Doctor.

It is now my pleasure to call on Dr. Resneck and you are recognized for five 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 does these shares? 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 copay 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 authorization. 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 authorization.

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 authorization 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 authorization 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 authorization 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 authorizations 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:]

STATEMENT

of the

American Medical Association

U.S. House of Representatives
Energy and Commerce Committee
Health Subcommittee

RE: Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain
Presented by: Jack Resneck, MD
Chair AMA Board of Trustees

May 9, 2019

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Statement

of the

American Medical Association

U.S. House of Representatives
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Health Subcommittee

Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain
Presented by: Jack Resneck, MD
Chair, AMA Board of Trustees

May 9, 2019

The American Medical Association (AMA) appreciates the opportunity to provide testimony to the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health as part of the hearing on Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain. The AMA strongly supports congressional efforts to identify the causes that have led to the high cost of prescription medication. We welcome the opportunity to support congressional efforts to develop well-crafted and effective public policy solutions that would alleviate these high costs and the rapidly multiplying burdens these high costs impose on patients, physicians, other health care providers, and the health care system.[1] Since the AMA last testified before the Energy and Commerce Committee costs have continued to rise for a number of prescription medications. In early 2019, it was reported that three dozen manufacturers of prescription medication had raised prices on 250 prescription medications with an average price increase of 6.3 percent, with some rising by 10 percent or more—well in excess of the rate of inflation over the corresponding period of time.[2] Physicians are focused on ensuring that our patients have access to and receive the right medical treatment at the right time, and we welcome the opportunity to share with the Subcommittee the steps that physicians take to help patients receive their medically necessary pharmacy-dispensed prescriptions or physician-administered drug and biological treatments. Below we briefly outline what the high cost and complexity of obtaining these treatments mean for patient adherence, timely access, and health outcomes.

The underlying causes contributing to the high cost of prescription medication, including rapid price hikes for certain medications, are exacerbated by industry non-disclosure and confidentiality agreements or policies. The AMA has a large body of policies that address the high cost of prescription medications and looks forward to continuing a dialogue that will improve patient access to medication while reducing their costs and balancing the need for appropriate innovation incentives. The solutions must also reduce the administrative burdens largely shouldered by patients and their health care teams. Among these policies, the AMA strongly recommends that policymakers prioritize legislation and regulatory action to: (1) require manufacturer and pharmaceutical supply chain transparency; (2) increase competition and curtail anti-competitive practices; (3) ensure prescribers have accurate point-of-care coverage and patient cost-

[1] Throughout this document the term pharmaceuticals and prescription drugs are referenced—both encompass innovator and follow-on biologicals as well.
[2] Drugmakers Celebrate the New Year by Raising Prices on Hundreds of Drug an Average of 6.3%, Forbes, January 2, 2019 citing RX Savings Solutions.

sharing information as part of their workflow including in the electronic health record (EHR); and (4) streamline and modernize the utilization control methods used by health insurers in response to higher prescription drug costs.

Manufacturer and Supply Chain Transparency

The AMA has launched a grassroots campaign and website, TruthinRx.org, the goal of which is to address the opaque process that pharmaceutical companies, pharmaceutical benefit managers (PBMs), and health insurers engage in when pricing prescription drugs. To date, more than 338,000 individuals have signed a petition in support of greater drug pricing transparency, with the campaign also generating more than one million messages sent to Congress demanding drug price transparency. This begins with shining a light on industry agreements and rebates. The AMA strongly supports federal legislation that would require manufacturers and insurers participating in federal health care programs to provide price and cost transparency so that physicians receive accurate, real-time formulary data at the point-of-prescribing as well as transparency for patients at the pharmacy point-of-sale. Also, the AMA supports: drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10 percent or more each year or per course of treatment and provide justification for the price increase; and legislation that authorizes the Attorney General (AG) and/or the Federal Trade Commission (FTC) to take legal action to address price gouging by pharmaceutical manufacturers and other measures to address anticompetitive behaviors.

The AMA applauds passage of legislation, now law, in the last Congress to curb gag clauses in both public health programs and commercial plans. Consistent with the AMA's long-standing efforts to increase transparency, we also support the Energy and Commerce Committee's efforts in passing H.R. 1781, the "Payment Commission Data Act of 2019. H.R. 1781 would provide access to essential data that the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC) need to evaluate the practices of various entities within the pharmaceutical supply chain that are either not readily available or not available for independent analysis, including drug pricing and rebate data. It is essential that MedPAC and MACPAC have this information to provide data driven recommendations to Congress in order to improve the affordability of prescription medication while still providing adequate incentives to support innovation.

Combatting Anti-Competitive Practices

We applaud the Committee for taking steps to advance legislation to increase competition of less costly alternative medication and combat anti-competitive practices. The AMA strongly supports legislation considered by the Committee that expands the authority of the FTC and the U.S. Department of Justice to stop "pay-for-delay" arrangements between brand and generic manufacturers. We also strongly support legislation considered by the Committee that would stop brand manufacturer gaming of FDA requirements in order to inappropriately extend exclusivities including through "parking exclusivities," use of proprietary risk evaluation mitigation strategies, and preventing generic applicants from obtaining brand samples needed to establish bioequivalence. We also support the Committee's efforts to stop the misuse of patents and maneuverings that delay or prevent generic entry through misuse of risk evaluation mitigation strategies.

Workflow Integrated Point-of-Care Transparency

When prescribing a pharmaceutical for a patient, physicians must consider clinical factors, patient preferences, and other circumstances, as well as the cost to the patient based on variable insurance benefit designs, such as drug formularies. Yet physicians rarely have readily accessible, accurate, up-to-date information on a patient's coverage and the insurer's or PBM's utilization management policies, along with clinical options and cost, at the point-of-prescribing. This is compounded by time-consuming and

antiquated communication methods used by insurers to process utilization management and exceptions requests, including faxes, non-standardized forms, and understaffed telephone call lines. PBMs and public and commercial insurers now have a large number of utilization management programs, such as medication step therapy, dosing limits, and prior authorization, that the physician and patient must navigate.

Access to accurate patient coverage and cost-sharing information at the point-of-care would streamline the process, reduce burden for the physician and the patient, and speed delivery of the most appropriate care. In the larger context of health system costs, physicians do not have access to information about drug cost for the patient and the health care plan that they need to be good stewards and bring more value to the health care system.

The AMA urges Congress to consider what public policies are needed to ensure that manufacturers, PBMs, insurers, and electronic health record vendors move quickly to develop point-of-care software that provides patient coverage and cost-sharing information. There are several promising pilots underway by Surescripts, OptumRx, and others to deliver real-time pharmacy benefit data to physicians at the point-of-care. The AMA strongly advocates that this data should be available to all physicians, regardless of EHR vendor, and regardless of which PBM the patient has.

Insurer and PBM utilization control methods

Physicians experience and see first-hand the difficulty and burden high pharmaceutical costs have imposed on their patients, on physician practices, and the broader health care system. The burden, however, is not solely caused by the escalating cost of pharmaceuticals, but the increase in medication utilization management policies as well, some of which are the result of increased pharmaceutical costs but also may be driven by other imbalances in the current drug supply chain. As a result, patients and physicians often must navigate complex and resource intensive requirements imposed by health insurers and PBMs. These are consequential problems that may negatively impact the ability of patients to obtain needed medications in a timely manner and to maintain treatment. If patients delay, forgo, or ration their pharmaceutical treatment, their health status may deteriorate and eventually require medical interventions in more costly care settings, such as emergency departments, when their condition is at a more advanced stage of disease.

The time and expense that physicians and the extended care team, patients, and their caregivers spend complying with documentation requirements is another significant issue that needs to be addressed. Physicians and their staff will frequently undertake multiple steps before the patient is able to receive their prescription, including finding clinically appropriate but more affordable alternatives, identifying and applying for discounts or patient assistance programs, and filing appeals or exception requests. These time-consuming processes continue to divert the finite resources away from direct patient clinical care to a large volume of paperwork, emails, facsimiles, and phone calls. Administrative burdens have also led to increasing delays in medically necessary care. As outlined below, the high cost of pharmaceuticals not only negatively impacts the patient who requires them and cannot afford them. The cost is also passed on to other patients when physicians and the extended heath care team are consumed with repetitive administrative minutiae documenting, often repeatedly, medical need in order to comply with expanding insurer medication utilization management program policies. In addition, the two pincers that patients and physicians are squeezed between—high-priced pharmaceuticals and increasingly onerous documentation requirements—continue to erode the physician-patient relationship, as well as lower morale and fuel burn-out among the health care team members.

Prior authorization

Insurers outline in their coverage design that certain pharmaceuticals are subject to the insurer's review and approval before a prescription will be covered, even if it is on the formulary. Frequently, a physician and patient learn that prior authorization is required when the pharmacy staff notify them—that is, after the prescription has been received by the pharmacy and the medication claim has been rejected by the insurer or PBM. The physician and clinical staff will then need to provide documentation in the format required by the insurer and meet the insurer's criteria. This will often entail a significant amount of physician, pharmacist, and their extended teams' time. Every insurer has its own forms, criteria, and processes. This lack of standardization exacerbates delays and overall complexity. If an adverse decision is made by the insurer or PBM, the physician and staff will often need to assist the patient with filing an exceptions request or an appeal. Both an exceptions request and an appeal involve additional time and paperwork. But more importantly, the entire process results in significant delays in patient care or patients not receiving covered care that was determined by their physician to be medically necessary. In a 2018 AMA survey,[3] 91 percent of physicians reported that prior authorization is associated with delays in care and 91 percent also reported that prior authorization can have a negative impact on patient clinical outcomes. Significantly, 28 percent of physicians reported prior authorization led to a serious adverse event (e.g., hospitalization, disability, or even death) for a patient in their care. Moreover, 75 percent of surveyed physicians reported that prior authorization can lead to treatment abandonment, meaning the patient never received the care prescribed. This is a common occurrence with pharmacy-dispensed pharmaceuticals, as patients who arrive at the pharmacy to pick up their medication and learn that there is a delay due to prior authorization requirements may not return. Prior authorization is thus an important contributor to medication nonadherence.

Step therapy

Insurers and PBMs have developed formularies that require a patient for certain covered pharmaceuticals to try a preferred drug to ascertain whether it is effective before other alternatives will be covered. This step therapy requirement may not be known to the patient or physician in advance. The pharmacy staff will frequently notify the patient and physician practice after the patient submits the prescription to the pharmacy and the medication claim is rejected by the insurer or PBM. This, in turn, will require additional clinician and staff time (for both the physician practice and the pharmacy) to determine whether the alternative medication is appropriate based on the particular medical needs of the patient. If it is not, the physician will, after consulting with the patient, submit an exceptions request or appeal requiring the submission of additional documentation. In addition, it may require a subsequent patient visit and more time to assess the effectiveness of the treatment including submitting documentation to satisfy the insurer that the less expensive alternative was not effective for the patient. For patients who have had to complete a step therapy protocol, they may be required to re-do it again if they switch plans. These therapy interruptions can have devastating consequences for chronically ill patients, who may lose control of their disease until the original treatment can be reinitiated. Treatment disruptions for complex biological medications may result in long-term term loss of disease control if the therapy is no longer effective or causes adverse events when the drug is reintroduced.

Quantity and dosing limits

Increasingly, insurers are placing quantity and dosing limits on certain pharmaceuticals that are part of the covered formulary. Certain drugs may be limited to the amount that a patient may be prescribed per prescription for a certain time period. For example, one insurer limits patients to 30 tablets per prescription for levothyroxine per 30 days. Physicians may have to navigate the appeals or exceptions

[3] 2018 AMA Prior Authorization (PA) Physician Survey. Available at: https://www.ama-assn.org/system/files/2019-02/prior-auth-2018.pdf.

process for the patient, delaying necessary treatment and expending additional time and resources. In addition, insurers may alter the dose that they will cover midway through treatment, which can cause confusion and potentially life-threatening consequences for patients.

Modifications to Formularies

Health plans and PBMs may also change their formularies at any point during a patient's plan year to remove one pharmaceutical in favor of another. This means that the patient may be forced to switch to a drug that is less effective or experience care disruptions during an exceptions process, and it also is highly unlikely the patient receives a cost discount when the change is made. This switch may destabilize a patient or it will require additional resource expenditure by the physician and extended health care team to file an exceptions request and/or to file an appeal. This is exacerbated by the continued restrictions of formularies by PBMs to remove previously covered medications.[4]

There is considerable variation between utilization review entities' prior authorization criteria and requirements and extensive use of proprietary forms. This lack of standardization is associated with significant administrative burdens for physicians and the extended health care team, who must identify and comply with each public and commercial insurer's unique requirements. Furthermore, any clinically based utilization management criteria should be similar—if not identical—across clinical utilization review entities.

Delays, costs, and administrative burden associated with helping a patient obtain a prescription written by their physician or other duly authorized prescriber on the health team has prompted the AMA—along with a growing number of national medical specialty societies and state medical associations—the American Hospital Association (AHA), the American Pharmacists Association (APhA), and other stakeholders to call upon health plans, benefit managers, and any other party conducting utilization management, as well as accreditation organizations, to follow Prior Authorization and Utilization Management Reform Principles (Reform Principles) developed by these stakeholders. The AMA strongly urges Congress to require health insurers participating in federal health care programs to adhere to these Reform Principles. We are also urging states to enact legislation requiring similar reforms. In addition, the AMA is directly working with commercial health plans to "right-size" prior authorization programs. Using the Reform Principles as a starting point for discussion, the AMA joined with the AHA, APhA, Medical Group Management Association, Blue Cross Blue Shield Association, and America's Health Insurance Plans to develop the Consensus Statement on Improving the Prior Authorization Process, which was released in early 2018. This document reflects agreement between providers and insurers on the need for prior authorization reforms that will reduce the overall volume of requirements, improve transparency, protect patient care continuity, and increase automation of the current manual process. Unfortunately, progress in implementing these reforms has been sluggish, as detailed in additional 2018 AMA survey results.[5] For example, 88 percent of physicians report that the number of prescription medications requiring prior authorization has increased, despite the agreement in the Consensus Statement to encourage overall reduction in these requirements. In addition, 85 percent of physicians report that prior authorization interferes with continuity of care.

The Impact on Patients of Utilization Management Programs

The foregoing can create significant barriers for patients by delaying the start or continuation of necessary treatment and negatively affect patient health outcomes. The manual and time-consuming processes used in these insurer utilization management programs place excessive burdens on patients whose medically

[4] See https://www.statnews.com/pharmalot/2017/07/31/express-scripts-formulary-epipen/)
[5] Industry checkup: Measuring progress in improving prior authorization. Available at: https://www.ama-assn.org/system/files/2019-03/prior-auth-survey.pdf

necessary treatment is delayed as well as physicians, the health care team, and pharmacies, and divert valuable resources away from direct patient care. Commercial and public health insurers tout the benefits of these programs to drive value. This comes, however, at the cost of delayed or denied patient care and wasted time and increased inefficiencies on the part of physicians and other clinical staff. As detailed in the 2018 AMA survey, practices report completing an average of 31 prior authorizations per physician per week, a workload that consumes 14.9 hours—nearly two business days—of physician and staff time every week.

The most appropriate course of treatment for a given medical condition depends on the patient's unique clinical situation and the care plan developed by the physician in consultation with his/her patient. While a particular pharmaceutical might generally be considered appropriate for a condition, the presence of comorbidities or patient intolerances, for example, may necessitate an alternative treatment. The failure to account for this can obstruct proper patient care. Too often, insurer utilization management programs do not allow for flexibility, including the timely overriding of step therapy requirements and appeal of prior authorization denials. Physicians and their patients do not have rapid, standard appeals processes for negative medication utilization management program decisions or other needed exceptions. Too many insurers still do not provide physicians with direct access, such as a toll-free number, to a provider of the same training and specialty/subspecialty for discussion of medical necessity issues.

The AMA's prior authorization grassroots advocacy reform campaign and associated online hub, FixPriorAuth.org, put a human face on the care delays and clinical harms associated with utilization management programs. Since July 2018, the website has captured over 500 patient and physician stories underscoring the troubling impact that prior authorization has on the delivery of timely, medically necessary care. The concerns raised in both the site's story gallery and patient and physician videos emphasize the importance of ensuring that patients generally, and Medicare beneficiaries in particular, are not subjected to the harmful prior authorization policies that have been inappropriately deployed in the commercial insurance market in order to prevent patients from obtaining medically appropriate and covered treatments. Notably, over 90,000 site visitors have signed a petition to Congress urging action on prior authorization reform.

Conclusion

The AMA thanks the Subcommittee for this hearing and for careful consideration of the patient harm, health system, cost and administrative burdens associated with high pharmaceutical costs. We welcome the opportunity to work with the Subcommittee and Congress to seek solutions moving forward.

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 five minutes for your testimony, sir. Thank you.

STATEMENT OF RICHARD ASHWORTH, PHAR.D.

Dr. 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 eight million customers and patients across the country. Our core purpose is to champion the health and well being 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 decision making 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 Dr. Ashworth follows:]

Prepared Testimony of Richard Ashworth, PharmD.
President, Pharmacy and Retail Operations
Walgreen Co.

Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain

Submitted to the House Energy and Commerce
Subcommittee on Health
May 9, 2019

Chairwoman Eshoo, Ranking Member Burgess, and Members of the Subcommittee, thank you for the invitation to speak in front of the House Energy and Commerce Health Subcommittee about the important role community pharmacy plays in the lives of Americans all across this country.

I am Richard Ashworth, president of pharmacy and retail operations for Walgreen Co., based in Deerfield, Illinois. I began my career with Walgreens in 1992 as a service clerk, later becoming a pharmacist and moving up through the company in various pharmacy and store management roles. In 2007, I became vice president of pharmacy benefit management services for Walgreens Health Services, our former managed care division.

Over the next several years, I took on executive leadership roles for pharmacy operations and later corporate operations for the western U.S. I also spent a year overseas in the United Kingdom and Republic of Ireland where I led the development and delivery of health care and pharmacy strategy, following Walgreens merger with UK-based Alliance Boots. I have been in my current position since 2014.

Above all, after over 27 years with Walgreens and many role and title changes, being a pharmacist has been the core focus in all of my work. Helping patients has been my singular passion since the beginning. Walgreens, as a company, has provided an ideal platform to serve patients, with approximately 9,500 store locations across all 50 states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands. Through our locations, approximately 8 million customers and patients each day are using the most convenient, multichannel access to consumer goods and trusted, cost-effective pharmacy, health and wellness services and advice. Walgreens scope of pharmacy services includes retail, specialty, medical facility and mail service, as well as online and mobile services. Ultimately, our services improve health outcomes and lower costs for payers, including employers, managed care organizations, health systems, pharmacy benefit managers (PBMs) and the government.

My testimony today is grounded in Walgreens core purpose to champion the health and well-being of every community in America. We are eager to assist the Subcommittee seek out ways for community pharmacy to further help patients afford their medications and stay adherent to their drug therapy.

Pharmacy's Role in the Supply Chain

Community pharmacists are all too familiar with the financial hardship many patients face when paying for their prescription medications. The pharmacy counter is where the issue of drug pricing and patients intersect, and pharmacists work every day to find ways to lower costs for patients. However, under the current system in Medicare Part D, pharmacies are limited in what they can do to help patients save money.

The pharmacist is largely reliant on the information returned to the pharmacy from the PBM and health plan as part of the claims process. The claim will guide the pharmacist as to what medication to dispense, and provide coverage and out-of-pocket (OOP) cost information based on coverage phase, formulary placement, tiering and other factors. Walgreens pharmacists are often able to piece together additional savings for patients by examining lower cost alternatives, facilitate financial assistance (when available), and offer the cash price without insurance (when lower than the cost-sharing amount with insurance). We present our patients with this information at the point-of-sale, and we recently developed a digital enhancement to provide this information to existing patients before they even arrive at the pharmacy.

Unfortunately, the diligent work of the pharmacist to find additional savings occurs within (and in spite of) a system with perverse incentives that artificially increase the price of drugs at the pharmacy counter. Patients deserve more. It is incumbent upon every stakeholder in the supply chain to deliver savings to patients in the form of the lowest possible OOP costs based on the "true" price of their prescription drugs. Currently, there are systemic barriers that prevent this from occurring.

What Occurs Now

Walgreens maintains two guiding principles on drug pricing:

1. Drug prices must be transparent as they move through the supply chain and are ultimately dispensed to patients
2. Savings must be passed on to patients at the pharmacy counter to lower their OOP costs

While seemingly simple, Walgreens believes these principles are central to delivering affordable prescription drugs to patients.

Key to achieving transparency are transactions that occur in the opaque middle ground of the supply chain, between the bookends of a system that begins with drug manufacturers and ends at the pharmacy counter. Many transactions often occur after the point-of-sale to the patient, and impact the final cost of a drug, which can increase patients' OOP drug costs. Primary examples of such transactions include manufacturer rebates and pharmacy price concessions negotiated and collected by PBMs on behalf of plans—known as direct and indirect remuneration (DIR).

Currently, DIR transactions increase the OOP costs for beneficiaries at the point-of-sale. Although rebate negotiations between manufacturers, PBMs and plans are generally confidential, they are typically

offered in exchange for placement on the plan's drug formulary and improved market access. Rebates are also generally adjudicated after a drug is dispensed to a patient. Similarly, pharmacy price concessions are fees that PBMs and plans charge pharmacies outside of normal administration fees, and are generally adjudicated and collected after the point-of-sale. Typically, such fees are related to network participation and quality performance arrangements. Total DIR in Medicare Part D has grown substantially, from $13.4 billion in 2013 to $35.1 billion in 2017—an increase of 162 percent in only four years.[1]

Savings generated by DIR are generally used, in part, to reduce the price of a drug for the health plan. However, as this reduced price is a better reflection of the final, true cost of a drug, beneficiary cost-sharing amounts should also be based on the plan's "net" drug cost. Beneficiaries currently pay cost sharing amounts based on a drug's undiscounted, pre-DIR negotiated price, or "gross" price. The delta between net prices and gross prices is growing and has resulted in a phenomenon often referred to as the "gross to net bubble."[2]

For example, and using simple math, if a beneficiary's cost-sharing obligation is 20 percent, a beneficiary would pay $60 for a drug with gross price of $300. The same drug with a 50 percent point-of-sale reduction—inclusive of all manufacturer and pharmacy DIR—would require the beneficiary pay $30 for a drug with a net price of $150. When extrapolated to more expensive brand and specialty drugs whose costs can range in the thousands, cost-sharing obligations on a gross, pre-DIR negotiated drug price can be out of reach for many beneficiaries, resulting in abandonment of their drug therapy, negative health outcomes and higher overall medical costs for the government and taxpayers. In fact, studies consistently show that between 20-30 percent of prescriptions are never filled at the pharmacy, mostly due to cost, which I will discuss in more detail later.[3]

A Better Approach

A more transparent, full pass-through approach is necessary to help eliminate the perverse incentives that currently exist in the Part D program. But more can be done. Walgreens believes complete transparency is possible, and can be achieved through a new "open source" benefit design data clearinghouse.

Today, patient, benefit design and drug pricing information are held exclusively by PBMs and plans. As discussed earlier, a limited amount of this information is shared with the pharmacy, as part of the claim and at the point-of-dispensing. However, neither the manufacturer rebate amount nor any other potential discounts or lower cost alternatives are shared. Prescribers also generally do not have access to this information, which they could use to help their patients navigate the financial decisions necessary when starting or continuing drug therapy. The limited information that is available to prescribers is only accessible through disparate, proprietary PBM and plan platforms that are not standardized nor widely integrated with electronic medical records systems. Thus, prescriber adoption of such technology is extremely low. Finally, some PBMs and plans share

[1] "CMS Considers Point-of-Sale Pharmacy DIR: Another Prelude to a World Without Rebates?" Drug Channels Institute. Dec. 4, 2018.
[2] "New Data Show the Gross-to-Net Rebate Bubble Growing Even Bigger." Drug Channels Institute. June 14, 2017.
[3] Ann Intern Med. 2012 Dec 4;157(11):785-95.

benefit-level information with their members through online portals and other tools. However, this information is limited, not transparent and often difficult to navigate—and many patients are not even aware of such tools.

A benefit design data clearinghouse that is democratized and open-source would introduce next level transparency, ensuring patients, along with prescribers and pharmacies, have the best, most accurate and granular drug-related information available—well before the patient even arrives at the pharmacy. This would enable better financially sound decision-making at all levels, with the patient ultimately benefiting from lower OOP cost and a greater level of adherence. The clearinghouse could be further augmented by facilitating fully transparent pricing accessible through an Application Programming Interface (API), which would allow technological innovation to occur across care settings and through consumer solutions while simultaneously operating within HIPAA[4] standards.

Medication Adherence is Paramount

Out-of-pocket prescription drug cost is a key predictor of medication adherence. When patients cannot afford the copays or coinsurance for their medications, they may altogether abandon their drug treatment. One study found that prescriptions with copayments between $40 and $50 and those greater than $50 were almost 3.5 times and nearly 5 times more likely, respectively, to be abandoned by patients than prescriptions without copayments.[5] Additionally, a study conducted by Walgreens found that patient OOP cost is the most significant predictor of abandonment and primary medication non-adherence.[6] Specifically, the study found that the abandonment rate for Zostavax increased when copays were above $15, and increased substantially when copays were above $50.[7] Overall, according to Walgreens internal data, we found that significant predictors for abandonment include patients paying cash, higher cost sharing obligations, low income and prescriptions for branded drugs.

Medication non-adherence is a widespread problem among Americans taking prescription medications, and is a growing concern because of mounting evidence of its prevalence and association with adverse outcomes and higher costs of care. Up to one-half of the 187 million Americans taking prescription drugs do not take their medications as prescribed.[8] According to a study by the Network for Excellence in Health Innovation (NEHI), the costs of medication non-adherence are enormous, estimated at nearly $300 billion annually.[9] Medication non-adherence costs over $100 billion a year in excess

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[4] Health Insurance Portability and Accountability Act

[5] Shrank WH, Choudhry NK, Fischer MA, Avorn J, Powell M, Schneeweiss S, et al. The Epidemiology of Prescriptions Abandoned at the Pharmacy. Ann Intern Med. 2010.

[6] Akinbosoye OE, Taitel MS, Grana J, and Macpherson C. Factors Associated with Zostavax Abandonment. Am J Pharm Benefits. 2016.

[7] Ibid. Patient abandonment was 1.66 times higher at copay levels between $15-$34.99, and 3.27 times higher at copay levels between $50-$64.99.

[8] National Council on Patient Information and Education. "Accelerating Progress in Prescription Medicine Adherence: The Adherence Action Agenda. A National Action Plan to Address America's 'Other Drug Problem.'" October 2013.

[9] Network for Excellence in Health Innovation, "Bend the Curve: A Health Care Leader's Guide to High Value Health Care." 2011.

hospitalizations; non-adherent diabetes and heart disease patients have significantly higher mortality rates; approximately 90,000 hypertensive patients die prematurely every year because of poor medication adherence; and 25 percent of all emergency room visits are the result of non-adherent asthma patients.[10]

The Role of Pharmacy: Helping Patients

Pharmacies and pharmacists are truly on the frontlines of neighborhood healthcare in the United States. This is demonstrated not only by proximity of the pharmacy but also by the increasingly important clinical role pharmacists play in helping patients with needed care. Walgreens, for example, is located within five miles of approximately 75 percent of Americans. This distance shrinks when extrapolated to the many other chain and independent community pharmacies, making the pharmacy the most accessible healthcare destination for the majority of the population.

In addition, pharmacists play an increasingly important role in the healthcare system that extends beyond "putting pills in a bottle" to providing a broad range of clinical services. Pharmacists today practice at the top of their license and training to manage chronic diseases and provide medication management, conduct health tests and educate patients on the results, administer immunizations, and partner with health systems to advance health and wellness as well as hospitals to transition patients to the community and reduce readmissions. Yet, because of the disjointed healthcare system in our country, pharmacists cannot provide the full range of their clinical capabilities across all payer environments, including across state Medicaid programs and in Medicare.

Even so, the value of pharmacy cannot be understated. We see our role as augmenting continuity of care—furthering the healthcare goals of patients and their providers. Clearly, the pharmacist relationship with patients is deeply rooted in trust; however, we believe more is needed to better integrate pharmacists across clinical settings to help address increasing care shortages, especially in medically underserved communities.

The challenge, as projected by the Association of American Medical Colleges, is by 2032 there will be approximately 121,900 fewer doctors than needed to meet growing demand.[11] This confluence represents an important situation that must utilize all available healthcare professionals to their fullest capability in order to adequately manage the growing pressures and demands on the nation's healthcare system. The effects of a physician shortage will be compounded in the Medicare program where, over the next two decades, the number of beneficiaries is projected to rise from approximately 58 million to nearly 90 million.[12]

Conclusion

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[10] Ibid.

[11] The Complexities of Physician Supply and Demand: Projections from 2017 to 2032, prepared for the Association of American Medical Colleges. April 2019. IHS Markit Ltd.

[12] 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds

The evidence is clear: increases in drug pricing and patient OOP costs and the significant impact these have on medication adherence are too important to go unanswered. Walgreens believes passing on all the savings generated from manufacturer rebates and discounts as well as pharmacy price concessions is the best policy solution currently under consideration. Coupling this approach with an open source benefit design clearinghouse will facilitate absolute transparency and prevent potentially new perverse incentives from taking hold.

Thank you, again, for the invitation to speak to the Subcommittee today, and I look forward to continuing to work with you on this important issue.

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 five 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, DC, 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:]

STATEMENT OF LEIGH PURVIS
ON BEHALF OF
AARP

BEFORE THE
U.S. HOUSE ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH
ON

"Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"

May 9, 2019
Washington, DC

For further information contact:
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Federal Health and Family
Government Affairs
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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, where I lead AARP's prescription drug policy work. AARP is a nonpartisan, nonprofit, nationwide organization with nearly 38 million members in all 50 States, DC, 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. Older Americans struggle to afford needed and life-saving medications. Medicare Part D enrollees take an average of 4-5 prescriptions per month, and over two-thirds have two or more concurrent chronic illnesses. At the same time, most Medicare beneficiaries live on modest incomes, with an annual median of just over $26,000. One-quarter have less than $15,000 in savings. This is not a population that has 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.

It should come as no surprise that our members consistently tell us they cannot afford the medications they need and are forced to make difficult choices as a result. In a recent survey of voters age 50 and older, 80% say they take at least one prescription medication and 72% say they're concerned about the cost of their medications. Moreover, 60% say prescription drug costs are unreasonable and many indicate they have or will need to make trade-offs in order to afford their medications.

In response to these calls for action, AARP launched our "Stop Rx Greed" campaign in March. 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: 1) increasing generic competition; 2) imposing an out-of-pocket cap for Medicare Part D; and 3) 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 scope, we believe that these three reforms will go a long way to making prescription drugs more affordable for older Americans and taxpayers and help protect critical programs like Medicare and Medicaid.

We hear from our members about the challenges they face in affording their medications. One of our members – 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's pays for his medications with "credit cards and juggling Peter to pay Paul," and has recently started tapping into his IRA to help pay for his prescription drugs.

Then there's the story of Joan Tramontano, an AARP member from Florida. Diagnosed with a gastrointestinal cancer, Joan was prescribed Gleevec following surgery, hoping to prevent her cancer from returning. After spending approximately $60,000 on this drug, Joan made the wrenching decision to stop taking it and risk her cancer returning rather than go bankrupt. Joan – like many retirees – lives on a fixed income, and simply cannot afford to drain her retirement savings to pay for a medication—even one that could potentially save her life. No one should be asked to make that kind of choice.

Today's high 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.

AARP has been tracking the prices of widely-used prescription drugs since 2004. A recent Rx Price Watch Report found that the retail prices of widely used brand name drugs increased by an average of 8.4% in 2017 – four times the rate of inflation.

We also examined how drug companies' relentless price increases add up over time and found that the annual cost of one brand-name drug therapy – now around $6,800 – would have been just under $2,200 in 2017 if retail price changes had been limited to general inflation between 2006 and 2017.

Our work also found that the average annual price increases for brand name drugs has exceeded the corresponding rate of inflation every year since at least 2006. More importantly, 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.

On the other hand, our most recent Rx Price Watch Report focused on widely used generic drugs found that the vast majority had price decreases in 2017. In fact, generic prescription drug prices fell by an average of 9.3% that year. 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 also 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 health care premiums, deductibles, and other forms of cost-sharing, as well as to all taxpayers.

We have also seen massive increases in Medicare spending on prescription drugs. Between 2009 and 2017, Medicare Part B drug spending more than doubled from $15.4 billion to $32.0 billion. Total Medicare Part D spending is approaching $150 billion. 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 one yourself.

In conclusion, current prescription drug price trends are simply not sustainable. There is no reason 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 they need.

It is long past time for Congress to take action to reign 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 health care 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.

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 five minutes for questioning.

Dr. Greene, Blue Cross Blue Shield of North Carolina holds an ownership of a PBM called Prime Therapeutics. Is that correct?

Dr. GREENE. Correct.

Ms. ESHOO. You had that in your testimony.

Does Prime Therapeutics receive any money from drug manufacturers during its negotiations?

Dr. 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?

Dr. 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?

Dr. 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.

Dr. 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.

Dr. 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?

Dr. 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.

Dr. 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 dis-

counts 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?

Dr. 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. Yes.

Dr. 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. OK, 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?

Dr. ASHWORTH. Thank you for the questions. So we buy——

Ms. ESHOO. And how do you negotiate the price to pay the drug manufacturers?

Dr. 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. Yes.

Dr. 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?

Dr. 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. OK, at your suggestion, Dr. Burgess, I would like to recognize the gentleman from Illinois, my pal, Mr. Shimkus, for five 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, OK. 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?

Dr. GREENE. Yes, changes are necessary.

Mr. SHIMKUS. And helpful, that would be helpful.

Dr. 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?

Dr. 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?

Dr. 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.

Dr. 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. OK, what is good for the goose is good for the gander.

Dr. RESNECK. Absolutely, I totally agree with you.

Mr. SHIMKUS. OK.

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 [continuing]. 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 returned his time.

The gentleman from North Carolina, Mr. Butterfield, five 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 five 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 Web site. Did I understand you to say that it is a non-profit organization?

Dr. GREENE. No, not-for-profit organization.

Mr. BUTTERFIELD. Well, that is the same thing—non-profit/not-for-profit.

Dr. 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?

Dr. 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?

Dr. 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 OK 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?

Dr. 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 authorization 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?

Dr. 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 4. 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 logins 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 authorization or waiting to deal with a non-transparent formulary,

many times, after several days by the time I have worked it out, it has at least got me out for a while.

Mr. BUTTERFIELD. Does the prior authorization process need to be reformed?

Dr. ASHWORTH. I would comment on that.

Mr. BUTTERFIELD. Major reforms or just tweaking around the edges?

Dr. 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 represented 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 five 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?

Dr. 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?

Dr. 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 three 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 authorization 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 authorization for that.

When I prescribe common medications like a retinoid for acne and there are silly prior authorization rules well if the patient is

over age 18, we don't believe they have acne so you have to complete a prior authorization 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 authorization 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 authorization 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 authorities 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 authorization 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 five 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. OK. 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?

Dr. 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?

Dr. 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?

Dr. 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. OK. 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.

Dr. 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?

Dr. 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. OK. And I guess Lilly is having a generic insulin I think they testified coming forward, coming out, or has just come out.

Dr. 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.

Dr. 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. OK. 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?

Dr. 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——

Dr. 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. OK. 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?

Dr. 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?

Dr. 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 3, 4, 5 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 brings 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 five 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. OK. 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. OK. Very good. Very good. Dr. Resneck, in other hearings a little bit I suppose today, there had been discussion about reimbursing doctors ASP plus six 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, 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. OK. 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 five 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 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, OK, 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 Web site. 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 these three or four 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 [continuing]. 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 copay 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 clearer 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 [continuing]. 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. OK. 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 [continuing]. 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 six or seven 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 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 appears at the conclusion of the hearing:]

Ms. ESHOO. And now I would like to recognize the gentleman from Indiana, Mr. Bucshon, for five 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 five years? Because 340B is going like this, right? Are 340B discounts passed to the patient at the contract pharmacy counter?

Dr. ESCHENBACHER. Not today.

Mr. BUCSHON. Not today. OK. So where do they go?

Dr. ESCHENBACHER. So when we get the funds back into Ascension—so it doesn't happen at the counter. It happens when they come back to Ascension and all of the programs that we provide across Ascension. We do medical missions at home. We do nurses in school districts. We do free medical care.

The comprehensive care of the patient, we use those monies. Also, contrary to popular belief, the 340B price of the medication, some of our patients actually can't even afford that. So we also help to pay for the products for those patients.

So if they go to a contract pharmacy and they are not able to afford it there, they come back to our own retail pharmacies, and we have a National Patient Assistance Program where we help to care for our patients within own system.

Mr. BUCSHON. OK. Because I was going to ask, is this the same for all patient types? And you just described——

Dr. ESCHENBACHER. Yes.

Mr. BUCSHON [continuing]. That it is not. Yes. So currently do you have—are all of the facilities DSH hospitals that are participating in 340B?

Dr. ESCHENBACHER. We have got a variety within them, 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 Web site, and we are putting all of that information on a Web site.

Mr. BUCSHON. OK. 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. OK. And burden on whom?

Dr. ESCHENBACHER. On the organizations. The reporting——

Mr. BUCSHON. OK. 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. OK. Because my understanding is patients don't really have any idea that they are a 340B, that they would be iden-

tified 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. OK. 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. OK. 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. OK. 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. OK.

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 gentle lady yield?

Ms. ESHOO [continuing]. Let the——

Mr. BUCSHON. Yield for just a brief second?

Ms. ESHOO. I would be glad to.

Mr. BUCSHON. Yes. My point 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 two 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 five 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. OK.

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 five 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 one day, and that is our average turnaround time is less than a day right now because of that streamlined process.

Mr. BILIRAKIS. OK. 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. BILIRAKIS. 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 five 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 three 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, OK? Thank you so much.

With that, I request unanimous consent to enter the following letters, testimony, and other information into the record: a statement from America's Health Insurance Plans, a statement from the American Society of Health System Pharmacists, a statement from the National Association of Chain Drug Stores, a statement from American Pharmacists Association, and a statement from the National Community Pharmacists Association as well.

Is that it? OK. No objection? So ordered.

Ms. ESHOO. Thank you, everyone. The subcommittee is adjourned.

[Whereupon, at 4:12 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. ELIOT L. ENGEL

Thank you, Madame Chairwoman Eshoo for holding today's important hearing on the prescription drug supply chain. Every day, my constituents tell me that the skyrocketing cost of prescription drugs is becoming unbearable. I have heard too many stories of hard-working New York families that have had to make the unimaginable decision between purchasing groceries or filling a life-saving prescription for their child.

On top of that, I find it absurd that our nation-the wealthiest in the world-pays more for the same drugs than our peer countries. Take insulin for example, a drug which seven million Americans rely on to manage and control their diabetes. A box of insulin pens costing around $700 in the United States reportedly costs $73 in Germany and even less in Israel at $57.

Other developed nations are able to achieve these savings because they are not afraid to leverage the purchasing power of their national insurance programs.

As Chairman of the Foreign Affairs Committee, I travel all over the world and meet with leaders from every corner of the globe. Even though these countries negotiate drug prices, they still have access to the same life-saving medications as Americans.

As we begin the next phase of our drug pricing work, I encourage my colleagues, on both sides of the aisle, to work on commonsense legislation which would repeal the so-called 'non-interference clause' in the 2003 Prescription Drug, Improvement and Modernization Act.

This horrendous policy, which I voted against, prevents Medicare from leveraging its purchasing power to lower the cost of life-saving drugs.

Empowering Medicare to do so would bring immediate relief to my constituents.

Statement for Hearing on

"Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"

Submitted to the House Energy and Commerce Committee Subcommittee on Health

May 9, 2019

America's Health Insurance Plans (AHIP) and our members are strongly committed to ensuring that Americans are able to get the medications they need at a price they can afford.

We thank the committee for focusing on issues surrounding the drug supply chain and solutions that are needed to help millions of people who are burdened by out-of-control prescription drug prices. As the bargaining power of the American people, health insurance providers collaborate with their pharmacy benefit manager (PBM) partners to negotiate lower prices from drug makers. These savings are delivered to patients and consumers through lower premiums and out-of-pocket costs.

We are deeply concerned about the lack of transparency in how drug makers set list prices—and those prices are controlled solely by manufacturers, no one else in the supply chain—and why drug prices go up on the same exact product year after year. These factors create a barrier to

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America's Health Insurance Plans (AHIP) is the national association whose members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.

developing new solutions to lower drug prices. Drug prices are out of control, and hardworking American families shouldn't have to choose between paying their bills and getting the medications they need.

Our statement for today's hearing focuses on: (1) the role of health insurance providers in the drug supply chain; and (2) our support for market-based solutions that hold drug makers accountable for high list prices and put downward pressure on prescription drug prices through competition, consumer choice, and open and honest drug pricing.

The Role of Health Insurance Providers in the Supply Chain: Negotiating Lower Costs for All Consumers

It is an understatement to say that prescription drug pricing in the United States is extraordinarily complex. Despite this complexity, in many cases, but especially where competition exists among prescription drugs (either from similar therapeutic alternatives or from generic or emerging biosimilar products), health insurance providers have leverage to negotiate with drug makers to provide savings for all consumers.

Health insurance providers negotiate with drug makers for lower net prices—and then pass those savings on in the form of lower premiums and lower out-of-pocket costs for all consumers. The focus on how some of these savings, which sometimes take the form of "rebates," are distributed to consumers—whether to a small group of patients or across the broader covered population—is a deliberate tactic to obscure the more serious issues surrounding the lack of competition, transparency, and accountability in the pricing of prescription drugs.

In discussing rebates, it is important to understand the role they play within the broader system for setting the cost of drugs that consumers pay at the pharmacy. It is also important to understand that for some branded drugs and biologics without therapeutic alternatives, the willingness of drug makers to negotiate on price is small or nonexistent. Further, rebates are not commonly found for physician-administered drugs, which account for 30 percent of prescription drug spending.[1]

The bottom line is that the original list price of a drug is solely determined and controlled by the drug company—not the market—and it drives the entire pricing process. And if the original list

[1] "Trends in Specialty Drug Benefits," Pharmacy Benefit Management Institute, 2017.

price is high, the final cost that a consumer pays will be high. If manufacturers took steps that are fully within their control to lower drug prices, consumers would pay less. **It is that simple: the problem is the price.**

Unfortunately, manufacturers of branded drugs and biologics are working to divert attention from high prescription drug prices and instead point to problems in the drug supply chain and the role of wholesalers and PBMs. However, we should focus on how the supply chain actually works.

Drug makers sometimes sell their products directly to the pharmacy (e.g., large chain retail pharmacies), but more often sell their products through a wholesaler. The price that pharmacies and wholesalers pay is highly correlated to the original list price set by the drug maker. Wholesalers and some pharmacies may acquire the drug at a modest reduction off the list price as a result of volume and/or prompt pay discounts. These discounts are not significant because wholesalers do not influence the "market share" of specific prescription drugs. Wholesalers then take possession of the drug and distribute and resell the drug to pharmacies (e.g., smaller community pharmacies) after a small markup above the discounted price. This total cost represents the pharmacy's acquisition cost.

At this point, the consumer enters the process. For individuals who lack health insurance but are prescribed a medication, they often pay the highest prices, especially for branded drugs. Typically, they pay the full list price set by the drug company (i.e., the wholesale acquisition cost, or WAC) plus a markup.

By contrast, for individuals with prescription coverage who are dispensed a covered prescription drug from a pharmacy in the health plan's network, the pharmacy typically communicates electronically with a PBM, which administers drug benefits under a contract with the health insurance provider. From the PBM, the pharmacy receives confirmation of coverage; whether the drug is subject to any formulary tools (e.g., step therapy or quantity limits); whether there are any potential safety issues (e.g., drug-drug interactions or other contraindications for the patient); the reimbursement amount to be paid by the plan; and the co-payment (usually a flat dollar amount) or co-insurance (usually a percentage tied to the reimbursement amount) owed by the consumer. The total payment to the pharmacy is typically based on a negotiated contract rate between the pharmacy and the health insurance provider (or the PBM acting on behalf of the health insurance provider). This contract reimburses the pharmacy for its acquisition cost and provides a dispensing fee.

The amount that the consumer or patient pays depends on several factors: (1) the negotiated rate between the plan and pharmacy; (2) the type of drug (i.e., branded or generic); (3) the plan's benefit design (e.g., co-pay or co-insurance); and (4) where the enrollee is within that benefit design at the time of purchase (e.g., in the deductible period, copayment period, maximum out-of-pocket (MOOP) limit or catastrophic phase for those in Medicare Part D). The pharmacy collects the appropriate cost sharing amount from the consumer and receives the remainder from the health insurance provider or PBM at later settlement time based on the payment terms under the contract. (The process described above assumes that there are no manufacturer-sponsored drug coupons and/or co-payment cards, where the drug maker directly pays a large portion of the consumer's cost sharing. These payment schemes are often not operationally transparent to payers, distort an already dysfunctional pricing market, and further complicate a confusing process for consumers.)

Given that the amounts charged by pharmacies for branded drugs reflects the pharmacies' acquisition costs, these charges are closely correlated to the list price set exclusively by the drug maker. That is why out-of-control drug prices show up at pharmacy counters. It is also why health insurance providers aggressively negotiate with drug makers for ways to reduce the impact of these prices, so they can pass savings onto consumers.

For example, if a health insurance provider's pharmacy and therapeutics (P&T) committee[2] determines that two or more drugs are therapeutically equivalent from a purely clinical perspective and eligible for formulary inclusion, health insurance providers (or PBMs) negotiate with drug makers for rebates in exchange for plans placing the drugs on a preferred formulary tier and/or waiving utilization management tools, such as step therapy protocols. Since drug costs comprise a significant portion of a health insurance provider's total costs, these discounts, which typically take the form of rebates, reduce the net price of the drug.

Rebate amounts typically are calculated and paid by a drug maker to a health insurance provider on an aggregate basis, long after an individual prescription is filled by a consumer. Because

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[2] P&T Committees are external advisory bodies of experts with broad clinical backgrounds regarding prescription drugs and typically are comprised of physicians from different medical specialties and pharmacists. P&T Committees review medications from a purely clinical perspective and make decisions based on several factors, including clinical and scientific evidence, standards of practice, peer-reviewed medical literature, accepted clinical practice guidelines and other relevant information. P&T Committees do not consider any information on drug rebates, discounts, or net prices/costs.

rebates are provided based on actual aggregated utilization by a specific population, they are paid several months after the drug has been prescribed and dispensed and all the data can be reconciled.

In designing their plan benefits and developing premium rates in advance of the upcoming coverage year, health insurance providers calculate an estimate of the aggregate rebates they expect to receive. Since drug costs comprise a significant portion of a health insurance provider's total costs, plans may use these estimated discounts to reduce the premiums they charge for the overall benefit and/or reduce co-payment amounts. Alternatively, health insurance providers may incorporate the estimates into lower point-of-sale pricing for individual drugs that generate the rebates.

By reducing the net price and cost of drugs, all consumers benefit when health insurance providers negotiate lower prices. The savings from discounts and rebates are passed on through improvements to benefit packages, reductions in premiums, and/or lower out-of-pocket costs. This represents a broad and direct benefit for millions of consumers whether they get their coverage through Medicare, on their own, or through their employer.

Market-Based Solutions for Reducing Drug Prices

There is no one silver bullet to reduce drug prices. A combination of bold legislative and regulatory steps is needed to hold drug makers accountable for high list prices and ensure that the American people have access to affordable medications.

In recent months, AHIP has submitted statements to the committee for several previous hearings in which we discussed our support for market-based solutions that put downward pressure on prescription drug prices. With solutions that deliver real competition, create more consumer choice, and ensure open and honest drug prices, we can deliver more affordable pharmaceutical products—while at the same time protecting and supporting innovations to deliver new treatments and cures for patients.

Below we briefly identify key areas where we see opportunities for Congress and the Administration to provide relief to the American people from out-of-control prescription drug prices:

- Stopping gaming by drug makers that limits the entry of new generic and biosimilar competitors—the "Creating and Restoring Equal Access to Equivalent Samples (CREATES)

Act" and a prohibition against pay-for-delay settlements, both of which the committee approved on April 3, would be important steps toward achieving this goal;

- Preventing the "evergreening" of patent protections—a scheme through which drug makers make minor changes to a drug's chemical composition or delivery mechanism to extend patents that otherwise would have expired;
- Shortening the exclusivity period for biologics to promote greater price competition and help alleviate cost pressure for payers, patients and consumers for biologics;
- Revisiting the incentives in the Orphan Drug Act to ensure that this law is used as intended by those developing medicines to treat rare diseases—not as a gateway to premium pricing and blockbuster sales and profits beyond orphan indications;
- Ensuring that federal rules promote the availability of interchangeable biosimilars;
- Providing more transparency and timely information about drug and biologic patents to promote greater generic drug and biosimilar competition;
- Requiring drug makers to publish true research and development costs and explain price setting and price increases;
- Mandating that drug maker coupons and/or co-pay cards cover a patient's entire out-of-pocket expenses for the duration of the drug therapy;
- Disclosing list prices in direct-to-consumer advertisements;
- Informing patients and physicians on the effectiveness and value of drugs;
- Eliminating barriers to value-based pricing; and
- Exercising HHS' authority to introduce market competition when manufacturers fail to engage in reasonable, good-faith negotiations with payers.

Conclusion

Thank you for considering solutions to address the pharmaceutical cost crisis. We look forward to working with the committee to make prescription drugs more affordable. Everyone deserves access to the medications they need at a price they can afford. We should not have to choose between innovation and affordability. With the right solutions and genuine collaboration, we can have both.

Health Subcommittee on Energy and Commerce

Hearing on: "Lowering Drug Prices: Deconstructing the Drug Supply Chain"

May 9, 2019

Statement for the Record Submitted by ASHP

American Society of Health-System Pharmacists
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ASHP (American Society of Health-System Pharmacists) respectfully submits the following statement for the record to the House Energy and Commerce hearing on lowering drug prices.

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's nearly 50,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP's vision is that medication use will be optimal, safe, and effective for all people all of the time. A primary tenet of that vision includes access to affordable medications needed to save or sustain lives. Addressing the issue of skyrocketing drug prices, including excessive price increases on commonly used generic medications, is one of ASHP's highest and longstanding public policy priorities. According to a Kaiser Health Tracking Poll, 1 in 4 Americans cannot afford their medications.[1] Poor access to medications can lead to increased morbidity and mortality, and can cause healthcare costs to rise.

ASHP has been proactively addressing challenges related to the rapid increase of prescription drug pricing on several fronts, including working with like-minded stakeholders and educating members of Congress about the unsustainable burdens faced by patients, healthcare providers, and the entire healthcare system.

ASHP is a lead member of the Steering Committee of the Campaign for Sustainable Rx Pricing (CSRxP), a coalition of prominent national organizations representing physicians, consumers, payers, hospitals, health systems, and patient advocacy groups. CSRxP has developed a policy platform promoting market-based solutions supported by three pillars: competition, value, and transparency.

The goal of the campaign is to identify policy options that have bipartisan support and, therefore, a greater likelihood of passage. To that end, CSRxP focuses on policies to incentivize a more competitive marketplace to help stimulate lower drug prices. The campaign has also expressed support for efforts to loosen restrictions that prevent generic drug companies from obtaining the samples necessary to manufacture a competing product. In this regard, we are supportive of bills such as the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019 (S.974) (H.R.1499) which address this specific issue.

ASHP, along with the American Hospital Association (AHA) and the Federation of American Hospitals (FAH), recently released a report on the impact that the cost of and access to prescription drugs is having on hospital budgets and operations.

Specifically, the report showed that:

- Average total drug spending per hospital admission increased by 18.5% between fiscal years (FY) 2015 and FY2017.
- Outpatient drug spending per admission increased by 28.7%, while inpatient drug spending per admission increased by 9.6% between FY2015 and FY2017.
- Hospitals experienced price increases of over 80% across different classes of drugs, including those for anesthetics, parenteral solutions, and chemotherapy.
- Over 90% of surveyed hospitals reported having to identify alternative therapies to manage spending.
- One in 4 hospitals had to cut staff to mitigate budget pressures.

ASHP does not collect, store, or report drug pricing information. However, we continually hear from pharmacy leaders in hospitals and health systems that sudden, inexplicable, and unpredictable price

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[1] DiJulio, Bianca, et al. "Kaiser Health Tracking Poll: August 2015." The Henry J. Kaiser Family Foundation, The Henry J. Kaiser Family Foundation, 20 Aug. 2015, www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-august-2015/. Accessed February 10, 2019.

increases in connection with some of the most commonly used, longstanding generic medications are becoming more prevalent — and are occurring on a nationwide basis.

In this statement, we address five additional issues as they relate to drug pricing: Competition, Risk Evaluation and Mitigation Strategies (REMS), Direct and Indirect Remuneration (DIR Fees), importation of prescription drugs, and the 340B Drug Pricing Program.

COMPETITION

In particular, ASHP would like to learn more about the marketplace dynamics that could contribute to this issue, as we have worked diligently to address the issue of drug shortages for nearly 15 years. Although drug shortages are caused by a number of factors, we have observed that drugs in short supply made by only one or two manufacturers often result in higher-than-normal prices. If, for example, there is a lack of competition in the generic marketplace, we urge the committee to look at ways to stimulate more marketplace presence. ASHP supports bills such as S. 64, the "Preserve Access to Affordable Generics and Biosimilars Act" and H.R. 1499 the "Protecting Consumer Access to Generic Drugs Act of 2019." Both bipartisan bills would prohibit brand name drug manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the marketplace. Passage of this legislation would in essence prohibit companies from engaging in "pay-to-delay" tactics which drastically affects patient access to care.

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

ASHP recognizes that there may be limited circumstances in which constraints on the traditional drug distribution system may be appropriate for reasons of patient safety, including through the use of manufacturer-driven REMS. However, we believe that REMS should never be used to artificially inflate drug prices, nor should they interfere with the professional practice of pharmacists, physicians, nurses, and other providers. We believe that there may be current cases in which a manufacturer-driven REMS using restricted distribution are causing higher prices for those drugs, having adverse effects on patient access, and delaying treatment. In some cases, there is evidence to suggest that the use of restricted or limited distribution channels has resulted in the inability of a potential competitor to acquire enough of a drug to conduct the required testing to bring a generic competitor to market. For this reason, we support bills such as S. 340, the "Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019." The CREATES Act will help ensure that brand-name pharmaceutical companies cannot manipulate regulatory rules to prevent competition, which is essential for patient access to affordable medications. Additionally, we recommend that Congress require the Food and Drug Administration (FDA) to investigate restricted distribution under a REMS as a means to artificially increase drug prices and limit access to critical medications.

DIRECT AND INDIRECT REMUNERATION FEES (DIR Fees)

DIR fees are a growing nationwide concern among pharmacies that dispense medications in a community pharmacy or outpatient clinic setting. Created under the Medicare Part D Program, DIR fees were originally intended as a way for CMS to account for the true cost of the drug dispensed, including any manufacturer rebates. Often these fees are unknown until the drug is dispensed and the claim adjudicated. Moreover, the fees themselves, which are often arbitrary in nature, have mushroomed over the past decade, to the point that pharmacies regularly see annual DIR totals in the tens of thousands of dollars.

Recently, a concerning trend has emerged where pharmacy benefit managers (PBMs) have begun to charge DIR fees to their pharmacy providers. Under this scenario, PBMs are inappropriately applying their own plan performance measures as a way to assess fees on pharmacies. This is problematic for the following reasons:

- Pharmacy providers are essentially being penalized with backdoor fees without any requirement that PBMs define, justify, or explain these charges to providers and to CMS.
- It is an arbitrary application of quality measures meant for total plan performance as opposed to pharmacy-level metrics.
- The quality measures applied were never intended to be applied to specialty medications or to other specialized disease states such as oncology, yet PBMs assess DIR fees against the gross reimbursement for all prescriptions received by pharmacy providers, not just maintenance medications.

DIR fees assessed on pharmacies providing specialty medications have been especially hard-hit, due to the fee structure. Fees could be a flat rate of per dollar per claim or a percentage (typically 3–9%) of the total reimbursement per claim. Using the percentage-based structure, the fees would increase markedly for specialty drugs, which are typically much more expensive than maintenance medications, sometimes resulting in thousands of dollars. For example, a 9% fee on a drug costing $100,000 is $9,000. Additionally, these fees are assessed retroactively, sometimes months after the claim has been adjudicated, providing no recourse for the pharmacy impacted by the assessment.

DIR fees have led to higher cost-sharing responsibilities for Medicare beneficiaries, which has, in turn, caused more of these beneficiaries to enter the Part D donut hole, where the patient is solely responsible for the cost of the drug. Along with the higher costs absorbed by patients, adherence rates tend to be lower among Medicare beneficiaries who are in the donut hole and may not have the financial resources to pay for their medications. This is in stark contrast to the very reason DIR fees targeting manufacturer rebates were created — so that savings could be passed on to patients.

Pharmacies are not alone in their concern about abused DIR fees. In January 2017, CMS published a fact sheet expressing concern over DIR fees and cited those fees as contributing to increased drug costs, which, in turn, increased patients' out-of-pocket spending and Medicare spending overall. Additionally, questions remain as to whether Part D plan sponsors have the authority to assess these fees on pharmacies. DIR fees collected on pharmacies were not authorized in either the Part D statute or corresponding CMS regulations.

ASHP recommends that Congress:

> *Advocate that payers and pharmacy benefit managers be prohibited from recovering direct and indirect remuneration fees from pharmacies on adjudicated dispensing claims; further,*
>
> *Oppose the application of plan-level quality measures on specific providers, such as participating pharmacies.*[2]

DRUG IMPORTATION

A number of bills introduced in the House of Representatives, H.R. 478, the "Safe and Affordable Drugs from Canada Act of 2019," and H.R. 447, the "Affordable and Safe Prescription Drug Importation Act,"

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[2] ASHP Policy 1814, *Direct and Indirect Remuneration Fees.*

would allow for importation of prescription drugs by individuals, wholesalers, or pharmacies. ASHP does *not* support these bills, as they put patients at unnecessary risk. ASHP recommends that Congress:

> *Advocate for the continuation and application of laws and regulations enforced by the Food and Drug Administration and state boards of pharmacy with respect to the importation of pharmaceuticals in order to (1) maintain the integrity of the pharmaceutical supply chain and avoid the introduction of counterfeit products into the United States; (2) provide for continued patient access to pharmacist review of all medications and preserve the patient-pharmacist-prescriber relationship; and (3) provide adequate patient counseling and education, particularly to patients taking multiple high-risk medications; further,*
>
> *Urge the FDA and state boards of pharmacy to vigorously enforce federal and state laws in relation to importation of pharmaceuticals by individuals, distributors (including wholesalers), and pharmacies that bypass a safe and secure regulatory framework.*[3]

We urge the committee to carefully consider how any bill that includes an importation policy could negatively affect a drug's pedigree and potentially allow adulterated and/or counterfeit drugs into the supply chain. Importation is in direct conflict with the Drug Supply Chain Security Act passed by Congress in November 2013, which sought to better track and trace drugs through the supply chain. ASHP understands that bills to allow for importation seek to create access to lower cost medicines. We believe, however, that safer and more comprehensive means to improve affordability and accessibility are needed.

THE 340B DRUG PRICING PROGRAM

For 25 years, the federal 340B program has allowed safety-net hospitals "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." This program has been essential to expanding access to lifesaving prescription drugs and comprehensive healthcare services to low-income and uninsured individuals, at no cost to the federal government. *The federal 340B program is not causing high drug prices*. The program accounts for less than 5% of annual drug purchases in the United States, while safety-net providers give 30% of the care. Given the increasingly high cost of pharmaceuticals, the federal 340B program provides critical support to the entities eligible to participate in the program.

The federal 340B program enables these hospitals to serve their communities by providing vital care such as:

- Free or lower cost medications to patients.
- Programs to increase medication adherence, including clinical pharmacy services to high-risk patients who are on multiple and/or complex medications.
- Increased access to primary care.
- Screenings and preventive care services to detect health problems early and decrease morbidity and mortality, as well as to decrease healthcare costs and hospital admissions.

The federal 340B program is at risk because of a recent change in Medicare payment policy that reduces payment from Average Sales Price plus 6 percent to Average Sales Price minus 22.5 percent. Cuts of this

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[3] ASHP Policy 0413, *Importation of Pharmaceuticals*.

magnitude undermine the intent of the program, reducing resources that hospitals use to expand access to care and services to vulnerable communities.

CONCLUSION

ASHP thanks the Committee on Energy and Commerce for holding this important hearing. In summary, ASHP supports; policies incentivizing generic competition and curtailing practices that reduce entry of competitor drugs into the marketplace; does not support prescription drug importation as a means to reduce drug prices because it places patients at needless risk; strongly supports the safeguarding of the 340B program and the benefits it provides to patients, and rejects the notion that it contributes to high drug prices. ASHP remains committed to working with Congress and industry stakeholders to ensure that patients have affordable access to lifesaving and life-sustaining medications.

Statement

Of

The National Association of Chain Drug Stores

For

United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

On

Lowering Prescription Drug Prices:
Deconstructing the Drug Supply Chain

May 9, 2019
10:00 a.m.

2322 Rayburn House Office Building

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1) Introduction

The National Association of Chain Drug Stores (NACDS) thanks Chairwoman Eshoo, Ranking Member Burgess, and the Members of the Subcommittee on Health for the opportunity to submit a statement for the hearing on "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain."

NACDS and the chain pharmacy industry are committed to partnering with Congress, HHS, patients, and other healthcare providers to find solutions to lower the cost of prescription drugs and improve access to quality, affordable healthcare services. NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 157,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

As a key stakeholder in the drug supply chain, community pharmacists have for generations been trusted, highly accessible healthcare providers deeply committed to providing accurate prescriptions and helping patients take medications as prescribed. Community pharmacists provide a critical role in the continuum of care for patients. Importantly, not only do pharmacist interventions improve patient health and outcomes, but also pharmacy care has been shown to save downstream health care dollars.

As the demand for healthcare services continues to grow, pharmacists have expanded their role in healthcare delivery, partnering with physicians, nurses, and other healthcare providers to meet their patients' needs. Through quality-driven, innovative services pharmacists help avoid more costly forms of care and help improve patient quality of life. As the Subcommittee explores policies to lower the cost of prescription drugs, we offer the following recommendations we believe will help achieve that goal while improving patient health.

2) Lowering Costs Through Pharmacy DIR Reform

a) CMS Proposed Rule

On November 30, 2018, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule, "Modernizing Part D and Medicare Advantage to Lower Prices and Reduce Out-of-Pocket Expenses" that included policy reforms that would increase competition in the Medicare Part D program and lower beneficiary out-of-pocket costs by reforming pharmacy direct and indirect remuneration (DIR) fees.[1] Specifically, these reforms include:

- **Redefining the "negotiated price" to include all pharmacy price concessions.** Including all pharmacy price concessions in the negotiated price would reduce its amount and result in lower beneficiary cost sharing;

- **Developing a broad definition of "price concession" to include all forms of discounts, direct or indirect subsidies, or rebates that serve to reduce costs incurred by Part D sponsors.** Again, this would help ensure the lowest negotiated price and thus, lower beneficiary cost-sharing; and

- **Developing standardized pharmacy performance metrics for 2020. NACDS believes such metrics would be a good first step toward the development of Medicare Part D pharmacy quality incentive program.** The Department of Health and Human Services (HHS) needs to develop a pharmacy quality incentive program to align incentives between plans, pharmacies and beneficiaries. Pharmacy incentive payments would drive higher quality health outcomes. Opportunities to increase medication optimization and improve medication adherence would improve patient outcomes and reduce future healthcare costs.

CMS has recognized the harms caused by pharmacy DIR fees.[2] Between 2010 and 2017 the use of pharmacy DIR fees grew 45,000 percent.[3] As a result, Medicare beneficiaries are paying more out-of-pocket costs, the federal government is not fully understanding what it is paying for prescription drugs, and retail pharmacies are conducting business in an environment where they are unsure whether a payment will be clawed back at some later date as DIR.

CMS also recognizes that pharmacy DIR fees harm pharmacies by reducing transparency and predictability of reimbursement.[4] Pharmacy DIR fees undermine drug price transparency, which is necessary for efficient market competition that would reduce

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[1] 83 Fed. Reg. 62152, 62190-92 (Nov. 30, 2018).
[2] *See, e.g.*, 82 Fed. Reg. 56336, 56420-21 (Nov. 28, 2017) (explaining how pharmacy DIR fees increase beneficiary costs and decrease drug price transparency necessary for competition among plans); CMS, Medicare Part D – Direct and Indirect Remuneration (DIR) (Jan. 19, 2017) (noting the negative impact of pharmacy DIR fees on beneficiary drug costs, taxpayer subsidies and plan cost-avoidance); CMS, "Fact Sheet - Medicare Part D – Direct and Indirect Remuneration (DIR)" (January 19, 2017), available at https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir.
[3] *Id.* at 62147.
[4] *Id.* at 62191.

prescription drug costs.[5] Such transparency is vital to allow all stakeholders, notably patients and providers, to make informed decisions about how to best meet healthcare needs. As CMS also points out, "consumers cannot efficiently minimize both their costs and costs to the taxpayers by seeking and finding the lowest-cost drug or a plan that offers them the lowest-cost drug and pharmacy combinations."[6]

Beneficiaries are likely unaware that the increasing use of pharmacy DIR fees has led to inflated drug costs and higher cost-sharing. The impact of higher cost-sharing for beneficiaries negatively impacts medication adherence, leading to increased total cost of care and poorer health outcomes.

Moreover, finalizing pharmacy DIR reform needs to be coupled with the development of standardized achievable pharmacy quality metrics and a pharmacy quality incentive program. Without a standard set of metrics, beneficiaries, pharmacies, and plans are unable to make comparisons of pharmacy quality. Consequently, there is not an effective means for consumers to compare plans and pharmacies within the Part D program, undercutting market competition, which can contribute to higher costs.

b) Better Medication Adherence and Medication Optimization Reduce Healthcare Costs

Pharmacy DIR fee reform and the development of a standardized pharmacy quality incentive program will save taxpayers billions of dollars by aligning incentives for the entire Medicare program. By establishing a pharmacy quality incentive program, HHS will encourage a more systematic investment in pharmacy quality designed to facilitate care coordination, reduce medical errors, advance population health, and empower and motivate beneficiaries to achieve better health outcomes through medication optimization services and improved medication adherence.

Medication optimization services encompass patient-centered activities that improve health outcomes by addressing medication appropriateness, effectiveness, safety, adherence, and access. Medication optimization services delivered by community pharmacies are central to the care of beneficiaries. Nearly all Americans (91.7 percent) live within 5 miles of a community retail pharmacy and in 2017 nearly 73 percent of prescriptions dispensed in the U.S. were filled at retail pharmacies. Face-to-face interactions with beneficiaries at the point-of-dispensing allow the pharmacist to counsel and educate the patient and are critical to achieving national-scale improvements in health outcomes and lowered costs.[7]

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[5] *Id.* at 62176.
[6] Id. at 62176
[7] Patients who participated in brief face-to-face counseling sessions with a community pharmacist at the beginning of statin therapy demonstrated greater medication adherence and persistency than a comparison group who did not receive face-to-face counseling. The intervention group had statistically greater Medication Possession Ratio (MPR) than the control group every month measured. Taitel M, Jiang J, Rudkin K, Ewing S, Duncan I; "The impact of pharmacist face-to-face counseling to improve medication adherence among patients initiating statin therapy;" *Patient Prefer Adherence;* 2012;6:323-9. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3340117/. Likewise, a systematic review was conducted using 51 studies determining the optimal modes of delivery for interventions to improve adherence to

The better use of medicines will also reduce medication non-adherence—that is, patients not taking their medications as prescribed by their healthcare provider. Medication non-adherence contributes to $100-290 billion in unnecessary healthcare expenditures every year as a result of increased hospitalizations and other avoidable, expensive medical services.[8,9,10] Numerous studies have shown that reducing patient drug costs increases medication adherence, which, in turn, reduces overall healthcare costs. For example, a recent study found that medication nonadherence for diabetes, heart failure, hyperlipidemia, and hypertension resulted in billions of dollars in Medicare fee-for-service expenditures, millions of hospital days, and thousands of emergency department visits that could have been avoided.[11] Specifically, the study estimated that avoidable costs from medication nonadherence of four chronic conditions is $28.9 billion, representing 8 percent of the total expenditures. A 2017 white paper found that the direct medical costs and consequences related to not taking medication as prescribed is estimated to be 7 to 13 percent of national health spending annually—approximately $250 billion to $460 billion in 2017, translated to a potential cost to taxpayers of $6 trillion over 10 years.[12] And a 2016 cost-benefit analysis concluded that between one and two thirds of medicine related hospitalizations are caused by poor adherence. Improving adherence could result in annual per-person savings ranging from $1,000 to $7,000, depending on the disease state.[13] Multiple, credible sources have drawn the same conclusion: medication non-adherence is a costly, preventable problem that dramatically affects total cost of care.

c) Subcommittee Support

As detailed above, pharmacy DIR reform as proposed by CMS would lead to lower prescription drug costs for both Medicare Part D beneficiaries and federal taxpayers. In addition, pharmacy DIR reform would lead to better medication adherence among Part D beneficiaries, which would lead to further healthcare cost savings. With these cost saving benefits in mind, we urge the Subcommittee to communicate support to CMS in favor of finalizing pharmacy DIR reform, including the development of standardized pharmacy quality metrics that would lead to a pharmacy quality incentive program.

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cardiovascular medications. Among person-dependent interventions (nonautomated phone calls, in-person interventions), phone calls showed low success rates (38%). In-person pharmacist interventions were effective when held in a pharmacy (83% successful) but were less effective in clinics (38%). Cutrona SL, Choudhry NK, et al; "Modes of Delivery for Interventions to Improve Cardiovascular Medication Adherence;" *AJMC*; December 2010. https://www.ajmc.com/journals/issue/2010/2010-12-vol16-n12/ajmc_10dec_cutrona929to942?p=1

[8] Rosenbaum L, Shrank WH; "Taking Our Medicine - Improving Adherence in the Accountability Era;" *New England Journal of Medicine*; Aug. 22, 2013

[9] Network for Excellence in Health Innovation; "Bend the Curve: A Health Care Leader's Guide to High Value Health care;" 2011.

[10] The NCPIE Coalition; "Enhancing Prescription Medicine Adherence: A National Action Plan;" 2007.

[11] Lloyd, Jennifer T., Maresh, Sha, Powers, Christopher, Shrank, WH, Alley, Dawn E; "How Much Does Medication Nonadherence Cost the Medicare Fee-for-Service Program?"; Medical Care, January 2019.

[12] "A Treatable Problem: Addressing Medication Nonadherence by Reforming Government Barriers to Care Coordination;" *Prescriptions for a Healthy America*; October 2017.

[13] Patterson JA, et al; "Cost-Benefit of Appointment-based Medication Synchronization in Community Pharmacies;" *American Journal of Managed Care*; 2016.

3) Reform to Manufacture Rebates

a) NACDS Supports Goals of Proposed Rule but Changes and Clarifications are Needed

Earlier this year, HHS and the Office of Inspector General (OIG) released a proposed rule with the goal of lowering the cost of prescription drugs by requiring that manufacturer reductions in prescription drug prices to health plans/pharmacy benefit managers (PBMs) be passed on to the patient at the pharmacy counter. We support the goals of the proposed rule and believe the changes could lead to reduced patient out-of-pocket costs and could lower government program costs by improving medication adherence.

However, we believe HHS and OIG must include specific revisions in the final rule, as well as issue other regulatory or sub-regulatory guidance to maximize the impacts of passing manufacturer reductions in price to patients at the point-of-sale, reduce costs for all stakeholders, and increase efficiencies by utilizing and leveraging current capabilities and technologies. Specifically, the following changes and clarifications are needed in the final rule or in concurrent guidance:

- **Timeliness of payments** – Payment of discounts to pharmacies under a new system must follow current prompt payment requirements. Without prompt pay requirements applying to all elements of pharmacy claims, pharmacies would face devastating cash flow challenges resulting from having to wait months after dispensing medications before receiving payment of manufacturer reductions in price.

- **Transparency** - The total reimbursement due to the pharmacy, including the amount of any payment related to manufacturer reductions in price, must be known by the pharmacy at the point-of-sale at the time of dispensing. Failure to account for the manufacturer reductions in price at the point-of-sale claim adjudication would make it nearly impossible for pharmacies to track the collection of open receivables and could put pharmacies at substantial financial risk.

- **Protection from Unnecessary Fees** - Pharmacies should not be responsible for fees or other costs associated with administering manufacturer reductions in price. Specifically, pharmacies should not pay additional transaction, administrative, or other fees either directly, or indirectly through reduced reimbursements. The total and final reimbursement to the pharmacy must consist of the full contracted reimbursement from the plan/PBM, the reduction in price negotiated between the manufacturer and the plan/PBM, and the cost-sharing payment from the beneficiary; and shall not be affected by the reduction in price negotiated between the PBM and the manufacturer.

- **Maximize Efficiency and Minimize Additional Costs** – The final rule should maximize the use of existing technology, standards, systems, and business relationships. A new system potentially requiring the development of new

capacities and technologies for data sharing, processing and auditing of payments to pharmacies, as well as new financial relationships, will only add unnecessary cost and complexity into the healthcare system.

b) HHS Must Address Pharmacy DIR First

HHS must finalize reforms in the use of pharmacy DIR fees in the Medicare Part D program (as discussed in detail above) before moving forward with finalizing changes to the treatment of manufacturer rebates. Moving forward with reforms to manufacturer rebates without reforming the use of pharmacy DIR fees could incentivize even more aggressive use of pharmacy DIR fees, which would increase beneficiary and taxpayer costs, and lead to poorer medication adherence and worsening overall beneficiary health. We ask the Subcommittee to communicate with HHS the importance of finalizing the proposed CMS rule that reforms pharmacy DIR before finalizing manufacturer rebate reform.

4) Electronic Prescribing and the Part D Prescription Drug Plan

NACDS supports the efforts of HHS and CMS in integrating a patient-specific real-time benefit tool (RTBT) into the Part D benefit to drive lower prescription drug spending and minimize beneficiary out-of-pocket costs. Beneficiaries often arrive at the pharmacy counter with little or no insight as to what a medication will cost them, which can lead to overuse of unnecessarily expensive medications and the underuse of essential medications. We strongly agree with CMS that "reducing medication cost also yields benefits in patients' medication adherence" and that "increasing patient cost-share for a medication [is] associated with a significant decrease in medication adherence."[14] The integration of a RTBT into the Part D benefit will give providers and beneficiaries the information needed to make better informed choices on their healthcare treatment.

NACDS cautions that policies utilizing RTBTs must be designed in a manner that allows the prescriber to decide whether a prescribed drug is covered by the beneficiary's insurance plan without fear of "steering" a beneficiary to certain pharmacies or to mail order. This could be accomplished by requiring the beneficiary to select his or her pharmacy of choice prior to the prescriber utilizing the RTBT to access the enrollee cost-sharing information. Moreover, we believe that the RTBT must provide enough information to the prescriber and pharmacy to facilitate clinical decision making and assist in determining optimal patient medication regimens.

[14] 83 Fed. Reg. 62152, 62165 (Nov. 30, 2018).

RTBTs must also be able to take into consideration pharmacy-level cost-containment programs, such as $ 4.00 generic programs, or patient assistance programs. Moreover, absent system safeguards, RTBTs can inadvertently drive physician prescribing of expensive, therapeutic alternatives that are subject to high rebate arrangements between PBMs and manufacturers. Such results would negate the goal of using a RTBT and needlessly drive up overall spending in the Part D program. Policies utilizing RTBTs must:

1. Preserve patient's right to pharmacy selection at the outset;
2. Ensure accurate and complete patient's out-of-pocket costs at formulary and pharmacy levels;
3. Avoid unintended economic costs to taxpayers and beneficiaries associated with steering patients to therapeutic alternatives that are subject to "spread pricing" due to excessive list prices and rebates;
4. Prohibit commercial messaging within RTBT transmissions; and
5. Ensure information integrity, fairness and accuracy.

We ask members of the Subcommittee to communicate to HHS the need for RTBTs to be implemented in a way that serves its goals of providing timely information that would lower prescription drug costs.

5) Conclusion

NACDS thanks the Subcommittee for your consideration of our comments. We urge members of the Subcommittee to voice their thoughts to HHS to use their authority to include pharmacy DIR fee reform, the development of standardized pharmacy quality metrics, and the development of a pharmacy quality incentive program in the Final Part D Rule for FY2020 and to move forward with requiring manufacturer reduction in prices be passed on to patients at the pharmacy counter in a manner that does not harm the supply chain or jeopardize patient health. Finally, we ask members of the Subcommittee to communicate to HHS the benefit of incorporating a RTBT into the Medicare Part D program in a manner that will drive lower spending on prescription drugs while protecting patient choice.

AMERICAN PHARMACISTS ASSOCIATION
STATEMENT FOR THE RECORD

BEFORE THE U.S. HOUSE COMMITTEE ON ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH

LOWERING PRESCRIPTION DRUG PRICES:
DECONSTRUCTING THE DRUG SUPPLY CHAIN

THURSDAY, MAY 9, 2019

2215 Constitution Avenue, NW • Washington, DC 20037-2985 • 202-628-4410 • Fax: 202-783-2351
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Chairwoman Eshoo, Ranking Member Burgess, and Members of the Committee, the American Pharmacists Association (APhA) is pleased to submit the following Statement for the Record for the U.S. House Committee on Energy and Commerce Hearing "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain."

APhA, founded in 1852 as the American Pharmaceutical Association, represents nearly 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians' offices, hospitals, long-term care facilities, specialty pharmacy, community health centers, managed care organizations, hospice settings and the uniformed services.

Pharmacies are where millions of Americans are first exposed to the impact of complex pharmaceutical pricing policies or confronted with changes in coverage, formularies, prior authorization, deductibles and co-payments or co-insurance, many of which they didn't know existed or understand. Everyday, pharmacists help our patients navigate through confusing and convoluted policies related to the coverage of their medications and management of their out of pocket costs. We are not compensated for this time or directly for most of our patient care services that support optimization of medication therapy. Our comments focus on the following areas – cost versus value, patients' access to medications, pharmacy benefit managers (PBMs), pharmacy access to medications, drug shortages, medications' safety and affordability and importation concerns.

Cost Versus Value

As drugs become more expensive, complex, and personalized, the need to optimize their impact also increases. In order to get the greatest benefit from medications, patients must understand how to use their medications safely and effectively, and pharmacists are best positioned to help patients optimize the medication therapies available to them. Pharmacists have more medication-related education and training than any other health care professional. Pharmacists provide medication management services, which are especially important for patients who have complex care plans, take multiple drugs or have chronic conditions. Additionally, to reduce the risk of hospital readmissions, pharmacists help patients transition between care settings. The most expensive medication is one that is inappropriate for a patient or used incorrectly.

Unfortunately, despite the fact that many states and Medicaid programs are turning to pharmacists to increase access to health care and address medication-related costs, efforts supported by the Centers for Medicare and Medicaid Services (CMS),[1] Medicare Part B does not cover many of the impactful and valuable patient care services pharmacists can provide. Pharmacists are trained to do more than place medication in a container and while 91.7% of Americans live within 5 miles of a community pharmacy[2] many of our Nation's seniors are medically underserved. Pharmacists are an underutilized and accessible health care resource who can positively affect beneficiaries' care[3] and the entire Medicare program.

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[1] CMS/ CMCS Informational Bulletin. State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols. January 17, 2017, available at: https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf

[2] NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

[3] CMS. Evidence Supporting Enhanced Medication Therapy Management. Center for Medicare and Medicaid Innovation. 2016, available at: https://innovation.cms.gov/Files/x/mtm-evidencebase.pdf

APhA strongly believes bipartisan legislation introduced in the 115th Congress, the *Pharmacy and Medically Underserved Areas Enhancement Act* will improve patient care, health outcomes, impact of medications,[4] and consequently, the viability of the Medicare program. Introduced by former Congressmen Brett Guthrie and G.K. Butterfield, H.R. 592 enjoyed the support of 296 bipartisan cosponsors last year, including many Members of this Committee.

This legislation would enable Medicare patients in medically underserved communities to better access health care through state-licensed pharmacists practicing according to their own state's scope of practice. In medically underserved communities, pharmacists are often the closest health care professional and accessible outside normal business hours. Helping patients receive the care they need, when they need it, is a common sense and bipartisan solution that will improve outcomes and reduce overall costs.

The importance of medication-related services cannot be overstated, especially in the Medicare program. Medications are the primary method of managing chronic disease and are involved in 80 percent of all treatment regimens. Moreover, the United States spends nearly $672 billion annually on medication-related problems and nonoptimized medication therapy, including nonadherence.[5] Accordingly, not only will such legislation increase beneficiaries' access to health care, it will help improve their outcomes—particularly those impacted by medications. APhA appreciates the support by many Committee members for the *Pharmacy and Medically Underserved Areas Enhancement Act* and urges its swift passage to allow pharmacists to deliver these vital services as providers in medically underserved areas.

We also encourage the Committee, when considering policy changes to lower drug prices, to look beyond isolated components of health care to determine cost and value. Because health coverage is frequently analyzed by the benefit type such as inpatient, outpatient, and drug coverage, a patient's overall services, costs and outcomes may never be reviewed comprehensively. Policies cannot continue to consider drug and medical coverage, and their related costs and outcomes, separately if we are to achieve true value in health care. Current coverage and payment policies related to prescription drugs place incentives on the short-term, focusing on cost containment for the product rather than weighing the overall clinical benefit to the patient and the impact to their medical costs. Breaking down the many silos within our health care system will help address that billions of dollars spent on medication-related problems—many of which are preventable.[6]

Patients' Access to Medications

As the organization representing pharmacists in all practice settings, APhA has been, and is, a strong supporter of policies which increase patients' access to affordable and cost-effective medicines. Decisions along the entire drug supply chain impact patients' medication costs, including arrangements between manufacturers, wholesalers, insurers, and PBMs. Because of these upstream stakeholder

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[4] *See*, Avalere Health. Exploring Pharmacists' Role in a Changing Healthcare Environment. May 2014, available at: http://avalere.com/expertise/life-sciences/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment Also, *See*, Avalere Health. Developing Trends in Delivery and Reimbursement of Pharmacist Services. October 2015, available at: http://avalere.com/expertise/managed-care/insights/new-analysis-identifies-factors-that-can-facilitate-broader-reimbursement-o

[5] Watanabe, Jonathan H. Et. al. Cost of Prescription Drug–Related Morbidity and Mortality. Annals of Pharmacology. First Published March 26, 2018, available at: http://journals.sagepub.com/eprint/ic2iH2maTdI5zfN5iUay/full

[6] Ibid.

policies, for most patients, pharmacists have limited options to impact patients' final drug costs. Moreover, complex coverage and payment policies hinder the full potential of community pharmacists' clinical education and training from being realized as much of their day is spent on the phone trying to find an appropriate treatment that is not only covered, but the patient can afford. Consequently, APhA supports a transparent pricing framework which would eliminate such mechanisms as hidden discounts, free goods and post point-of-sale price fees imposed on pharmacies.[7]

PBMs

Both Congress and the Administration have pointed out ongoing PBM practices in the Medicare program negatively impacting patient costs, care and access. Additional proposals from the Administration have emphasized PBMs operate in a consolidated, opaque space and pose a barrier to pharmaceutical companies lowering their prices[8] and spend a significant amount of effort trying to rectify the negative impact certain PBM practices have had on patients and pharmacies.[9]

APhA appreciates the strong bipartisan support of the Committee for recent legislation signed into law that prohibits PBMs' use of so-called pharmacist "gag clauses" in Medicare and private health plans, to support the flow of information between pharmacists and their patients. These laws increase patients' access to more affordable and cost-effective medicines by empowering pharmacists to inform patients that a medication may be less expensive if purchased at the "cash price," rather than through their insurance plan. For years, pharmacists have been frustrated by our inability to help our patients who we knew were struggling with high co-payments. APhA also looks forward to continuing to work with you to lower patients' out-of-pocket costs.

Similarly, APhA hopes the Committee will build off these bipartisan results to pass H.R. 803, the *Improving Transparency and Accuracy in Medicare Part D Spending Act*, that would prohibit Medicare Part D plan sponsors and their PBMs from retroactively reducing payment on clean claims submitted by pharmacies under Medicare Part D. CMS has acknowledged a notable growth in Direct and Indirect Remuneration (DIR) fees, which have more than tripled in recent years.[10] Prohibiting Medicare Part D plan sponsors/ PBMs from retroactively reducing payment on clean claims submitted by pharmacies would, in turn, increase transparency in drug pricing, decrease beneficiaries' out-of-pocket costs and Medicare catastrophic coverage costs, and reduce the negative impact of these practices on the sustainability of patient access to the services provided by pharmacists.

APhA also supports H.R. 1035, the *Prescription Drug Price Transparency Act,* a bill that will bring greater transparency and accountability by requiring PBMs to disclose the sources used in their Maximum Allowable Cost (MAC) price determinations by ensuring the list is updated every seven days for Medicare Part D, Medicare Advantage and the Federal Employee Health Benefits Program (FEHBP). Most importantly this legislation preserves patient access to the pharmacy they choose.

We also support H.R. 2376, the *Prescription Pricing for the People Act of 2019,* recently passed on a bipartisan basis by the House Judiciary Committee, which shares jurisdiction with the Energy and

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[7] *See,* Addendum: APhA House of Delegates Policies Related to Drug Pricing.
[8] HHS. American Patients First - The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. May 2018, available at: https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf
[9] HHS/ OIG. Fraud and Abuse: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. Proposed Rule. February 6, 2019, available at: https://www.regulations.gov/document?D=HHSIG-2019-0001-0001
[10] See, Wakely Consulting Group analysis. 2017, available at: http://www.ncpa.co/pdf/wakely-report.pdf

Commerce Committee. H.R. 2376 would require the Federal Trade Commission (FTC) to evaluate whether PBMs charge certain payers, including Medicare and Medicaid, a higher price than reimbursement rates for competing pharmacies while reimbursing pharmacies in which the PBMs have an ownership interest at the rate charged to payers; steer patients to pharmacies in which the PBM has an ownership stake; and use formulary designs to depress the market share of low-cost, lower-rebate prescription drugs.

In 2018, APhA's House of Delegates passed a resolution stating "APhA opposes retroactive direct and indirect remuneration (DIR) fees and supports initiatives to prohibit such fees on pharmacies."[11] As recognized by CMS, certain PBM practices can result in higher prices at the point-of-sale and consequently, higher beneficiary co-pays. DIR fees were originally designed to capture rebates and other mechanisms not included at the point-of-sale. However, DIR fees by PBMs are now being used beyond their original purpose to retroactively adjust pharmacies' payment months after the sale, sometimes below the price paid for the product by the pharmacy. As stated by CMS in the November 2017 proposed Medicare Part D rule, "[b]etween 2010 and 2015, the amount of all forms of price concessions received by Part D sponsors and their PBMs increased nearly 24 percent per year, about twice as fast as total Part D gross drug costs, according to the cost and price concession data Part D sponsors submitted to CMS for payment purposes."[12]

There is simply no connection between price concessions given by manufacturers to PBMs and the prices paid by pharmacies to their wholesalers. Thus, DIR fees "recovered" from pharmacies by PBMs are totally illogical (i.e., recovering money from pharmacies that pharmacies did not "receive" in the first place). Because current point-of-sale prices or copays paid by beneficiaries can be based on the contracted price before DIR is extracted, many beneficiaries actually pay higher out-of-pocket costs. CMS has cited numerous research that further suggest higher cost-sharing can impede beneficiary access and adherence to necessary medications, which leads to poorer health outcomes and higher overall medical care costs for beneficiaries and Medicare. Therefore, APhA strongly urges the Committee to prohibit PBMs' use of such fees as part of their payment methodology for pharmacies.

As you know, Medicare-enrolled seniors pay pharmacies a co-pay for medications, while the full price of the drug is credited against the patient's coverage limit. The PBM administering Medicare's prescription benefit decides to use retroactive DIR fees to take back a portion of the product reimbursement to the pharmacy for the actual costs of the patient's medication, often causing pharmacies to ultimately dispense a medication below their product cost, which jeopardizes the sustainability of patient access. In addition, the original higher price – not the DIR adjusted price – is still counted against the patient, pushing them more quickly into Medicare's "doughnut hole" coverage gap in which they become responsible for a much greater portion of their prescription costs. Even after the coverage gap closes in 2020, the use of DIR fees significantly increases costs as these patients enter Medicare's catastrophic coverage phase, in which taxpayers are now on the hook for 80% of each patient's health care expenses.

An additional problem facing some pharmacies' ability to offer medications to patients is the inability to enter into contracts with health plans due to the growth in narrow networks. APhA urges the Committee to require Part D plans to contract with any pharmacy willing to accept their contractual

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[11] APhA. House of Delegates. Current Adopted Policy Statements 1963-2018. (JAPhA 58(4):356 July/August 2018). Pg. 115, available at: https://media.pharmacist.com/hod/APhA_Policy_and_Procedures_2018.pdf

[12] CMS. Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. Proposed Rule. November 28, 2017, available at: https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare

terms and conditions. Increasing patient choice will not only improve patients' access to benefits and services, but will likely positively impact patient satisfaction and outcomes, such as adherence.

Pharmacy Access to Medications

Another issue impeding patient access to medications from a pharmacy of their choice is manufacturer-imposed limited distribution policies. As more costly and complex medications are being developed, some manufacturers and/or distributors restrict distribution by identifying few pharmacies who may purchase and subsequently provide the medication to patients. Often, these limited distribution policies will impose requirements beyond those required by the state or Food and Drug Administration (FDA). Assuming a pharmacist eventually identifies, deciphers and meets the requirements to obtain the medication, they may still be denied the ability to purchase the medication. Consequently, patients are effectively forced to receive care from multiple pharmacists which leads to siloed and fragmented care. To address these issues, APhA encourages the Committee examine limited distribution of certain medications and the impact these mechanisms have on patients and competition. Patients should have access to medications from pharmacy providers of their choice who are willing to meet reasonable and meaningful expectations that support optimal outcomes from provided medications.

Drug Shortages

Drug shortages are another factor that can negatively affect patients in terms of cost and the availability of their treatments. APhA urges the Committee to consider mechanisms to both better control the price of medications in shortage and improve tracking and prediction systems used to identify drugs in shortage. APhA also strongly supports the appropriate prosecution of entities that engage in price gouging and profiteering of medically necessary drug products in response to drug shortages.

Medications' Safety and Affordability

APhA supports congressional efforts to increase patients' access to appropriate, safe, effective, and affordable prescription medications. We encourage the development and implementation of a framework by the FDA for determining biologic product interchangeability. APhA opposes practices which circumvent the intent of drug product review laws and negatively impact the pharmacist's ability to substitute medications for safe, effective, lower-cost alternatives. Conversely, APhA supports pharmacists collaborating with prescribers and patients to design cost-effective treatment regimens, identify formulary or generic products as a means to reduce costs, and intervene on behalf of the patient to identify alternate therapies.

Importation Concerns

Although APhA supports congressional efforts to address patients' medication costs, APhA has significant concerns with turning to drug importation to achieve lower prices. We believe proposals to legalize importation of non-FDA approved drugs is not a comprehensive solution to the complex issue of drug pricing, threatens patient safety, disrupts care, and directly conflicts with efforts by Congress and federal agencies to increase the integrity and security of the U.S. drug supply pursuant to the *Drug Supply Chain Security Act* (DSCSA). Furthermore, APhA is concerned savings, if any, will be short-term and importation will instead result in long-term costs to patients and the health care system.

Because drug importation policies effectively encourage patients to buy medications online from foreign sources, APhA fears patients will be at an even greater risk of taking ineffective, adulterated or harmful medications, including controlled medications they were not prescribed. The lack of a strong regulatory framework for internet pharmacies in certain foreign countries has led to a large number of illegitimate

foreign internet pharmacies. APhA's concerns regarding foreign internet pharmacies are compounded by the large number of internet "pharmacies" which have increased and become more sophisticated in recent years, making them difficult to track and permanently stop.

Importantly, broader importation laws will further fragment care and hinder the progress made by Congress to move U.S. health care delivery and payment towards coordination and value. Value-based care models and other efforts to produce savings and promote quality, such as outcomes-based reimbursement, will be more difficult to measure and optimize if patients are allowed to receive uncoordinated care outside the model's mechanisms to drive results.

Because Canadian pharmacists may only fill prescriptions written by Canadian prescribers, expanded importation policies will encourage Americans to seek care from foreign prescribers and pharmacists, whose systems and standards are not integrated into, or consistent with, U.S. systems or care. Therefore, in March 2019, APhA issued a joint statement with the Canadian Pharmacists Association (CPhA) in opposition to U.S. federal legislation authorizing personal and commercial importation of prescription drugs from Canada because of the risks these policies pose to patient safety and continuity of care.[13]

As previously noted, obtaining safe and effective medications is only one part of appropriate medication use. It also requires a health practitioner's knowledge of the patient's complete medication profile and an understanding by the patient of how to take the medication, side effects and/or potential interactions — all of which could be negatively affected by importation proposals. APhA believes importation of non-FDA approved drugs could hurt the very patients intended to benefit from importation proposals. Consequently, the risks to patient safety from harmful or ineffective products or avoidable medication errors due to fractured care outweighs any increase in access or cost-savings.

APhA would like to thank the Committee for continuing to work with us and other pharmacy stakeholders to lower drug prices and increase transparency of PBM practices for pharmacies and patients. We also appreciate your ongoing leadership addressing the barriers to innovation which continue to increase America's rising health care costs. Please contact Alicia Kerry J. Mica, Senior Lobbyist, at AMica@aphanet.org or by phone to (202) 429-7507 to arrange a meeting with us to discuss the many services pharmacists provide to improve patient care, outcomes and reduce costs.

Addendum: APhA House of Delegates Policies Related to Drug Pricing

[13] CPhA/ APhA. American and Canadian pharmacist associations warn that drug importation policies could put patients at risk. Joint Statement. March 2019, available at: https://www.pharmacist.com/sites/default/files/audience/Joint%20Statement%20APhA%20and%20CPhA%20Importation%20.pdf

2018 **Direct and indirect Remuneration Fees**
APhA opposes retroactive direct and indirect remuneration (DIR) fees and supports initiatives to prohibit such fees on pharmacies.
(JAPhA 58(4):356 July/August 2018)

2004, 1968 **Manufacturers' Pricing Policies**
APhA supports pharmaceutical industry adoption of a "transparent pricing" system which would eliminate hidden discounts, free goods, and other subtle economic devices.
(JAPhA NS8:362 July 1968) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2006)(Reviewed 2011)(Reviewed 2016) (Reviewed 2018)

1985 **Pharmaceutical Pricing**
APhA supports a system of equal opportunity with the same terms, conditions, and prices available for all pharmacies.
(Am Pharm NS25(5):52 May 1985) (Reviewed 2004) (Reviewed 2006)(Reviewed 2011)(Reviewed 2016)

2004, 1977 **Prescription Drug Advertising**
APhA does not oppose the dissemination of price information to patients, by advertising or by any other means.
(JAPhA NS17:448 July 1977)(JAPhA NS44(5):551 September/October 2004)(Reviewed 2006)(Reviewed 2011)(Reviewed 2016)

1999 **Direct-to-Consumer Advertising of Medications**
1. APhA supports legislative and regulatory activities permitting direct-to-consumer advertising concerning medical or health conditions treatable by prescription or nonprescription drug products. These advertisements must conform to rules and regulations that ensure complete, comprehensive, and understandable information that informs consumers of potential benefits and risks of the product.
2. APhA opposes false or misleading advertising for prescription or nonprescription drugs or any promotional efforts that encourage indiscriminate use of medication.
3. APhA supports the availability of accurate information to consumers about medication use and recognizes the responsibility of pharmacists to provide appropriate responses to consumer inquiries stimulated by direct-to-consumer advertising as a compensated pharmaceutical service. In addition, APhA recommends that health care professionals, including but not limited to pharmacists, receive new product information on direct-to-consumer advertising campaigns prior to this information being made available to consumers.
(JAPhA 39(4): 447 July/August 1999)(Reviewed 2004) (Reviewed 2006)(Reviewed 2011) (Reviewed 2016)

2016, 1994 **Pharmacy Services Benefits in Health Care Reform**
A single set of pricing rules, eliminating class-of-trade distinctions, for medications, medication delivery systems, and other equipment so that no payer, patient, or provider is disadvantaged by cost shifting.
The right for every American to choose his/her own provider of medications and pharmacists' services and for all pharmacists to participate in the health plans of their choice under equally applied terms and conditions.
(Am Pharm NS34(6):58 June 1994) (Reviewed 2004) (Reviewed 2010) (Reviewed 2011)(JAPhA 56(4); 379 July/August 2016) (Reviewed 2018)

2016 **Biologic, Biosimilar, and Interchangeable Biologic Drug Products**

APhA urges the development of programs and policies that facilitate patient access to and affordability of biologic products.
(JAPhA 56(4); 369 July/August 2016)

2005, 1977 **Government-Financed Reimbursement**
APhA supports only those government-operated or -financed, third-party prescription programs which ensures that participating pharmacists receive individualized, equitable compensation for professional services and reimbursement for products provided under the program.
(JAPhA NS17:452 July 1977) (JAPhA NS45(5):558 September/October 2005) (Reviwed 2009(Reviewed 2011)(Reviewed 2012)(Reviewed 2017)

2012 **Drug Supply Shortages and Patient Care**
APhA encourages the active investigation and appropriate prosecution of entities that engage in price gouging and profiteering of medically necessary drug products in response to drug shortages.
(JAPhA NS52(4) 457 July/August 2012)(Reviewed 2017)

2005, 1981 **Third-party Reimbursement Legislation**
APhA supports enactment of legislation requiring that third-party program reimbursement to pharmacists be at least equal to the pharmacists prevailing charges to the self-paying public for comparable services and products, plus additional documented direct and indirect costs, which are generated by participating in the program.
(Am Pharm NS21(5):40 May 1981) (Reviewed 2005) (Reviewed 2009)(Reviewed 2014)

1967 **Drugs Provided Under Social Security Act: Guidelines for Pharmaceutical Service**
Since it is probable or likely that APhA may have to consider and act upon some proposals in the area of drug costs before the next annual meeting, we recommend that APhA Board of Trustees be guided by whether the proposals: (a) Permit pharmacists to select and dispense a quality drug product; (b) Establish some mechanism to assist pharmacists in selecting quality, drug products under the cost and other criteria established; (c) Permit the use of any available drug product when unique medical circumstances so require; (d) Establish a reasonable remuneration base for pharmacists rendering services under the program; (e) Guarantee recipients free choice of pharmacy; and (f) Limit the reimbursement for pharmacists' services to those provided by duly licensed pharmacists.
(JAPhA NS7:315 June 1967) (Reviewed 2005) (Reviewed 2009)(Reviewed 2014)

2013, 1980 **Medication Selection by Pharmacists**
APhA supports the concept of a team approach to health care in which health care professionals perform those functions for which they are educated. APhA recognizes that the pharmacist is the expert on drugs and drug therapy on the health care team and supports a medication selection role for the pharmacist, based on the specific diagnosis of a qualified health care practitioner.
(Am Pharm NS20(7):62 July 1980) (Reviewed 2003) (Reviewed 2007) (Reviewed 2008) (Reviewed 2009)(Reviewed 2011)(Reviewed 2012)(JAPhA 53(4):366 July/August 2013) (Reviewed 2018)

2017 **Pharmacy Performance Networks**
APhA supports performance networks that improve patient care and health outcomes, reduce costs, use pharmacists as an integral part of the health care team, and include evidence-based quality measures.
(JAPhA 57(4): 441 July/August 2017)

National Community Pharmacists Association
Statement for the Record
U.S. House Committee on Energy and Commerce, Subcommittee on Health
Hearing: "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"
May 9, 2019

Dear Chairman Eshoo, Ranking Member Burgess, and Members of the Subcommittee:

The National Community Pharmacists Association ("NCPA") appreciates the opportunity to submit this statement for the record on the Committee on Energy and Commerce, Subcommittee on Health's hearing titled, "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain," held on May 9, 2019. NCPA represents America's community pharmacists, including 22,000 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care settings.[1] Together, our members represent a $76 billion healthcare marketplace, employ 250,000 individuals, and provide pharmacy services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits this statement on behalf of both community and long-term care independent pharmacies.

Community and long-term care independent pharmacists are the healthcare providers on the front-lines that regularly talk to patients about their concerns with rising prescription drug costs and work diligently to address these concerns. Through these conversations, it has been clear that the issue of rising drug prices cannot be solved without addressing the role of pharmaceutical benefit managers ("PBMs") in increasing costs for healthcare's most vulnerable patients. NCPA submits this statement to address those concerns in the hopes that community and long-term care independent pharmacists can add meaningful solutions for patients' pocketbooks.

NCPA supports changes to manufacturer rebates and pharmacy DIR in Medicare Part D as a way to address rising costs

A conversation about rising prescription drug costs is incomplete without addressing the way in which PBM practices have contributed to patients' out-of-pocket spending in certain federal programs. Of late, there has been growing concern over the ways in which rebates and other price concessions are negotiated by PBMs and structured in the Medicare Part D program, which ultimately contribute to higher patients' out-of-pocket spending.

NCPA recognizes that the administration is focused on changes to the application and usage of manufacturer rebates as outlined in the pending proposed rule titled, *Fraud and Abuse; Removal of*

[1] *NCPA 2018 Digest by Cardinal Health* (2018).

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Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees.[2] NCPA has provided our position on this proposal in comments to the agency submitted on April 8, 2019.[3] For purposes of this statement, however, NCPA contends that rebates are not the only concession that leads to inflated drug prices and higher out-of-pocket costs for seniors. The out-of-pocket costs conversation is incomplete without specific discussion regarding direct and indirect remuneration ("DIR"), including all pharmacy price concessions in the Part D program, and how PBMs leverage these fees to pad their pockets at the expense of patients, the government, and small business community pharmacies.

Pharmacy price concessions (also known as "pharmacy DIR") are imposed on pharmacies participating in Medicare Part D networks by plan sponsors and their PBMs. As CMS noted in a recently proposed rule, these fees have exploded in recent years.[4] The treatment of these pharmacy price concessions as DIR rather than as reductions in the "negotiated price" of a drug at the point of sale has had a crippling impact on patients, the government, and community pharmacies. The retroactive nature of these fees means beneficiaries face higher cost-sharing for drugs and are accelerated into the coverage gap or "donut hole" phase of their benefit. What's more, beneficiaries reach the catastrophic phase of the benefit, for which CMS incurs almost 80 percent of the cost. Thus, costs to the government have surged as liability for Part D costs is increasingly being shifted from Part D plan sponsors to CMS. Finally, all retroactive pharmacy price concessions are taken back from community pharmacies months later rather than deducted from claims on a real-time basis. This reimbursement uncertainty makes it extremely difficult for community pharmacists to operate their small businesses.

Earlier this year, the administration underwent rulemaking on a proposal that sought to assess all pharmacy price concessions, excluding positive contingent amounts, at the point of sale.[5] The force of this proposal would effectively eliminate the retroactive nature of pharmacy price concessions in Medicare Part D. While the final rule has not been issued for this proposal, NCPA seeks needed relief from Congress as an avenue to ensure savings to patients and transparency for small business community pharmacies.[6] Therefore, NCPA urges Congress to pass H.R. 803, *Improving Transparency and Accuracy in Medicare Part D Drug Spending Act*, legislation that would eliminate the retroactive nature of pharmacy price concessions.

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[2] 84 Fed. Reg. 2340 (Feb. 6, 2019).

[3] NCPA Comments to *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, OIG-0936-P (Apr. 8, 2019), *available at* https://www.regulations.gov/document?D=HHSIG-2019-0001-19758.

[4] Pharmacy price concessions are the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates. CMS states, "[t]he data show that pharmacy price concessions, net of all pharmacy incentive payments, grew more than 45,000 percent between 2010 and 2017." 83 Fed. Reg. 62,152, 62,174 (proposed Nov. 30, 2018).

[5] *Id.* at 62,152.

[6] Patients win when pharmacy price concessions are included in the negotiated price and applied at the point of sale. In fact, CMS estimates that beneficiaries would save $7.1 to $9.2 billion over 10 years resulting from reduced cost-sharing, offset by slightly higher premiums. *Id.* at 62,154.

NCPA also urges Congress to limit and control the way in which PBMs and plan sponsors impose arbitrary and inconsistent performance-based standards and incentive-payment schemes on community pharmacies. While not all pharmacy DIR is performance based, the proliferation of pharmacy DIR is now intricately tied to performance-based standards. PBMs and plan sponsors have argued they should have the ability to create programs that are accounted for as DIR to reward pharmacies for achieving contractual, performance-based metrics. However, these retroactive fees are based on a payment methodology that withholds a certain amount with the opportunity for the pharmacy to either "earn back" or have the retroactive fees decreased based on achieving certain arbitrary quality measures. Therefore, NCPA requests Congress define pharmacy quality within the Medicare Part D program and hold plans accountable for determining performance-based payments by passing H.R. 1034, *Phair Pricing Act*. This piece of legislation will ensure that performance-based payments should be based on standardized, achievable, and proven criteria that measure pharmacy performance, as opposed to criteria that focus on measuring plan performance or criteria which pharmacies have little to no opportunity to influence.

NCPA urges Congress to consider the two pieces of legislation on pharmacy price concessions as a way to meaningfully address PBM practices in the Medicare Part D program that contribute to higher patients' out-of-pocket spending and today's rising drug prices.

NCPA urges Congress to continue to examine PBMs' spread pricing practices that may contribute to rising prescription drug prices

Legislators and Medicaid officials in several states are actively considering substantive regulation and reform to rein-in practices by PBMs that may drive up drug costs, increase state spending on prescription drug benefits, and disadvantage pharmacy patients and pharmacies. Much of the focus is on Medicaid spending on prescription drug benefits and the profit-taking by PBMs that results from the difference between what the PBM reimburses pharmacies and what it bills the plan sponsor, a practice that is typically called "spread pricing."

From initial data-reporting, legislators are seeing that savings associated with moving from a spread model for compensating PBMs towards a transparent model of PBM pricing are large enough to simultaneously lower administrative costs to the state Medicaid agency or state health plan, reimburse pharmacies in a fair manner, lower any copayments or premiums a patient might be charged, and free up funding for pharmacy performance-based incentives. For example, in Virginia, a requirement effective July 1, 2017 requires health plan sponsors to report pharmacy reimbursements and the amount charged to the plan sponsor for each claim by its PBM. Initial data for Q3 2017 show a considerable spread between reimbursements to pharmacies and medication charges to the health plan.[7]

In that same vein, West Virginia's state Medicaid agency carved the prescription drug benefit out of Medicaid managed care in that state effective July 1, 2017, citing an actuarial study showing that Medicaid could save $30 million annually by administering the benefit directly, and that doing so

[7] Department of Medical Assistance Services, Common Wealth of Virginia, *Report on Managed Care Pharmacy Benefit Manager (PBM) Transparency* (Dec. 1, 2017), *available at* https://rga.lis.virginia.gov/Published/2017/RD595/PDF.

would also put $34 million back into local economies in the form of pharmacy reimbursements. NCPA has been told by a state official that preliminary results showed a $12 million savings in Q3 2017 alone.[8] Therefore, NCPA urges Congress to examine how PBMs' spread pricing models may be impacting other federal and commercial payers, thus contributing to the rise in prescription drug costs.

NCPA encourages Congress to be ensure certain pricing information is made available to empower consumers and reduce costs

To empower consumers, reduce costs, increase quality, and improve the system PBMs should be required to disclose maximum allowable cost ("MAC") pricing lists, which are used to reimburse community pharmacies for generic drugs. Consumers and plan sponsors may not be aware that they may be paying more for a drug than the PBM is reimbursing the pharmacy, allowing the PBMs to "pocket the spread" (another aspect of PBMs' spread pricing practices is outlined above). The opaque nature of MAC pricing keeps any meaningful information about drug costs from plan sponsors and consumers. Moreover, because pharmacies are not privy to the reimbursement methodology for any generic drug, it hinders the ability to foresee expenses and allocate funds accordingly, which in turn can hinder consumer access.

As a solution, H.R. 1035, the *Prescription Drug Price Transparency Act* would codify Medicare transparency provisions concerning MAC pricing for generics and apply them to the Federal Employees Health Benefits ("FEHBPs") Program. It would also establish a MAC appeals process and prohibit PBM requirements or incentives to use a PBM-owned pharmacy, a clear conflict of interest. NCPA supports this legislation as a way to provide transparency in drug pricing, which could ultimately contribute to lowering sky-rocketing drug prices.

NCPA encourages Congress to advance greater awareness and usage of information for patients

A way to ensure greater awareness and usage of information is to support meaningful prescription drug coverage and pharmacy choice in all plans. For example, in Part D plans NCPA supports giving seniors more access to discounted copays for prescription drugs at their pharmacy of choice. CMS can implement its proposed "pharmacy choice" policy to allow patients to use any pharmacy that accepts the drug plan's terms and conditions, including pricing, for "preferred pharmacies." CMS has called this "the best way to encourage price competition and lower costs in the Part D program."[9] Absent action from CMS, however, NCPA supports legislation that would allow community pharmacies to participate in Part D preferred pharmacy networks so long as they are willing to accept the contract terms and conditions which would empower more seniors to choose the pharmacy that best fits their needs. Allowing patients to have access to their pharmacy of choice will allow patients to select pharmacies based on a number of factors including location and access to discounted copays for prescription drugs.

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[8] West Virginia Bureau of Medical Services, *Pharmacy Benefit Changes for Medicaid Managed Care Members* (May 31, 2017), *available at* http://dhhr.wv.gov/bms/News/Pages/Pharmacy-Benefits-Changes-for-Medicaid-Managed-Care-Members.aspx.

[9] Centers for Medicare & Medicaid Services, *Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* (Apr. 1, 2013).

Congress should collaborate with federal antitrust agencies to evaluate PBM consolidation and its impact on drug pricing

Consolidation in the health care industry may also be contributing to higher drug costs and negatively impacting patient choice. Such consolidation includes the recently consummated merger of Express Scripts ("ESI") and Cigna, as well as the CVS Health Corporation/Aetna merger, for which a consent decree is currently under review at the United States District Court for the District of Columbia. To address PBM market dominance, NCPA has long argued for additional scrutiny of PBMs, including their inherent conflicts of interest, lack of transparency, and one-sided take-it-or-leave-it contract negotiations with independent pharmacies. We urge Congress to work with the antitrust agencies to take a closer look at PBM consolidation and vertical mergers in the health care market for their effects on patient access, costs, and competition, and whether the purported savings from these mergers will, in fact, be passed on to customers.

PBMs already have extraordinary market power; the top three PBMs control as much as 89 percent of the market: 238 million lives[10] out of 266 million lives.[11] This dominance has allowed PBMs to leverage their market power to the detriment of plan sponsors (government and commercial payors), providers, and consumers. Additionally, PBMs claim that they help plan sponsors generate savings by negotiating rebates, however, recent reports have shown the opposite. A report from 2017 found that PBMs have been utilizing their market power to try to increase their profits and encourage higher list prices for prescription drugs, which increases co-pays for patients.[12]

Health care costs have clearly continued to rise despite previous vertical mergers. Continued vertical healthcare consolidation could further impede competition and foreclose any meaningful entry into the market, leading to fewer choices and higher healthcare costs. These huge entities increasingly rely on limited preferred networks that have impacted consumer choice. For example, as stated above, not all Part D sponsors and their PBMs prioritize access to local community pharmacies in their preferred networks. Instead, these networks are often limited to a smaller number of select pharmacies and regularly exclude independent community pharmacies even when such pharmacies are willing to accept the terms and conditions of a Part D sponsor's network. For this reason, NCPA is concerned that, with consolidation, major PBMs will continue to limit their networks and further worsen patient choice and access.

In addition, merging parties typically state that proposed transactions will create efficiencies and save hundreds of millions of dollars for consumers. They often do not explain, however, whether or how those purported savings will be passed on to consumers. The largest PBMs already claim their size enables them to achieve significant efficiencies and cost savings. As patients' out of pocket costs and premiums continue to rise, there is evidence to suggest that these savings are not, in fact, being passed on to consumers. NCPA suggests that whether the purported cost savings will be passed on to consumers remains unclear.

The CVS/Aetna merger is an example of a specific transaction that is likely to significantly decrease competition for pharmacy products and services. Although CVS and Aetna agreed to sell Aetna's Part D

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[10] Mathematical calculation based on number of covered lives CMS/Caremark, UnitedHealth and ESI self-reported.

[11] Council of Economic Advisers, *Reforming Biopharmaceutical Pricing at Home and Abroad* (Feb. 2018), *available at* https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf; *see also* testimony of PCMA CEO Mark Merritt before the U.S. House of Representatives Energy & Commerce Committee Subcommittee on Health (Dec. 13, 2017).

[12] Steve Pociask, *Pharmacy Benefit Managers: Market Power and Lack of Transparency* (2017), *available at* http://www.theamericanconsumer.org/wp-content/uploads/2017/03/ACI-PBM-CG-Final.pdf.

prescription drug plan business to address their horizontal competitive overlap as a condition of approval of the deal, substantial anticompetitive concerns were not addressed. In fact, Aetna's Part D assets were sold to WellCare Health Plans, Inc. who is using CVS Caremark as their PBM. Therefore, this divestiture of Aetna's Part D business essentially just maintains CVS' market share instead of resolving any anticompetitive concerns.

CVS Caremark, the PBM for CVS, is the second largest PBM in the U.S., accounting for nearly 34 percent of covered lives.[13] This significant market share allows CVS Caremark (as well as the other largest PBMs) to exercise undue market leverage and generate outsized profits for themselves. Community pharmacies have very little negotiating power when contracting with PBMs like CVS Caremark, and routinely must agree to take-it-or-leave-it contracts to be part of a PBM's pharmacy network. Having the opportunity to be part of a plan's preferred network can be critical, as nearly all Part D plans include preferred networks that offer lower co-pays to beneficiaries.

Further, some states have found that CVS and other large PBMs engage in questionable pricing and reimbursement practices towards pharmacies. Last year, the Kentucky Department of Insurance fined CVS Caremark a $1.5 million civil penalty for violations related to reimbursements to pharmacists, including claim denial violations and providing inaccurate information.[14] In addition, the Auditor of the State of Ohio found that Ohio, where CVS Caremark is the PBM for four of Medicaid's five managed care plans, was charged around $225 million in spread amounts for Medicaid prescription drugs in a one-year period while other pharmacies were reimbursed at, or below, cost.[15] Of the total $225 million, Optum Rx was paid $28.9 million in spread. The report also confirmed that these drastic reimbursement cuts from the Ohio Medicaid PBMs caused a significant amount of independent pharmacy closures in the state. Lastly, the Auditor in Pennsylvania conducted a similar investigation, indicating that three PBMs made between $2 million and nearly $40 million on spread pricing.[16] Thus, NCPA recommends that Congress work with the antitrust agencies to more thoroughly evaluate the effects of consolidation on the health care market to ensure that plan sponsors and consumers continue to have competitive choices.

Conclusion

In conclusion, NCPA supports Congress in implementing policies that ensure prescription drug access and affordability for the American patient. As established above, however, this issue cannot be solved without addressing the role of PBMs in increasing costs. Thank you.

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[13] According to CVS, it has 90 million PBM plan members. *See* CVS, *available at* https://cvshealth.com/about/facts-and-company-information. The Pharmaceutical Care Management Association ("PCMA") testified that PBMs administer drug plans for more than 266 million Americans. *See also* Testimony of Mark Merritt, PCMA.

[14] Commonwealth of Kentucky Public Protection Cabinet Department of Insurance, *Kentucky Department of Insurance Issues Penalty Against PBM, CaremarkPCS Health LLC, a subsidiary of CVS Caremark*, *available at* http://ppc.ky.gov/Lists/News%20Releases/Kentucky%20Department%20of%20Insurance%20Issues%20Penalty%20Against%20PBM,%20CaremarkPCS%20Health%20LLC,%20a%20subsidiary%20of%20CVS%20Caremark.pdf.

[15] Ohio's Medicaid Managed Care Pharmacy Services, *Auditor of State Report* (Aug. 16, 2018), *available at* https://audits.ohioauditor.gov/Reports/AuditReports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.

[16] Auditor General DePasquale, *Bringing Transparency & Accountability to Drug Pricing* (Dec. 2018), *available at* https://www.paauditor.gov/Media/Default/Reports/RPT_PBMs_FINAL.pdf.

Attachments-Additional Questions for the Record

Subcommittee on Health
Hearing on
"Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"
May 9, 2019

Justin McCarthy

The Honorable Michael C. Burgess, M.D.

1. Something I find particularly concerning about our drug supply chain is the possibility of drug shortages. These can occur because of natural disasters, manufacturing issues, or business decisions. What are each of your respective companies doing to prevent drug shortages?

   Pfizer is deeply concerned about drug shortages and their impact on the healthcare system and patient access to medically significant and necessary therapies. We plan to invest approximately $5 billion over the next five years in capital projects in the United States, including the strengthening of Pfizer's manufacturing presence in the United States. We have been hiring in manufacturing at Pfizer, including Kalamazoo, Michigan; Andover, Massachusetts; McPherson, Kansas; and Rocky Mount, North Carolina.

   While we have seen a reduction in the overall number of drug shortages in recent years, we must do more to address the root causes of the problem. New strategies and policies are necessary to achieve a healthy marketplace. Pfizer is committed to partnering with FDA and stakeholders to bring thoughtful solutions to the table, both for the short- and long-term. Some potential policy solutions include:

   - Creating a structured benefit/risk decision tool to help FDA staff balance the competing public health risks associated with a manufacturing concern and with shortages of medically necessary products and treatments, while also providing greater transparency to manufacturers and the public regarding compliance criteria interpretation or application.

   - Urging FDA to further align with the International Conference for Harmonisation (ICH) on current Good Manufacturing Practices (cGMP) guidelines and ensure consistent implementation with minimal variability by region.

   - Accelerating and building upon synergistic inspectional approaches and greater mutual recognition of inspections across mature regulatory authorities, including harmonized inspection guidance, common criteria for classification of observations, alignment on documentation requirements, mutual reliance on inspections, and/or recognition of third-party inspections.

- Ensuring a stable, sufficient, and redundant supply of essential medications for modern medicine and public health by allowing different payment mechanisms (separate inpatient and outpatient payments, and new add-on ambulance payments for drugs) for "critical medications" in shortage or at risk of becoming in shortage to stabilize the market by incentivizing more market entrants and longer-term contracts.

2. Do you have processes in place to minimize the negative effects of drug shortages should one of your manufacturing facilities offline?

   Pfizer's priority is to provide patients with a consistent and reliable supply of high-quality medicines, and if a drug shortage occurs we work diligently every day to meet our goal of full recovery.

   Pfizer prepares for potential shortages by proactively understanding supply chain risks and undertaking appropriate actions where possible. In situations that may result in supply disruptions, Pfizer forms rapid-response multi-disciplinary teams to review the root cause of the disruption and to develop remediation plans. Pfizer works proactively with the FDA Office of Drug Shortage to propose and discuss regulatory options that can avoid or minimize potential supply disruptions. Pfizer also works closely with FDA Drug Shortages staff to increase production of certain products when other suppliers may have supply constraints.

   While Pfizer is making significant investments to address supply challenges, we also must raise awareness of ongoing commercial and economic challenges and how they impact supply.

The Honorable John Shimkus

1. Given that most of the witnesses on the panel have referenced the role of creating value in the health care supply chain, please comment on: Existing areas where Congress or the Administration may have needlessly added to the cost that patients or the government pays for a particular product, service, or intervention. For example, do you have recommendations on how reforms to existing laws like Stark and the Anti-Kickback Statute could accelerate value-based contracting within Medicare and Medicare Advantage?

   Value based agreements (VBAs) are in the early stages of development in the United States. Many payers and manufacturers have tested different concepts, but to date VBAs have not achieved scale. There are multiple reasons why VBAs represent a small fraction of manufacturer/payer contracts (e.g. access to data, difficult and costly to administer, etc.). There are certain aspects of the current United States regulatory landscape that are perceived by many as not only complicating VBA implementation but also, in some cases, limiting their rapid uptake. Stakeholders have frequently identified two key regulatory hurdles as limiting the expanded adoption of VBAs: i) the Anti-Kickback Statute and ii) the Medicaid Best Price calculation requirement.

   While these regulations serve important roles within the current volume-based

reimbursement system they do not contemplate innovative value-based arrangements which have resulted in a lack of clarity on how to account for these under the current regulatory framework. Ultimately, an expansion of VBAs will require reforms to existing regulations that enable more flexibility in designing VBAs.

Offering protection for appropriately structured arrangements under a new Safe Harbor under the Anti-Kickback Statute is one potential solution to facilitate more VBAs. And since federal healthcare programs are subject to the Anti-Kickback Statute, a safe harbor could promote the proliferation of VBAs in Medicare and Medicare Advantage. This Safe Harbor should be crafted to accommodate the key variables that we often experience with these innovative arrangements. Additionally, VBAs should be either partially or fully exempt from Best Price and Average Manufacturer Price reporting, or at minimum, CMS should be authorized to adopt exemptions from Best Price and Average Manufacturer Price for innovative pricing models. This may impact other programs, such as 340B, and we would be pleased to provide further thoughts in that respect.

2. How do we ensure that these value-based reforms benefit patients and protect taxpayers?

Value based agreements (VBAs) provide a framework for manufacturers to be compensated based on a product's value to patients and the overall healthcare system. There are many different types of VBAs, but the optimal structure of a VBA includes clinical and/or financial performance metrics for a product. Based on the outcomes achieved, payers use this information to inform how they cover and pay for products.

Products that perform better should be covered in a more favorable manner which often includes lower out-of-pockets costs for patients which is a benefit to patients in the near-term. In the long term, patients can also benefit from other savings either directly, (e.g. reducing spending on other medications, lowering medical costs from reduced hospitalizations, doctor's visits, etc.), or indirectly through lower premiums based on reductions in total cost of care. VBAs can be implemented in federal and state programs so that the benefits described above can accrue to the federal programs, thereby benefitting taxpayers. If the VBA is structured to align the cost of pharmaceuticals to the value to the system, then both patients and taxpayers will benefit because the price paid will also align with the value to the system.

Kave Niksefat

Attachments—Additional Questions for the Record

Subcommittee on Health
Hearing on
"Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"
May 9, 2019

Kave Niksefat

The Honorable Joe Kennedy

Mr. Niksefat, during my questions to you at the Subcommittee hearing, I asked how Amgen sets the list price for medication, specifically Neupogen, and why there is significant variation in price between the United States and Denmark, two countries without government price controls. I would like to use this opportunity to allow you to clarify your responses to my questions.

1. When I asked if it is appropriate for Amgen to continue to charge American taxpayers for your company's research risks, on the back of an old product, you responded, "Neupogen is subject to direct biosimilar competition, and that biosimilar competition now has the vast majority of the market share".

   However, Neupogen faces biosimilar competition from only one biosimilar product: Zarxio, and another biologic drug, Granix. If we define "market share" by the percentage of total sales (in dollars) captured by the product, Neupogen remains in the lead. According to a February 19, 2019 article in the Journal of Clinical Pathways, Neupogen has 48 percent of the market share, and Zarxio has 31.7 percent. Granix has only 20.3 percent.

   Therefore, I again ask, it is appropriate for Amgen to continue to charge American taxpayers for your company's research risks, on the back of an old product? Furthermore, do you still contend that biosimilar competition has the "vast majority" of the market share? If so, please explain.

Amgen strongly supported the bipartisan Biologics Price Competition and Innovation Act (BPCIA), which established a pathway for the entry of biosimilar competition in the U.S., as well as a patent litigation structure and data exclusivity protections for biologics. Amgen embraced the opportunity to bring more affordable biologics therapies to U.S. consumers. We currently have ten biosimilars in our portfolio, including two oncology biosimilars that we launched in the U.S. in July 2019. Amgen uses revenues of its approved biologics (including NEUPOGEN® (filgrastim) and our own biosimilars) to support the research and development of new therapies; Amgen invested $3.66 billion in research and development in 2018 and close to

$19 billion over the past five years.[1]

NEUPOGEN has faced more intense competition in the U.S. since late 2013, with the introduction of GRANIX® (tbo-filgrastim) and biosimilar competition beginning in late 2015 with the launch of ZARXIO® (filgrastim-sndz). Amgen expects additional competition in this market through at least one more biosimilar competitor which launched in late 2018.

As of July 2019, NEUPOGEN had approximately 32 percent unit share of U.S. short acting granulocyte colony stimulating factors (GCSFs).[2] Based on gross sales, NEUPOGEN had 35 percent of share in the U.S.[3] ZARXIO gross sales in the U.S. have been exceeding NEUPOGEN since Q3 2018 and combined ZARXIO and GRANIX gross sales exceeded NEUPOGEN gross sales since mid-2017.[4]

Other analysts have reported similar findings. A recent Bernstein Research report based on IQVIA data through April 2019 states "US biosimilar adoption of Neupogen is progressing well, with biosimilars reaching 60 percent of the molecule by volume."[5] In written testimony submitted earlier this year to the Subcommittee on Health of the House Committee on Energy and Commerce, the Executive Director of the Medicare Payment Advisory Commission (MedPAC) stated "...utilization has shifted away from the more costly originator biologic Neupogen, with its biosimilars accounting for 63 percent of the market in the first quarter of 2018."[6]

2. Additionally, when I stated "...since competitive entry of Granix in 2012 and Zarxio in 2015, Neupogen's price has risen and is still the market share leader in both total revenue and unit volume," you stated, "It is not the case in unit volume... Neupogen unit volume, if I remember correctly, is approximately below a third of the entire market."

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[1] Amgen 2018 Letter to Shareholders, p.2, p10. Available at http://investors.amgen.com/static-files/e3bd5ffc-957d-4dac-a8b4-5ed9a9a34e94.

[2] Amgen data on file. Methodology: Calculation of unit share is based on units sold for the following products in the short acting GCSF market basket: NEUPOGEN, ZARXIO, GRANIX, NIVESTYM™ (filgrastim-aafi), and LEUKINE® (sargramostim) (note, ZARXIO and NIVESTYM are biosimilars). The analysis is based on IQVIA DDD® data, supplemented with Amgen proprietary data and estimates for select customer segments not included in IMS DDD. Because IQVIA DDD is not 100 percent complete, Amgen uses proprietary data and estimates to fill gaps.

[3] Amgen data on file. Methodology: Calculation of share by gross sales is based on units sold times wholesale acquisition cost (WAC) for the following products in the short acting GCSF market basket: NEUPOGEN, ZARXIO, GRANIX, NIVESTYM, and LEUKINE. The analysis is based on IQVIA DDD data, supplemented with Amgen proprietary data and estimates for select customer segments not included in IMS DDD. Because IQVIA DDD is not 100 percent complete, Amgen uses proprietary data and estimates to fill gaps.

[4] Ibid.

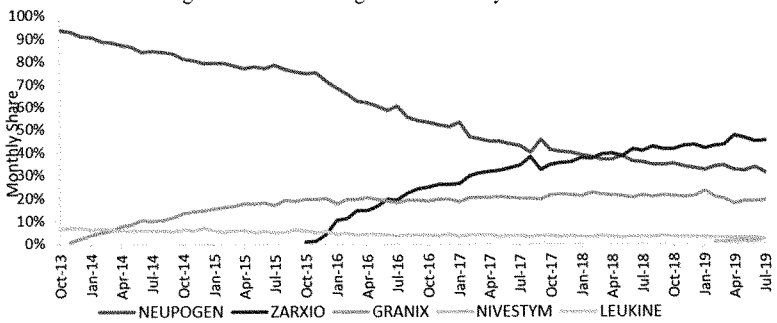
[5] Bernstein Research Report. Biosimilars in EU & US - Apr-May data; EU Humira market growth, EU oncology tracking stronger, material price impact in US, p. 28 (July 10, 2019). Note: Report states this includes one true biosimilar (ZARXIO) and one value brand (GRANIX).

[6] Statement of James E. Mathews, Ph.D., Executive Director, MedPAC, before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, p.14 (April 30, 2019). Available at https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/MedPAC_Testimony_for_EandC_04_30_2019.pdf.

> However, it is my understanding the sales volume of Neupogen and Zarxio are quite similar. Please describe the current sales of Zarxio, Granix, and Neupogen in sales volume and revenue, and then clarify your statement that "biosimilar competition now has the vast majority of the market share." Specifically how do you define "vast majority"?

Available data indicate that our competitors have a majority of both the unit share and gross sales. As mentioned in my response your first question, as of July 2019 NEUPOGEN unit sales share is 32 percent compared to biosimilar and biologic competitors which combined have more than double the short acting GCSF unit sales.[7] See Figure 1 below for monthly unit share since October 2013.

Figure 1: Short Acting GCSF Monthly Unit Share[8]



Based on gross sales, as of July 2019 NEUPOGEN had 35 percent of share in the U.S.[9] ZARXIO gross sales have been exceeding NEUPOGEN since Q3 2018 and combined ZARXIO and GRANIX gross sales exceeded NEUPOGEN gross sales since mid-2017.[10]

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[7] Amgen data on file. Methodology: Calculation of unit share is based on units sold for the following products in the short acting GCSF market basket: NEUPOGEN, ZARXIO, GRANIX, NIVESTYM, and LEUKINE. The analysis is based on IQVIA DDD data, supplemented with Amgen proprietary data and estimates for select customer segments not included in IMS DDD. Because IQVIA DDD is not 100 percent complete, Amgen uses proprietary data and estimates to fill gaps.

[8] Ibid.

[9] Amgen data on file. Methodology: Calculation of share by gross sales is based on units sold times WAC for the following products in the short acting GCSF market basket: NEUPOGEN, ZARXIO, GRANIX, NIVESTYM, and LEUKINE. The analysis is based on IQVIA DDD data, supplemented with Amgen proprietary data and estimates for select customer segments not included in IMS DDD. Because IQVIA DDD is not 100 percent complete, Amgen uses proprietary data and estimates to fill gaps.

[10] Ibid.

Kave Niksefat

3. You stated in the hearing you did not know the price of Neupogen in Denmark. Now that you are able to determine it, what is the price of Neupogen in Denmark today? If it is lower than Neupogen's price in the United States, does that support your contention that biosimilar competition is working in the Neupogen market? Also, can you please report how much more money patients and payers in the United States, including the Medicare program, have spent on Neupogen relative to what they would have paid had Neupogen sold for the price it had in Denmark during the same time period?

We respectfully disagree with your assertion that Denmark does not have government price controls. The Danish healthcare system differs from the U.S. system in significant ways. Denmark is a single payer system with price controls, such as the imposition of price caps for medicines and a national formulary, that result in restricted access to drugs.[11] An analysis looking at the availability of new cancer drugs between 2011 and 2018 demonstrates that access is more constrained in Denmark compared to the U.S. While 96 percent of new cancer drugs were available in the U.S., only 66 percent of new cancer medicines were available to patients in Denmark.[12] Denmark also currently utilizes national tenders with approximately 80 percent of volume adjudicated to the winner.[13] Further, biosimilars have been available in Denmark for a decade, since 2009. The current list price of a NEUPOGEN injection in Denmark is between US$84 and US$142 depending on presentation and dose, but that is not a like-to-like comparison to U.S. pricing given the tender dynamics and price controls in the Danish healthcare system.

Comparing the Denmark price for NEUPOGEN to the U.S. price is not the best metric to assess the performance of the U.S. biosimilar market given that Denmark uses a government-imposed pricing system while the U.S. uses a free market system that produces better access for patients. A better metric is to look at the effect of biosimilars in the U.S. market. As noted above, as of July 2019 the unit sales share of NEUPOGEN in the U.S. is 32 percent compared to biosimilar and biologic competitors which have more than double the short acting GCSF unit sales.[14] ZARXIO (a biosimilar) has Medicare reimbursement rates that are 38 percent below the reference product.[15] These data illustrate the impact that biosimilars are already having in the U.S. healthcare marketplace, promoting increased competition and cost savings to patients and payers as intended.

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[11] Badger, D. Examination of International Drug Pricing Policies in Selected Countries Shows Prevalent Government Control over Pricing and Restrictions on Access, p.11-12 (March 2019). Available at https://galen.org/assets/Badger-Report-March-2019.pdf.

[12] PhRMA Analysis of IQVIA Analytics Link and Food and Drug Administration/European Medicines Agency and PMDA Data (Nov. 2018). Available at http://phrma-docs.phrma.org/files/dmfile/IPI-Model---Comparison-of-Cancer-Medicine-Availability---012819.pdf.

[13] Background Note for the G-CSF Therapy Area, RADS (Rådet for Anvendelse af Dyr Sygehusmedicin), p. 22 (October 2014). Available at https://rads.dk/media/2548/baggrundsnotat-for-terapiomraadet-for-g-csf.pdf.

[14] Amgen data on file. Methodology: Calculation of market share is based on units sold for the following products in the short acting GCSF market basket: NEUPOGEN, ZARXIO, GRANIX, NIVESTYM, and LEUKINE. The analysis is based on IQVIA DDD data, supplemented with Amgen proprietary data and estimates for select customer segments not included in IMS DDD. Because IQVIA DDD is not 100 percent complete, Amgen uses proprietary data and estimates to fill gaps.

[15] CMS 2019 ASP Drug Pricing Files. Available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2019ASPFiles.html.

Kave Niksefat

In the U.S., biosimilars still are a new market, but growing rapidly with nine biosimilars currently on the market (six launched in the last year alone) competing against six separate originator medicines. The scientifically sound regulatory pathway in the U.S. has produced 23 biosimilar approvals as of July 2019.[16] In addition, the FDA's Biosimilar Development Program encompasses 77 manufacturer development programs as March 2019.[17] Biosimilars are on track to introduce competition in the U.S. that is projected to save billions. A recent analysis by IQVIA projects that biosimilars will save nearly $160 billion in the U.S. between 2019 and 2023.[18]

We are not able to report how much more payers and patients in the U.S. have spent on NEUPOGEN relative to what would have been spent if we sold the product at the Denmark price because it is not possible for us to calculate this accurately. For example, we do not know how much commercial payers in the U.S. paid for NEUPOGEN because ultimately that depends on the contractually agreed upon rate between each payer and each provider they contract with (e.g. physicians or physician groups, hospitals, and pharmacies). These contracts are not available to us. We also do not know what the patient cost is for the product because the patient out-of-pocket cost will depend on a patient's specific benefit plan design, as well as the availability of secondary insurance. Even if we had sufficient data to do this type of analysis, it would not be an apples-to-apples comparison given that it would be comparing a government-run healthcare system with price controls and access restrictions (Denmark) to a free market system (the U.S.).

The Honorable Michael C. Burgess, M.D.

1. Mr. Niksefat, you mentioned in your testimony that Amgen lowered the list price of Repatha by 60 percent last year, but that patients have largely not seen the benefit of this lower list price. At the end of the day, we should be working to lower out-of-pocket costs for patients, and Amgen's attempt to do so is not playing out as anticipated. Is there any action that Congress or the Department of Health and Human Services should consider to alter the incentive structure surrounding list prices, or is this something that the market can sort out on its own?

As discussed in my testimony, we believe there are a number of actions Congress or the Department of Health and Human Services could take to lower-out-of-pocket costs for patients and provide incentives to lower list prices. Below I briefly summarize two recommendations:

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[16] FDA Biosimilar Product Information (updated July 23, 2019). Available at https://www.fda.gov/drugs/biosimilars/biosimilar-product-information.

[17] FDA-TRACK: Center for Drug Evaluation & Research - Pre-Approval Safety Review - Biosimilars Dashboard (updated March 31, 2019). Available at https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-center-drug-evaluation-research-pre-approval-safety-review-biosimilars-dashboard.

[18] The Global Use of Medicine in 2019 and Outlook to 2023, IQVIA, p.21 (January 2019). Available at https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.pdf.

Kave Niksefat

- **CMS Guidance to Part D Plans Addressing List Price Reductions:** CMS can take immediate action by issuing guidance highlighting that, in instances where manufacturers lower list price for medicines that puts them below the specialty tier threshold of $670, plans should move the lower list price drug from the specialty tier to a tier with better (or no worse) cost sharing (e.g., preferred brand). We hope to work with the Committee on this specific policy solution since it is a way to quickly reduce out-of-pocket costs for patients taking Repatha® (evolocumab). If CMS is unwilling to issue mid-year guidance, then the Committee could introduce legislation requiring CMS to make this change given that it would help patients access medicines at more affordable cost-sharing when manufacturers reduce list prices.

- **Require Rebates to Be Passed on to Patients at the Pharmacy Counter:** We are supportive of policy changes that would ensure savings from rebates flow directly to patients. Even in the face of net price declines as we experienced last year, patients are not seeing the benefits of these declines. At both the state and federal level, we are supportive of lawmakers' efforts to look for ways to ensure patients can access these rebate dollars to improve affordability for patients.

2. Something I find particularly concerning about our drug supply chain is the possibility of drug shortages. These can occur because of natural disasters, manufacturing issues, or business decisions. What are each of your respective companies doing to prevent drug shortages?

With nearly four decades of experience in biotechnology and a record of reliably supplying medicines to patients, Amgen is known worldwide as a leader in research, development, and manufacturing of complex biologic therapies. Amgen has strong track record of reliable supply. According to ongoing data monitoring of drug shortages by the American Society of Health System Pharmacists dating back to 2007, Amgen had zero drug shortages.[19]

Drug shortages can have a significant impact on patients and healthcare providers. As identified by the U.S. Food and Drug Administration, quality, manufacturing, and capacity issues are major reasons for many of these drug shortages.

We are deeply committed to ensuring doctors and patients can rely on the quality and availability of our treatments. The Amgen approach to providing a continuous supply of biologic therapies has four key elements:

- PREVENTION which includes promoting exemplary regulatory compliance, robust quality management processes, operational excellence, supply chain security, infrastructure investments, and business continuity planning;

[19] Amgen's 2018 Biosimilars Trends Report. p. 4. Available at https://www.amgenbiosimilars.com/pdfs/2018_trends_report.pdf.

Kave Niksefat

- TECHNOLOGY to enhance product purity and the robustness of the manufacturing process;
- INVENTORY MANAGEMENT to help us have the right quantities of the product housed in diverse geographic locations; and
- REDUNDANT MANUFACTURING capacity in multiple geographic locations and back-up suppliers for raw materials.

Beyond complying with current good manufacturing practices (cGMP) and implementing a robust quality management system, Amgen takes extra steps to help ensure a reliable supply to every patient, every time. As a first step, Amgen invests in inventory management at multiple points in the supply chain to mitigate potential risks of disruptions to supply (e.g., natural disasters).

Additionally, Amgen maintains appropriate levels of raw materials by diversifying suppliers of sourced raw materials and storing high-risk raw materials in multiple geographical locations to safeguard their availability. By managing relationships with suppliers so that raw materials requirements are understood and shared between both parties, Amgen is able to source high-quality raw materials to minimize reprocessing and potential product manufacturing issues, and to help facilitate consistent product quality.

Maintaining diverse manufacturing capabilities requires significant investment in internal manufacturing and contract manufacturing capabilities. Amgen has invested more than $1.6 billion in supply management since 2005. By maintaining a network of plants across seven Amgen manufacturing sites (diversification), supplemented with additional capacity at contract manufacturers, Amgen is able to implement back-up manufacturing capabilities when needed. Amgen is also able to actively manage robust and secure distribution networks, by establishing well-controlled temperature ("cold chain") distribution channels to maintain the quality of each product and utilize multiple approaches to mitigate distribution-related security risks to supply. These include controlled shipping lanes using temperature-validated shipping containers to maintain chain of custody, anti-theft and anti-counterfeiting measures to mitigate the risk of diversion and adulteration, and risk management programs to systematically address risks as they develop.

3. Do you have processes in place to minimize the negative effects of drug shortages should one of your manufacturing facilities offline?

Amgen's significant investments in promoting reliable supply were tested in 2017 when Hurricane Maria hit Puerto Rico, where Amgen's largest manufacturing site is located. In the aftermath of the storm, Amgen provided support to our staff members and the local community while implementing our robust business continuity plans and restoring manufacturing operations at our site in Juncos. The company continued to provide an uninterrupted supply of medicines for patients around the world by:

Kave Niksefat

- Maintaining inventory levels to address unplanned situations:
  - Shortly after the storm, our warehouse in Puerto Rico resumed shipments of medicines from inventory maintained in a temperature-controlled bunker.
  - The majority of our finished goods inventory is maintained on the U.S. mainland.

- Investing in capacity and redundant facilities:
  - Amgen's global manufacturing network includes a redundant fill/finish facility in Ireland and we have relationships with established contract manufacturers in the U.S. and Europe for additional capacity.
  - We activated manufacturing and packaging lines at our own sites in Ireland and the Netherlands and at contract manufacturers in the U.S. and Europe to absorb some production volume and serve as a relief valve while our Puerto Rico site resumed full operations.

- Exercising our business continuity plans on a regular basis:
  - Following its established plans, the Puerto Rico site was prepared and responded before, during, and after the hurricane.
    - Amgen has a network of back-up generators which powered the site and regular deliveries of diesel fuel were supplied under pre-arranged contracts.
    - When municipal water service was interrupted, Amgen used on-site wells and water storage tanks.
    - Supplies of medical-grade oxygen and nitrogen on the island were limited. Amgen arranged deliveries via ship of both types of gas from the U.S. mainland and other countries, and established alternate supply chains until reliable service on the island was restored.

  - A cross-functional team from across the company supported the site recovery efforts with materials/supplies, logistics and engineering support, and resources for staff and the local community.

For more details on Amgen's response following Hurricane Maria, please see this video: https://youtu.be/h5AXDsQNX3A

The Honorable John Shimkus

1. Given that most of the witnesses on the panel have referenced the role of creating value in the health care supply chain, please comment on: Existing areas where Congress or the Administration may have needlessly added to the cost that patients or the government pays for a particular product, service, or intervention. For example, do you have recommendations on how reforms to existing laws like Stark and the Anti-Kickback Statute could accelerate value-based contracting within Medicare and Medicare Advantage?

Kave Niksefat

Amgen has strong interest in entering into additional value-based contracting arrangements. However regulatory barriers are preventing the ability to drive more innovative agreements. For example, if we enter into a value-based contract which results in a large payment because a patient did not achieve the expected clinical outcome, it could trigger Medicaid best price implications for our medicine in all 50 states. Similarly, we would like to see safe harbors created that would give the market confidence that these types of arrangements do not run afoul of the Anti-Kickback Statute. Therefore, we are supportive of regulatory or legislative approaches that would exempt value-based arrangements from Medicaid "best price" while at the same time creating a new Anti-Kickback Statute "safe harbor." These recommendations are consistent with the positions of a number of trade groups and coalitions, such as PhRMA and the Health Leadership Council.[20]

Amgen believes this could be done in a manner that requires such arrangements to entail some portion of risk assumed by both parties to the agreement to qualify for such exemptions. These changes would improve the ability of manufacturers to enter into more innovative value-based agreements with payers in a meaningful way, which in turn could yield savings and better deliver downstream quality of care.

2. How do we ensure that these value-based reforms benefit patients and protect taxpayers?

We agree with CMS that value-based reforms support the "three-part aim" of: 1) better care for individuals; 2) better health for populations; and 3) lower costs. We believe that robust market-based negotiations between payers and manufacturers will result in arrangements that enhance quality of care and reduce costs for patients, payors, and plans. That is why we support removal of outdated regulatory barriers that impede these arrangements.

To the extent that legislative changes allow greater flexibility for manufacturers to enter into value-based agreements with Medicare - this could enhance quality and would likely produce savings for the Medicare program, taxpayers, and beneficiaries.

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[20] See PhRMA and HLC comment letters on OIG–0803–N Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP available at https://www.regulations.gov/document?D=HHSIG-2018-0002-0317 and https://www.hlc.org/app/uploads/download.php?dl=app/uploads/2017/02/HLC-Comment-Letter-OIG-AKS_FINAL.pdf and PhRMA comments on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs available at https://www.regulations.gov/document?D=CMS-2018-0075-2808.

Attachments—Additional Questions for the Record

Subcommittee on Health
Hearing on
"Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"
May 9, 2019

Jeffrey Hessekiel

The Honorable Michael C. Burgess, M.D.

1. Something I find particularly concerning about our drug supply chain is the possibility of drug shortages. These can occur because of natural disasters, manufacturing issues, or business decisions. What are each of your respective companies doing to prevent drug shortages?

Exelixis takes seriously our responsibility to ensure that patients who are prescribed our medications have access to them immediately, and we recognize that a shortage can be devastating for the vulnerable population that we serve. Since cabozantinib was first approved by the FDA in 2012, Exelixis has not experienced any drug shortages, and we have put thorough policies and procedures in place to ensure a continuous drug product supply.

To ensure that we never have a supply interruption or shortage, we have built safety stock levels for each stage of our supply chain. We target a two year safety stock for our raw ingredients, active drug substance and finished product, and store these materials at multiple locations to further mitigate risk. Additionally, as our production volumes have grown, we have selected secondary or back up suppliers in different geographical locations who, once qualified, will further bolster our global supply chain network.

The Honorable John Shimkus

1. Given that most of the witnesses on the panel have referenced the role of creating value in the health care supply chain, please comment on: Existing areas where Congress or the Administration may have needlessly added to the cost that patients or the government pays for a particular product, service, or intervention. For example, do you have recommendations on how reforms to existing laws like Stark and the Anti-Kickback Statute could accelerate value-based contracting within Medicare and Medicare Advantage?

If they align the costs of cancer treatments with the value they provide to patients, value-based care arrangements have the potential to reduce treatment costs and generate patient outcomes data that providers may use to help improve patient quality of care.

In order to accelerate value-based contracting, Exelixis recommends policymakers develop a new safe harbor under the Anti-Kickback Statute specifically for value-based contracting arrangements. As Exelixis described in comments to the HHS Office of Inspector General last October, the lack of modern safe harbors to the Anti-Kickback Statute creates uncertainty and potential liability for the contracting parties, which inhibits the development of innovative value-

or outcomes-based contracting arrangements. A new safe harbor that provides flexibility in determining "value" and protects rebate arrangements that meet pre-defined criteria would encourage those developments by providing manufacturers and payors with regulatory clarity. By employing a broad definition of "value," leveraging any of a number of quality measures (including burden of illness, Clinical Outcome Assessments (COAs), Quality Adjusted Life Years (QALY), compliance, adherence, and persistence), payors and manufacturers will have the ability to negotiate individual value-based contracts for different diseases that reflect the value the product provided to the patient. Exelixis believes value should not be defined only in terms of cost-based measures, but should also include patient-reported outcomes. Because patients with advanced cancer, unfortunately, may have a limited life expectancy and care is unavoidably costlier as the disease progresses, cost-based definitions of value may disincentivize the creation of value-based arrangements for this vulnerable population. Furthermore, most value-based contracting arrangements must be implemented as rebate arrangements, because the outcomes data on which value-based rebates are paid are collected after the time of sale. Reforms to the Anti-Kickback Statute that address value-based contracting must clarify whether rebates that will reduce barriers and increase uptake of value-based contracting arrangements are acceptable. Finally, in implementing value-based contracting arrangements, Exelixis strongly encourages all relevant HHS agencies (e.g., OIG, CMS, FDA) to work collaboratively to harmonize regulatory policies. For example, depending on how a value-based arrangement is structured, there is a risk that any significant (or full) rebate based on the failure of the drug to meet an agreed upon measure of "value" could trigger reporting an artificially low Best Price for a product. This, in turn, could increase the manufacturer's Medicaid rebates on all Medicaid utilization, meaning that failure of a drug to reach a specified outcome for even a single patient could trigger outsized financial liability for the manufacturer. Exelixis urges regulators to collaborate to avoid creating unintended barriers to value-based arrangements.

Additionally, as detailed in Exelixis' comments on the Energy & Commerce Committee's draft Medicare Part D legislation, Exelixis strongly supports a policy change to permit manufacturers of certain clinically unique drugs, such as cancer medications, to provide copayment assistance to patients under Part D, as is permitted for patients with commercial insurance. While the current prohibition on manufacturer copayment assistance seeks to give patients "skin in the game" and protect the Medicare program from inappropriate utilization and resulting costs, neither of these arguments are applicable to the majority of cancer drugs. Instead, high beneficiary copays often lead to cancer patients delaying or forgoing treatment due to an inability to pay. Limited cost sharing assistance for those medicines with no generic alternative will increase patient access to lifesaving drugs by reducing the burden of out-of-pocket costs that patients face, with no added costs to the government. Exelixis believes that this reform is an important first step to enhance access, as the Committee continues to develop proposals to accelerate value-based contracting.

2. How do we ensure that these value-based reforms benefit patients and protect taxpayers?

Value-based contracting arrangements enable payors to align costs with the value an individual therapy provides, tying payment to their clinical value to patients. This approach better aligns the interests of taxpayers and patients than current payment policies that would restrict coverage of, and payment access to, expensive medicines like cancer therapies. To further ensure that the cost savings generated through value-based contracts benefit patients, Exelixis recommends requiring that at least a defined percentage, if not all, of savings generated through rebates be passed on to patients at the point-of-sale.

The Honorable Gus M. Bilirakis

1. Mr. Hessekiel – Often when discussing high drug prices, we tend to focus on what is wrong without mentioning what is going right to ensure we achieve the desired result in a way that does not undermine the progress that has already been made or produce other negative unintended consequences.

    - Can you share with us what is currently working and how we might double-down on these efforts?

The United States has established robust policies and incentive structures that have attracted investment in biopharmaceutical companies, which has enabled these companies to become global leaders in discovering innovative treatments and cures. Developing and commercializing new medicines is a difficult and expensive endeavor. But, the United States' strong intellectual property protections and dynamic market have made it possible for innovators — even relatively smaller companies, like ours — to take on substantial financial risks at the outset, betting on the small chance of ultimate success.

I was honored to be invited to testify on behalf of small and medium-sized biopharmaceutical companies that discover the majority of new drugs today. Since the inception of our company 25 years ago, investors have risked more than $3 billion supporting our research and development efforts, with over $2.1 billion spent before the company ever sold a single dose of medicine

We strongly urge Congress not to undermine, disrupt, or even destroy the biopharmaceutical innovation cycle that makes it possible for companies like ours to take on the overwhelming challenges and the inherent risks of failure at each step of the discovery, development, regulatory, and commercialization process. While other countries have implemented price controls or have weaker intellectual property protections, these countries continue to lag behind the United States in developing lifesaving medicines for patients. We request that you consider how weakening incentives for companies to invest in research and development would impact smaller companies the hardest, as companies like ours do not have an established suite of commercialized products or the capital structure needed to continue these substantial investments.

Additionally, the Orphan Drug Act and FDA User Fee Act are two programs that have worked well in accomplishing their intended purposes, and have resulted in a substantial increase in research and development investments and faster approvals of new drugs that treat patients with rare diseases. Congress can build upon these successful efforts by tailoring forthcoming drug pricing legislation to incentivize research and development investments, while discouraging companies who do not make significant investments from setting high list prices. The Senate Finance Committee has proposed a change to the manufacturer discount in the Medicare Part D benefit that would treat all biopharmaceutical companies the same, regardless of differences in their commitment to research and development. We encourage policymakers to consider an alternative approach, which would base manufacturer discounts in the Part D program on the amount of money invested in research and development relative to revenue. We believe that this proposal would address Congress' legitimate concerns with rising prescription drug costs on the federal government and patients, while also preserving the existing biopharmaceutical innovation cycle that delivers lifesaving treatments to patients.

701 Pennsylvania Avenue, NW
Suite 720
Washington, DC 20004

August 9, 2019

Subcommittee on Health
Additional Questions for the Record
Hearing on: "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"
May 9, 2019
Questions for: Amy Bricker, Senior Vice President

Cigna Corporation appreciates this opportunity to respond to follow-up questions for the record from the Subcommittee on Health relating to testimony received from Amy Bricker, Senior Vice President, at the hearing, "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain" on May 9, 2019.

Cigna Corporation, together with its subsidiaries (either individually or collectively referred to as "Cigna"), is a global health services organization dedicated to improving the health, well-being and peace of mind of those we serve. Our subsidiaries are major providers of medical, pharmacy, dental, disability, life and accident insurance, and related products and services, with over 160 million customer relationships in the more than 30 countries and jurisdictions in which we operate. Worldwide, we offer a sense of security to our customers seeking protection for themselves and their families at critical points in their lives. Cigna completed its merger with Express Scripts in December 2018, bringing together approximately 74,000 employees around the world. The combined company's medical, clinical, pharmacy, behavioral, and wellness insights empower us to deliver improved affordability, choice, predictability, and high-quality care through connected, personalized solutions that advance whole person health. This diverse range of businesses provides us with insight about how we can best serve our customers, and how federal and state laws and regulations can assist us in that effort.

Questions and answers by Representative:

The Honorable Michael C. Burgess, M.D.

1. What are Pharmacy Benefit Managers doing to ensure that patients are seeing the benefits of lower list prices when they reach the pharmacy counter?

   - *Response*: Express Scripts has long advocated for lower list prices, which are set by manufacturers. While list prices are not within our control, we have made and continue to make great efforts to ensure that patients have access to affordable medicine at the pharmacy counter. Express Scripts employs a system-driven "lesser of logic" approach at the point of sale for patients at the retail pharmacy. The patient is charged either their copay/coinsurance, the plan sponsor rate, or the pharmacy's cash price for their prescription, whichever is less.

     In May 2017, Express Scripts launched Inside Rx, a prescription savings program launched in partnership with drug manufacturers and retail pharmacies to expand affordable access to brand and generic

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medications for patients with no insurance, high deductibles, or high out of pocket costs, by offering discounts to these patients at point of sale. Since the launch of the program, we have helped patients save an estimated $400 million. Inside Rx continues to expand to provide savings to consumers who may be uninsured or underinsured.

With respect to insulin specifically, Express Scripts launched a new Patient Assurance Program within the first 100 days of the combination, which brings additional affordability and predictability to eligible customers who rely on insulin to manage their diabetes. This program establishes a lower fixed out-of-pocket cost for covered insulins, ensuring customers will pay no more than $25 out-of-pocket when filling a 30-day insulin prescription at a retail pharmacy or through home delivery.

2. Something I find particularly concerning about our drug supply chain is the possibility of drug shortages. These can occur because of natural disasters, manufacturing issues, or business decisions. What are each of your respective companies doing to prevent drug shortages?

   - *Response*: We do not manufacture or control the supply of a drug. Our contracts assume products will be available for patients, as it is in our collective interest to have adequate supply and competition to lower costs and improve quality. Further, there is rarely a single, predictable reason behind a drug shortage. In many cases, shortages are the result of disruptions in manufacturing processes, FDA orders to halt productions, etc., matters over which we have no control.

     Preventing drug shortages and ensuring adequate supply of necessary pharmaceutical products is critical to patient health. The majority of drug shortages occur in the hospital setting. We have predictive models that help to show us which drugs might be in short supply and make adjustments as we are able. In the United States, the biggest problems with drug shortages occur when there is a single source manufacturer. Decreasing the amount of time in which generics get to market can also play a key part in solving this problem.

The Honorable John Shimkus

1. Given that most of the witnesses on the panel have referenced the role of creating value in the health care supply chain, please comment on: Existing areas where Congress or the Administration may have needlessly added to the cost that patients or the government pays for a particular product, service, or intervention. For example, do you have recommendations on how reforms to existing laws like Stark and the Anti-Kickback Statute could accelerate value-based contracting within Medicare and Medicare Advantage?

   - *Response*: Cigna/Express Scripts urges Congress to take steps establishing additional flexibility under existing laws like Stark and the Anti-Kickback Statute to accelerate value-based contracting and other innovative solutions in public programs. In addition, we also urge Congress to pursue two other key policy changes that would allow plan sponsors to significantly improve the quality of care provided to beneficiaries while further driving down drug spend. First, the current "any willing pharmacy" requirements, whereby plan sponsors must include in their networks any pharmacy willing to meet the terms and conditions for inclusion, foregoes potentially substantial savings by limiting the program's ability to drive better quality of care and improved clinical outcomes while also controlling costs. Second, we have long advocated for the elimination of the six protected drug classes in Medicare, which severely hampers plans' ability to introduce value-based care concepts to address the most expensive drug therapies. We welcome the opportunity to work with your office on these and other needed reforms.

2. How do we ensure that these value-based reforms benefit patients and protect taxpayers?

- *Response*: Cigna/Express Scripts is committed to pursuing value-based reforms that benefit patients and protect taxpayers, and would welcome the opportunity to work with your office on this issue as well. Recently Cigna exceeded its value-based care goal of having 50 percent of U.S. Medicare and commercial health care provider payments through alternative payment arrangements in the company's top 40 markets by year-end 2018. Cigna established the goal in 2015 to accelerate the transition to alternative payment models that link health care provider payments to both quality and affordability.

  Cigna launched value-based care delivery a decade ago to begin to transition to a health care delivery system that pays health care providers based on improved health outcomes instead of the traditional fee-for-service model, which pays providers based on volume. The move helped the company shift 50.5 percent of provider payments to alternative payment arrangements, and improve the quality of health care for customers resulting in medical cost savings of more than $600 million from 2013-2017. In addition, it has contributed to Cigna maintaining the industry's lowest medical cost trend for six consecutive years.

  In the pharmacy benefit space, Express Scripts' SafeGuardRx product combines our specialized clinical models and value-based contracting strategies to help our clients improve patient care for the most challenging conditions while also controlling costs. In 2018, the SafeGuardRx program saved $2.4B for clients over nine specialty & chronic disease categories.

The Honorable Susan W. Brooks

1. During the hearing, I asked Express Scripts about how the company determines the lowest net cost for a product. Express Scripts responded that Express Scripts takes the list price less any discount that is offered by the manufacturer to determine the lowest net cost. The witness also said that administrative fees are considered when the company is determining the lowest net cost. Is this correct? If so, please answer the following questions:

   a. What is an administrative fee?

- *Response*: An administrative fee is generally a fee for services.

   b. Why is an administrative fee considered a discount?

- *Response*: Our clients, which are sophisticated entities and are often represented by benefit consultants and advisors, negotiate the overall arrangement they believe best suits their pharmacy benefit needs. Terms vary across clients and contracts, and some clients negotiate to receive amounts attributable to rebates as well as administrative fees collected by Express Scripts. Although administrative fees and discounts are distinct, our clients can realize overall value through both. These are some of the many ways we work to bring down drug costs for our clients.

   c. Are there any other fees or reductions of list price that are not considered a discount by Express Scripts? If so, please explain.

- *Response*: Our clients negotiate the overall arrangement they believe best suits their pharmacy benefit needs. Components can include various fees and discounts. Client contracts generally establish a client's pricing as a discounted percentage from drug products' average wholesale price ("AWP"). These discounts are typically backed by various guarantees that are individually negotiated and vary among clients.

d. Why are "administrative fees" considered separate and distinct from "rebates" if they are also considered a discount? Please include information about any ways in which rebates and administrative fees are considered differently by Express Scripts.

- *Response*: Please see our response to 1.b., above.

e. Are all administrative fees passed through to Express Scripts' clients? If so, how much of the administrative fee is passed through to your company's clients?

- *Response*: Whether Express Scripts pays to the client an amount attributable to administrative fees is individually negotiated with each client. Negotiations with Express Scripts' clients consider multiple components of a client's overall arrangement, rather than looking at rebates and administrative fees in a vacuum.

f. When Express Scripts discusses the lowest net cost drug, does it mean the lowest net cost for Express Scripts or the lowest net cost for the company's clients—the health plan? If the administrative fee is indeed considered in determining the lowest net cost drug, could it be the case that the lowest net cost drug to Express Scripts is different than the lowest net cost drug to an Express Scripts client?

- *Response*: The process Express Scripts uses to develop formularies has been constructed to ensure that clinical considerations are paramount and fully taken into account before cost considerations. Formulary management is a highly effective strategy that pharmacy benefit plan sponsors can implement to maintain a safe, affordable and meaningful benefit for patients. When discussing net cost, we mean net cost to clients. Financial impact to Express Scripts is expressly excluded and prohibited from consideration in the formulary development process.

Attachments—Additional Questions for the Record

Subcommittee on Health

Hearing on

"Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"

May 9, 2019

Brent Eberle

The Honorable Michael C. Burgess, M.D.

1. **What are Pharmacy Benefit Managers doing to ensure that patients are seeing the benefits of lower list prices when they reach the pharmacy counter?**

Navitus Response: While many PBMs do not operate the way we do, as a full pass-through PBM, Navitus ensures that our clients are receiving all of the benefits of the discounts and rebates we are able to achieve on their behalf. This approach results in an overall lower net per member per month drug cost and our clients use the associated savings to reduce their employees / members premiums and cost sharing. Navitus employs several strategies that directly benefit the member at the pharmacy counter.

Some examples of our efforts to make sure that patients receive the benefit of lower list pricing include:

a. Lower-of-Logic: In all of our pharmacy network agreements, the cost of the claim is based on the lower of our contracted discount, maximum allowable cost (MAC), or the pharmacy's usual and customary price. This ensures the member is receiving the lowest cost we were able to negotiate with that pharmacy.

b. Cost Compare Tools: We have also developed a cost compare tool that enables the member to search for the lowest cost pharmacy in their geographic area as well as provide access to the formulary so that they are aware if there are other lower cost options available on the formulary.

c. Plan Design Modeling: We work with our clients in helping them determine the benefit plan design that works best for them and their members / employees. An example of this is our point of sale rebate plan design, which adjusts the cost of the claim down based on the expected rebate amount reducing the patient's costs to reflect the rebate.

2. **Something I find particularly concerning about our drug supply chain is the possibility of drug shortages. These can occur because of natural disasters, manufacturing issues, or business decisions. What are each of your respective companies doing to prevent drug shortages?**

   Navitus Response: We share your concern on drug shortages and the impact they can have on our patients. In order to help address potential drug shortages and excessive price swings, our parent company, SSM Health, has joined a consortium of other concerned entities to form a new not-for-profit generic drug manufacturer, Civica Rx, which is intended to both help with reducing drug shortages and lower generic drug by building. Civica's mission is to ensure that essential generic medications are accessible and affordable to everyone, and while it is just getting started we have a hope that it will make a significant difference in a market dominated by pharmacy manufacturers driven completely by profits.

   As a PBM, Navitus is somewhat limited in what we can do to directly address this issue, because we are not involved in the manufacturing process. However, when shortages occur, we do the following:

   - Help our member find out if this product is available at another pharmacy. If that pharmacy is not in the network, we will make an exception to allow that member to use the out of network pharmacy.
   - Determine if there is another formulary option that may be appropriate and work with the member and their prescriber. If the other formulary option is non-preferred, we will often lower the copay to match the copay of the drug that is on shortage.
   - Communicate any information we have from the manufacturer and/or wholesaler as to when the shortage is expected to be resolved.

The Honorable John Shimkus

1. Given that most of the witnesses on the panel have referenced the role of creating value in the health care supply chain, please comment on: Existing areas where Congress or the Administration may have needlessly added to the cost that patients or the government pays for a particular product, service, or intervention. For example, do you have recommendations on how reforms to existing laws like Stark and the Anti-Kickback Statute could accelerate value-based contracting within Medicare and Medicare Advantage?

   Navitus Response: Our experience has been that regulations, in general, tend to increase costs for both the businesses being regulated and for the customers of those businesses as costs of compliance are passed through. Generally, we support reductions in regulations, and believe that this year's proposed changes related to the

Anti-Kickback Statute's Safe Harbor would not have had the intended effect of lowering drug costs. As an alternative to revising the Stark Law and the Anti-Kickback Statute, if Congress wanted to encourage value-based contracting for Medicare, it could directly require value-based contracting as a requirement for managed care plans providing coverage to Medicare beneficiaries.

2. How do we ensure that these value-based reforms benefit patients and protect taxpayers?

Navitus Response: Navitus recognizes the difficulties in legislating the details around value-based contracts and believe that this area likely requires long-term agency oversight with general goals and direction being provided by Congress.

The Honorable Susan W. Brooks

1. During the hearing, I asked Navitus Health Solutions about how the company determines the lowest net cost for a product. Navitus Health Solutions responded that, very generally, Navitus Health Solutions takes the list price less any discount that is offered by the manufacturer to determine the lowest net cost—although there are differences for generic medicines and brand medicines. Does Navitus Health Solutions consider administrative fees when determining the lowest net cost for a product?

Navitus Response: Yes, Navitus considers all discounts and payments available from manufacturers when determining the net cost of a product. Navitus does not retain any "administrative fees" paid by manufacturers, and passes all of the payments from manufacturers on to its clients. As, rebates provided by drug manufacturers are normally paid months after drugs are dispensed by pharmacies.

For purposes of clarifying how Navitus determines the reimbursable price at a pharmacy for a drug versus the lowest net cost for a benefit plan, after taking into account rebates, Navitus determines the price for a drug at a pharmacy by employing "lower of" logic, which selects the lower: (1) the maximum allowable cost (or "MAC") as determined by Navitus, plus a dispensing fee, if applicable (MAC is normally for generics rather than brand drugs); (2) each Participating Pharmacy's respective contracted price for the applicable product, including a discount, plus a dispensing fee; (3) such pharmacy's usual and customary price as reported by the pharmacy; or (4) the amount submitted by the pharmacy. This calculated price is then used to determine how much the benefit plan and how much the patient will pay at the point of sale based on the plan's benefit and patient co-insurance and/or co-pay amounts. Normally, the benefit plan later receives rebates, including "administrative fees" when they are paid months later by drug manufacturers. We also offer a program where some plans reduce the amount paid by patients based on

the amount of anticipated rebates, but most plans opt to receive the rebates after they are paid by manufacturers and use those amounts to reduce premiums or otherwise lower overall expenses.

If so, please answer the following questions:

a. What is an administrative fee?

Navitus Response: A rebate administration fee is typically a fee that a manufacturer provides to a PBM/Managed Care Organization (MCO) for access to the formulary and for activities the PBM / MCO is providing to the manufacturer. This can include providing utilization data necessary to calculate the rebate payment.

b. Why is an administrative fee considered a discount?

Navitus Response: Rebate administration fees are typically calculated as percent off the Wholesale Acquisition Cost (WAC). We consider it another discount available to our clients, reducing their overall costs.

c. Are there any other fees or reductions of list price that are not considered a discount by Navitus Health Solutions? If so, please explain.

Navitus Response: No.

d. Why are "administrative fees" considered separate and distinct from "rebates" if they are also considered a discount? Please include information about any ways in which rebates and administrative fees are considered differently by Navitus Health Solutions.

Navitus Response: At Navitus, we structure our agreements in a way that allows all of these discounts to be passed onto our clients. This is a key differentiator, as we do not use this term as a way to retain a portion of the discount. We strongly recommend that any change to the drug supply chain not limit our ability to pass through this discounts to our clients, directly or indirectly.

e. Are all administrative fees passed through to Navitus Health Solutions' clients? If so, how much of the administrative fee is passed through to your company's clients?

Navitus Response: Yes, all discounts we receive from manufacturers are passed through to our clients.

f. When Navitus Health Solutions discusses the lowest net cost drug, does it mean the lowest net cost for Navitus Health Solutions or the lowest net cost for the company's clients—the health plan? If the administrative fee is indeed considered in determining the lowest net cost drug, could it be the case that the lowest net cost drug to Navitus Health Solutions is different than the lowest net cost drug to a Navitus Health Solutions client?

Navitus Response: When discussing "lowest net cost drugs," we always mean the lowest net cost for our client health plans, because Navitus passes through all pricing and rebates (including rebate administrative fees) to its clients. As a 100% pass-through PBM, Navitus does incur a "lowest net cost," as the costs are paid by the clients, not Navitus. Navitus negotiates prices on behalf of plans and then facilitates the payments from the plans to the pharmacies. Navitus also does not retain any rebate administration fees, and those amounts are all passed through our health plan clients as well. There is no difference between Navitus negotiates and the amount our health plan clients pay.

Since Navitus does not retain any of the discounts, there is never a situation where the lowest net cost determination would be different for Navitus. We have worked hard to develop a model that removes any conflict of interest from our decision making process.

Attachments—Additional Questions for the Record

Subcommittee on Health
Hearing on
"Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"
May 9, 2019

Estay Greene

The Honorable Michael C. Burgess, M.D.

1. Something I find particularly concerning about our drug supply chain is the possibility of drug shortages. These can occur because of natural disasters, manufacturing issues, or business decisions. What are each of your respective companies doing to prevent drug shortages?

   As a payer, Blue Cross Blue Shield of North Carolina (Blue Cross NC) is not part of the drug supply chain and does not have an effect on drug shortages. However, Blue Cross NC closely monitors when these drug shortages occur to keep our members informed of potential impacts to their care and treatment.

2. With the success of 21st Century Cures we are beginning to see a remarkable number of treatments and potential cures moving through drug development pipelines. What is Blue Cross Blue Shield doing to prepare for the approval of these drugs to ensure that patients will be able to access and afford them?

   Blue Cross NC closely monitors the drug pipeline, including receiving information from manufacturers, to be ready and prepared when medication is approved. Blue Cross NC works with our network of pharmacies and providers to ensure contracts are in place as quickly as possible so members have cost-effective access to these new medications.

3. Yesterday, the Administration released a rule requiring manufacturers to include drug prices in direct-to-consumer (DTC) advertisements. This would shine a light on manufacturer drug pricing strategies and provide consumers more information about their prescription drug options. What would the effect of this type of price transparency have on Blue Cross Blue Shield and the overall market?

   Along with the Blue Cross Blue Shield Association (BCBSA), Blue Cross NC believes that disclosure of the list price will provide a catalyst for patients to discuss medications with their treating physician to determine if an equally effective, lower cost drug is available. In some cases, a conversation about affordability will lead to discussions about more affordable, alternative treatments for a patient, which will

lead to greater patient adoption of a therapy and improved adherence. We believe this new rule will have a positive effect on the overall market.

The Honorable John Shimkus

1. Given that most of the witnesses on the panel have referenced the role of creating value in the health care supply chain, please comment on: Existing areas where Congress or the Administration may have needlessly added to the cost that patients or the government pays for a particular product, service, or intervention. For example, do you have recommendations on how reforms to existing laws like Stark and the Anti-Kickback Statute could accelerate value-based contracting within Medicare and Medicare Advantage?

   One existing area where cost has been added is in Medicaid "best price" policy. Removing limits put on Medicaid "best price" to allow commercial payers to negotiate these contracts allows each entity, whether private or public, the ability to negotiate an agreement that meets the needs of the population they serve. Lifting this policy does not prevent Medicaid plans from attaining the same agreements.

2. How do we ensure that these value-based reforms benefit patients and protect taxpayers?

   A benefit of value-based reforms to patients is continued access to breakthrough medications at the lowest possible premium and out of pocket cost. For taxpayers, value-based agreements guarantee that dollars are spent on a cure or for a desired outcome. If a positive outcome is not achieved, dollars are refunded and taxpayers are not held responsible.

   Protections on initial pricing of medication should consider the value therapies will bring to patients that achieve outcomes. Prices should not be artificially inflated to cover costs for patients that do not have positive outcomes using the drug. If the pharmaceutical industry can increase prices to cover the risk of failure, the "value" of a value-based relationship disintegrates.

The Honorable Brett Guthrie

1. During the hearing, Blue Cross Blue Shield of North Carolina testified that some insulin products are excluded from the plan's formulary. How much will a plan beneficiary pay for an insulin product that is excluded from your plan's formulary?

   If a medication is approved through the formulary exclusion exception process, the member will pay a non-preferred brand copay or coinsurance in accordance with their benefit plan design. A member will pay the list price if the product is not approved through the exception process.

a. Will the amount the patient pays out-of-pocket for the insulin product count toward their deductible if they have one? Why or why not?

Yes

b. How many beneficiaries went through Blue Cross Blue Shield of North Carolina's step therapy protocol to try and get access to an insulin product that was excluded from the formulary for each of the past five years? For each year:

i. On average, how many different insulin products did an individual have to try before their request was approved to gain access to their preferred product?

1 product on average, consistent through all years.

ii. How many of these requests were approved?

YEAR	APPROVALS	DENIALS
2015	1118	712
2016	416	229
2017	727	420
2018	303	268
2019	Incomplete Data	Incomplete Data

iii. How much did an individual pay for the insulin product if the request was approved?

YEAR	PRICE PER DAY
2015	$1.64
2016	$1.69
2017	$2.15
2018	$2.37
2019*	$2.96**

* No rebate is available to pass through to members on these products at point of sale.

** Represents data YTD as of 8/7/2019 - average member cost share will

decrease through the year as deductibles are met.

iv. How long did it take for the request to be approved?

8.95 hours on average from submission of the provider's office to notification of approval. Authorizations are loaded within 1 hour of approval for pharmacies to process the claim.

v. Was the insulin product covered while the approval decision was pending?

No, but coverage can be retrospective if approved.

2. During the hearing, Blue Cross Blue Shield of North Carolina said that the company just removed an insulin product from its formulary mid-year, on April 1, 2019. The witness said that Blue Cross Blue Shield of North Carolina removed Basaglar because the company decided to pass-through rebates on insulin to its beneficiaries, and as a result, the company's preferred product, Lantus, was less expensive than Basaglar for beneficiaries. Previously, however, Blue Cross Blue Shield of North Carolina allowed beneficiaries the option of whether they wanted to use the Basaglar product—which had a lower list price—or Lantus. Why did Blue Cross Blue Shield of North Carolina remove Basaglar from its formulary entirely rather than continuing to give patients the option of choosing the lower or higher priced product?

   a. Why did Blue Cross Blue Shield of North Carolina previously think it was appropriate to give beneficiaries a choice between products, but now that rebates are passed through to the patient, decide that patients should not have that choice?

      Rebate pass through was not the only reason Basaglar was removed from the formulary. Blue Cross NC's decision to remove Basaglar from the formulary was made based on the clinical equality of Basaglar to Lantus, the number of long acting insulin products on Blue Cross NC's formulary, and the financial review of those products which is done at least annually.

      Pass through rebates allowed decision makers to worry less about the "sticker price" of products because members would now be subject to the sticker price, less the rebate in the deductible or their cost share portion of coverage. Since the clinical appropriateness of the medications is the same, Blue Cross NC's decision gave members access to the product with the lowest overall cost.

   b. How much of the rebate that Blue Cross Blue Shield of North Carolina receives for Lantus is passed through to the beneficiary at the point-of-sale?

This is proprietary information and cannot be shared.

c. Have the rebates, discounts, and/or fees that Blue Cross Blue Shield of North Carolina receives for Lantus changed at all since Blue Cross Blue Shield of North Carolina decided to pass-through rebates on insulin to the patient and remove Basaglar from the plan's formulary?

No.

d. Did all the patients that were taking Basaglar switch to Lantus or has Blue Cross Blue Shield of North Carolina received requests from beneficiaries to continue using Basaglar? If Blue Cross Blue Shield of North Carolina has received requests from beneficiaries to continue to use Basaglar, how many requests has it received and has the company granted these requests?

- Not all patients taking Basaglar switched to Lantus; patients also switched to other long acting insulins that are preferred products under the Blue Cross NC formulary such as Toujeo, Tresiba, and Levemir.
- Of the 129 patients that were on Basaglar prior to 4/1/19, 92 did not seek a formulary exception to continue using Basaglar.
- Of the 37 that requested a formulary exception to continue using Basaglar, 16 were granted approval and 21 were denied.

e. How much, on average, would a beneficiary pay for Basaglar before April 1, 2019, and how much, on average, would a beneficiary pay for Basaglar after April 1, 2019?

On average members paid $2.99/day for Basaglar Q1 of 2019. On average members paid $2.73/day for Basaglar Q2 of 2019. This number will decrease through the year as members meet their deductible.

Ascension

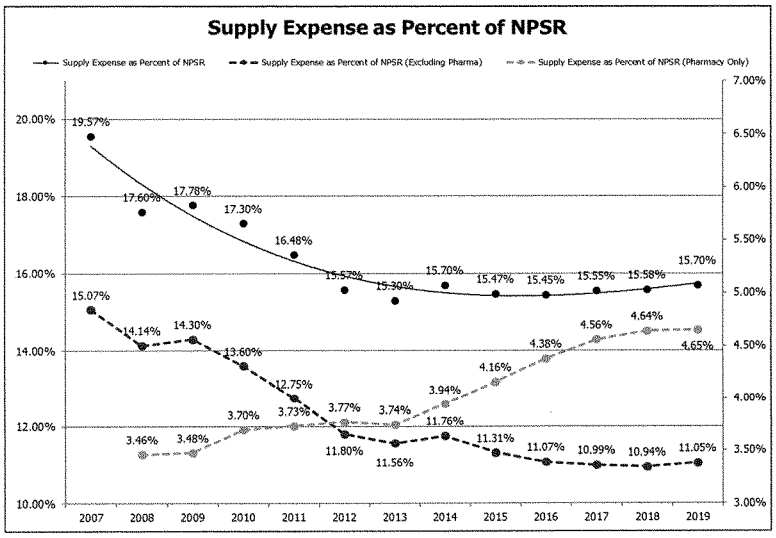
Subcommittee on Health Hearing: Follow Up Questions

Lynn Eschenbacher

The Honorable Joe Kennedy

Q1: You noted that Ascension experiences up to 40 new prices increased each week. What types of resources does Ascension have to use just to manage these price increases and how does this impact hospitals?

As mentioned in the testimony, managing the cost of our supply chain is critical for us to carry out our mission. For Ascension, drug costs are the fastest growing part of our supply chain and represent $1.2 billion in annual costs to our system – which continue to grow each year. At the time of the testimony, Ascension had to mitigate against a cumulative 34% increase in drug costs, totaling $564 million – and that's after 340B discount. Since the testimony, we have been able to update our inflation data to incorporate the most recent fiscal year. Based on the updated data, pharmaceutical inflation has attributed greater than $876M (40% cumulative increase) in additional costs over the last five years. To demonstrate the impact pharmacy has on a hospital supply chain, the below graph highlights how drug supply expense as a percent of NPSR has continued to increase as the non-drug supply expense percent has decreased.



As a large health system, a common misconception is that we are able to leverage our size to get significant discounts on drugs. While this is typically the case with the non-pharma supplies, pharmacy manufacturers are only willing to negotiate the price for about 50% of the drugs we buy. We have no leverage as these drugs are patent protected brand drugs or sole-source generics that create a lack of competition between manufacturers. They know this, and 80% of the manufacturers that we have contracts with do not lock in firm pricing for a full year.

In order to monitor and mitigate drug pricing increases, we must increase administrative time and cost to continuously monitor drug pricing and explore low cost alternative therapies that we can implement without compromising patient care. If an alternative therapy 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 involves clinical evaluations, physician buy-in, contracting for alternative, caregiver education, drug stocking, and updating of electronic medical records. During that time, we continue to absorb the higher price.

Q2: Can you share more about how drug shortages have impacted your patients and hospitals? Do drug shortages increase costs for hospitals?

Drug spend represents the fastest growing part of our supply chain and is utilized by nearly every patient during their visit or upon discharge. Therefore, one of pharmacy's primary goals as a health system is to ensure that hospitals have access to medications to ensure we get patients the right medications, at the right times. These drug shortages lead to an increase in hospital drug and administrative spend. More specifically, the drug shortages can lead to:

- Increased spend for medications due to switching to more expensive alternatives and purchasing off contract or through alternative channels
- Increased time and costs focused on the administrative tasks needed to identify and implement safe alternative therapies
- Increased risk for medication errors

Currently, Ascension is experiencing shortages on 187 medications, with 14 of those being deemed critical (18% of Ascension's critical drugs on shortage). This disruption in supply requires constant review and analysis, communication to the hospitals, exploration of clinically equivalent therapies, negotiation of new contracts when possible, and implementation of the new drug across the system. For Ascension, this requires a dedicated team that spends over 40 hours per week completing administrative tasks. In addition to the administrative costs, drug prices will typically increase as manufactures impose price increases for shortages where they may be the only alternative.

Q3 How much can patient out-of-pocket expenses change as a result of increased drug prices?

For hospitals, inpatient stays are generally reimbursed through fixed bundled payments that are set by payors in advance to cover the total cost of an admission. Generally, these bundled payment amounts are not adjusted during the year when costs go up. When drug costs go up, the bundle does not so as a health system we must make adjustments elsewhere to mitigate the rising costs and continue to deliver high quality care. Eventually, these increased costs affect consumers when they result in high premiums to cover the increased cost.

However, as patients transfer from the inpatient to the retail prescription setting, they begin to share in the rising drug costs. The continued new entrants of expensive medication therapies like specialty pharmacy (anticipated to account for 50% of the total drug spend by 2020) accelerates the growth in the prescription drug sector which is quickly becoming one of the fastest growing health categories. As the prescription drug economics continue to rise, insurers, government, and other payers will find it difficult to manage costs and it will result in increased cost sharing, increased member contributions to premiums, and potential elimination of health plans. In addition to the increasing spend on prescription drugs, patient outcomes will be impacted as their rising benefit cost will lead to reduced adherence as some will be unable to afford their chronic medications. This will put the patient at risk and could potentially lead to increased admissions to hospitals, resulting in a higher overall cost of care.

Q4: As a percentage, how large are the drug increases you have experienced in the past several years?

As highlighted in questions one, drug costs are the fastest growing part of our supply chain and represent $1.2 billion in annual costs to our system – which continue to grow each year. At the time of the testimony, Ascension had to mitigate against a cumulative 34% increase in drug costs, totaling $564 million – and that's after 340B discount. Since the testimony, we have been able to update our inflation data to incorporate the most recent fiscal year. Based on the updated data, pharmaceutical inflation has attributed greater than $876M (40% cumulative increase) in additional costs over the last five years. The following information highlights the year-over-year inflation percentage since 2015:

- FY15 = 11.2%
- FY16 = 9.8%
- FY17 = 6.3%
- FY18 = 6.8%
- FY19 = 4.5%

The Honorable Michael C. Burgess, M.D.

Q5: Something I find particularly concerning about our drug supply chain is the possibility of drug shortages. These can occur because of natural disasters, manufacturing issues, or business decisions. What are each of your respective companies doing to prevent drug shortages?

As a health system, one of our primary goals is to ensure that we have access to medications to ensure we get our patients the right medications, at the right times. Currently, Ascension is experiencing shortages on 187 medications, with 14 of those being deemed critical (18% of Ascension critical drugs on shortage). These drug shortages lead to an increase in administrative burden and hospital spend. More specifically, the drug shortages lead to:

- Increased spend for medications due to switching to more expensive alternatives and purchasing off contract or through alternative channels
- Increased time and costs focused on the administrative tasks needed to identify and implement safe alternative therapies
- Increased risk for medication errors

Currently, we are working with our distributors and contracted suppliers, as well as developing tools internally to help mitigate the risk of drug shortages. The Ascension contracting team works with our contracted distributors and suppliers to create a secured allocation program for select shortage products, whereby we work with suppliers to provide a dedicated allocation of critical products for our participants in times of shortage. Additionally, we are in the process of building a historical trend database that will allow us to predict when shortages will occur. Until this can be built, we have two full-time positions and data action analysts dedicated to managing shortages and backorders.

The Honorable John Shimkus

Q6: Given that most of the witnesses on the panel have referenced the role of creating value in the health care supply chain, please comment on: Existing areas where Congress or the Administration may have needlessly added to the cost that patients or the government pays for a particular product, service, or

intervention. For example, do you have recommendations on how reforms to existing laws like Stark and the Anti-Kickback Statute could accelerate value-based contracting within Medicare and Medicare Advantage?

The current regulatory framework created by the federal government for healthcare providers is overly complex, duplicative, and extremely burdensome. Hospitals, physicians, post-acute care providers, and other healthcare practitioners must dedicate far too much of their time to satisfying administrative regulatory requirements rather than caring for patients. We greatly appreciate and support the work that CMS has undertaken to reduce this regulatory burden through their Patients Over Paperwork Initiate.

Despite some progress that has been made, more works needs to be done. The American Hospital Association released a report that found hospitals must comply with more than 620 discrete regulatory requirements, costing hospitals, health systems, and post-acute care providers nearly $40 billion each year across the industry.[1] Notably, while the delivery of healthcare has modernized, HHS, CMS, and other agencies of the federal government continue to view and regulate healthcare as a volume-based system rather than a value-based delivery system where providers are increasingly taking risk for the care they furnish to their patients.

We believe Congress and the Administration can take a number of concrete steps to help reduce the burden on healthcare providers. Though not an exhaustive list, we strongly support the following regulatory reforms:

- **Promote delivery system transformation through**:
  - Expanded waivers of certain Medicare fee-for-service (FFS) regulations that hinder the broad implementation of delivery system reform models;
  - Center for Medicare and Medicaid Innovation (CMMI) reforms that would improve the uptake of transformational models of care; and
  - Modernization of fraud and abuse regulations—in coordination with the HHS Office of Inspector General (OIG), as appropriate—to promote the shift towards value-based, patient-centric care.

- **Reduce administrative burdens, redundancy, and unnecessary costs by**:
  - Removing redundancies and inaccuracies inherent to Medicare quality reporting programs by harmonizing program requirements and risk adjusting readmission and other outcome measures to account for sociodemographic factors. CMS should also continue the suspension of hospital star ratings from the *Hospital Compare* website until methodological flaws are fully addressed and suspend post-acute care quality reporting requirements associated with the IMPACT Act pending further provider engagement;
  - Providing regulatory relief under Medicare and Medicaid reimbursement systems, including through: reversal of the recent Medicare payment reduction and reporting mechanisms applicable to 340B drugs and program participants in favor of addressing the root causes of increasingly high drug prices; permanent non-enforcement of certain direct supervision requirements; permanent non-enforcement of the "96-hour rule" for critical access hospitals; adjustments to co-location requirements; increased flexibility around how hospitals advise patients on post-acute provider options; formal termination of the Pre-Claim Review Demonstration for home health agencies; increased coverage and payment for telehealth services in Medicare; and use of the original timeline for phasing-out Medicaid provider pass-through payments; and
  - Streamlining and simplifying Medicare health information technology requirements.

[1] Available at: http://www.aha.org/content/17/regulatory-overload-report.pdf

Regarding reforms to the Stark Law and the Anti-Kickback Statute, we have attached our White Paper entitled Legal Barriers: Inhibiting the Transition to Value-Based Care, which provides an in-depth examination of these issues. In summary, we believe strongly that our laws and regulations should support and protect clinical integration arrangements, as they can lead to better care and lower costs. While having appropriate protections against fraud and abuse, healthcare law and policy should encourage integration among hospitals, physicians, and other providers that establish incentive payments or shared savings programs to: (1) promote accountability for quality, cost, and overall care for patients; (2) manage and coordinate care for patients; or (3) encourage investment in infrastructure and redesigned care processes for high-quality and efficient care delivery for patients.

Q7: How do we ensure that these value-based reforms benefit patients and protect taxpayers?

Ascension is committed to a long-term vision of a sustainable, high-quality health system that serves individuals as whole persons throughout the course of their lifetime. As part of this, we strongly support the movement towards value-based care arrangements. It is crucial that, as we move forward with healthcare transformation, we do so with the patient's needs at the forefront. It is also vitally important that we address the rising cost of health care by moving away from fee-for-service models that reward volume of care to value-based models that support improving quality and reducing costs.

It is important that we continue to test new alternative payment models as we work toward finding the best methodologies for improving care that benefits patients while addressing rising costs by improving care coordinate and preventing more costly outcomes that result in increased use of the emergency department and the inpatient setting. While these models are being tested and evaluated, some delivery models are showing clear benefits. These include improving chronic disease management, better coordination of primary care services and the use of technology including improved information systems, remote patient monitoring, and telehealth services, which when managed appropriately can often facilitate early intervention in an exacerbation of a chronic disease that can prevent a costly inpatient stay and improve the quality of life for the patient.

It is also important that we manage prescription drug therapies carefully and appropriately. There is strong evidence that the delivery of medication therapy management by pharmacists is effective at improving care and lowering overall costs. Medication therapy management (MTM) is care provided by pharmacists with the goal of ensuring the most effective use of drug therapy and consists of five core elements designed to ensure the best therapeutic outcomes for patients. The five core elements include medication therapy review, a personal medication record, a medication-related action plan, intervention or referral and documentation and follow up. Studies have indicated that MTM can produce healthcare cost savings and a positive ROI for health systems.[2] Adherence to medication therapy is an important to ensure positive patient outcomes as well as lowering the overall cost of healthcare. Nationally, nonadherence costs the healthcare system an estimated $100 to $289 billion annually. Not only does nonadherence increase costs, but it also leads to poorer health outcomes for patients.[3] Pharmacist led MTM can directly impact these outcomes positively and reduce overall healthcare costs.

To facilitate the move toward value-based care arrangements, the federal fraud and abuse laws need to be modernized. These laws were written to protect against overutilization in FFS payment models where self-referrals and inducements can lead to higher payments from Medicare. Such protections make sense in FFS payment models. But the financial risk inherent to value-based payment models provides far stronger guardrails against overutilization and fraudulent practices. And appropriate use of quality performance metrics ensures

[2] https://www.cdc.gov/dhdsp/pubs/guides/best-practices/pharmacist-mtm.htm
[3] https://www.pharmacist.com/medication-adherence

protection against stinting and sub-standard care. Where fraud and abuse laws are a safeguard against practices that drive up costs *in a FFS system*, alternative payment models often create payment limits and quality thresholds for an entire episode of care, placing providers at risk for both costs and outcomes. In these models, if costs go up or quality goes down, participating providers may incur direct financial losses – or worse. These kinds of enforcement mechanisms provide stronger and more effective guardrails against increases in the volume and costs of services, or the decline in quality of care, than the fraud and abuse laws ever placed on the FFS system.

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August 9, 2019

The Honorable Frank Pallone
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20510

RE: Subcommittee on Health Hearing on "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"

Dear Chairman Pallone:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to respond to follow-up questions as part of the hearing before the U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health titled, "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain." The AMA remains strongly committed to advancing public policies that will increase access to affordable and medically necessary prescription medication by increasing competition, promoting transparency, reducing administrative burdens, and lowering costs for patients.

I have attached the AMA's responses to the committee's follow-up questions. We look forward to continuing to work with you on solutions to lower prescription drug prices and ensuring access to necessary medications for our patients.

Sincerely,

Jack Resneck, Jr., MD

Attachment

cc: Honorable Greg Walden, Ranking Member
Committee on Energy and Commerce

Honorable Anna G. Eshoo, Chairwoman
Subcommittee on Health

Honorable Michael C. Burgess, Ranking Member
Subcommittee on Health

The Honorable Frank Pallone
August 9, 2019

The Honorable Michael C. Burgess, MD

1. **Something I find particularly concerning about our drug supply chain is the possibility of drug shortages. These can occur because of natural disasters, manufacturing issues, or business decisions. What are each of your respective companies doing to prevent drug shortages?**

The AMA agrees that strategic focus should remain on addressing the current persistent shortages as well as developing contingencies to address those that may arise due to unforeseeable events, such as natural disasters. The AMA remains actively engaged in discussions to address shortages. We strongly support the work of the U.S. Food and Drug Administration (FDA) in this area and continue to work with their staff along with the U.S. Department of Homeland Security (DHS), Office of the Assistant Secretary for Preparedness and Response (ASPR), manufacturers, supply chain experts, as well as other members of the public and private sectors. The AMA has prioritized raising awareness that shortages must be addressed and all stakeholders must play a role in addressing current shortages and developing systematic contingencies. To address the drug shortage issue, the AMA supports policy, legislation, and/or regulation that:

- Encourages stakeholders in the drug supply chain to increase collaboration.
- Increases transparency along the pharmaceutical supply chain.
- Establishes plans for continuity of supply of vital medications, including the establishment of resiliency and redundancy in manufacturing capability.
- Reduces or removes regulatory hurdles and barriers while enhancing flexibilities.
- Incentivizes investment in expanded manufacturing production capacity for vital products.

Collaboration

The AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply. We urge stakeholders from the entirety of the drug supply chain and the FDA to work in a collaborative fashion to implement these recommendations.

Increase Transparency

The AMA strongly urges the FDA to require manufacturers to provide greater transparency regarding the drug manufacturing process from start to finish. Knowledge of the entire supply chain, including raw material suppliers, active pharmaceutical ingredient manufacturers and suppliers, distributors and distribution sites, as well as production locations of drugs, can provide the necessary metrics for much needed quality analysis and information regarding supply chain disruptions that contribute to medical product shortages and their causes. More information about the manufacturing process can inform the causes and anticipated duration of drug shortages and assist in shortage mitigation.

Continuity of Drug Supply

The AMA strongly supports conferring the FDA with enforcement authorities to ensure that drug manufacturers establish a plan for continuity of supply of vital medications and vaccines to avoid production shortages whenever possible. The continuity of supply plan should include the establishment of the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.

The AMA strongly supports the designation of drug shortages as a national security priority and the inclusion of vital drug production sites in the critical infrastructure plan. Several manufacturers were impacted by cyber events over the past year and product shortages were worsened by the recent hurricanes impacting Puerto Rico which demonstrate the need to evaluate risk and hazard and disaster response for drug and medical product manufacturing. The AMA urges the application of critical infrastructure policies to the drug shortage challenges clinicians, their patients, and families face each day.

Reduction in Regulatory Burden

The AMA strongly supports the FDA's effort to provide increased flexibilities and engagement when manufacturers have notified the Agency of a potential or actual drug shortage. The AMA continues to specifically support expedited facility inspections and the review of manufacturing changes, drug applications, and supplements that would assist manufacturers in mitigating or preventing a drug shortage.

Federal Policies, Market Forces, Investment Incentives

The AMA strongly supports the development of a comprehensive report on the root causes that also analyzes current manufacturing capacity, the number of manufacturers, mergers and consolidations, economic factors including federal reimbursement practices, as well as contracting practices by market participants on competition, access to drugs, and pricing. The AMA also urges careful consideration of federal health care program payment rates for drugs that are vulnerable to shortage. The Government Accountability Office identified low profit margins for drugs in shortage as a relevant contributing factor to persistent shortages. Carefully targeted policies to address potential underinvestment in vital products subject to intractable shortages should be evaluated.

The AMA strongly supports collaboration between the Federal Trade Commission (FTC) and the FDA during the evaluation of potential mergers and acquisitions involving pharmaceutical manufacturers and pharmacy benefit managers (PBMs). FTC consultation with the FDA can aid in determining the public health implications of mergers and acquisitions of manufacturers, including the potential impact on drug shortages. Likewise, careful attention to merger and acquisition activity that involves health plans and/or PBMs would be prudent, as consolidation of PBMs can limit contracting opportunities for pharmaceutical manufacturers. Where opportunities to sell products are limited, manufacturers may be pushed out of the space for certain drugs, sometimes leaving only one manufacturer in production for some drug products and increasing potential for drug shortages. Related to the foregoing, the AMA has expressed support for expanded resources and capacity at the FTC to more fully assess and evaluate the impact of mergers and consolidations in both the manufacturer and PBM spaces on competition as well as consumer access as part of the FTC's charge to advance consumer protection. Without oversight and intervention, drug shortages will exist into the foreseeable future if further consolidations occur reducing production capacity.

In support of the above recommendations, the AMA has presented at the National Academies of Science, Engineering, and Medicine (NASEM) as part of the drug shortages workshop, an American Society of Health-System Pharmacists (ASHP) drug shortages summit, an FDA listening session regarding their newly formed Drug Shortage Task Force, and in a public meeting hosted by the FDA, "Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions." We also submitted comments to the FDA public docket regarding the root causes of drug shortages and possible solutions outlining our policy and recommendations. Additionally, the AMA House of Delegates and members receives annual reports that update physicians on any current developments related to drug shortages and activities to address them.

The Honorable Frank Pallone
August 9, 2019

2. **Dr. Resneck, you mention in your testimony that you support physician access to accurate, real-time formulary and drug cost data at the point of e-prescribing. Express Scripts and others have created programs that can present some of that information to physicians so that they can engage in informed decision making with their patients.**

   Do physicians face any barriers to utilizing these programs during their patient visits? How integrated are existing programs in the workflow?

Yes, physicians face barriers in utilizing these programs during patient visits. First, these programs result in requiring a series of different stand-alone products for each PBM or health plan. Physicians need a non-proprietary system that seamlessly integrates into electronic health records (EHRs). Unfortunately, any technology solutions that provide drug pricing data for every patient in a physician's practice panel are years away from being widely available. Second, these programs need access to accurate data on formularies, prior authorization requirements, step therapy requirements, patient copayments, and health plan drug costs so that physicians can get patients treatments quickly and be good stewards of resources. Currently, pharmaceutical manufacturers, PBMs, and health plans are putting up barriers to making that information available even to the limited Real Time Benefit Tools (RTBTs) that exist. Thus, physicians currently lack accurate, granular, patient-specific formulary data at the point-of-care.

Formulary and benefit data must be seamlessly integrated within EHR systems, as well as reliable and sufficiently detailed (unlike currently available Formulary and Benefit batch files), to be widely adopted by physicians. Provision of accurate, current information about a patient's prescription benefit will enable physicians and patients to evaluate drug costs and consider possible alternative therapies when selecting a medication regimen. Drug price transparency at the point-of-care has the potential to reduce drug costs for patients. Additionally, and equally importantly, provision of these data within the e-prescribing workflow will ensure physician awareness and completion of prior authorization (PA) and step therapy requirements before a patient arrives at the pharmacy to pick up a prescription. Transparency of coverage restrictions in EHRs can thus prevent medication nonadherence and treatment abandonment. The 2018 AMA Prior Authorization Physician Survey reveals the magnitude of this problem, with 75 percent of physicians reporting that PA can lead to treatment abandonment.

The AMA supports the Centers for Medicare & Medicaid Services' (CMS) efforts to expedite industry implementation of RTBTs to support drug pricing transparency. However, the AMA disagrees with the specific approach detailed in the Medicare Advantage and Part D Drug Pricing Final Rule, which merely requires Part D plans to support a single RTBT that integrates with only one physician EHR/e-prescribing system. As such, physicians and their EHR vendors could presumably need to support a different RTBT for every Part D plan to have access to prescription benefit information for every patient treated by the practice. As projected by CMS in the proposed rule, this will be an overwhelming, expensive, and burdensome proposition for vendors and physicians and will discourage adoption of this technology. Expenditures in these proprietary tools will be particularly wasteful if CMS mandates a standard RTBT within the next few years, since vendors, physicians, and Part D plans will have to rebuild technology to support the mandated RTBT.

The AMA recommends that CMS require plans to support a single RTBT standard that will integrate with all EHR systems when made available. The National Council for Prescription Drug Programs (NCPDP) has been developing an electronic standard for the communication of real-time prescription drug coverage and pricing information, including therapeutic alternatives, between payers and prescribers over the past few years. The AMA participates in the NCPDP group involved in this effort and expects that a RTBT standard will be published by NCPDP within the next year.

payment policies should be structured so that federal health programs do not pay the full amount for drugs that are not clinically effective for patients.

The Honorable Frank Pallone
August 9, 2019

We believe that this approach will ensure that physicians have access to accurate, real-time formulary data across payers, without which this technology will not realize its full potential. We also note that in its current format, the draft NCPDP RTBT standard supports use of two different syntaxes (SCRIPT and Telecommunication standards). We have concerns that this will create interoperability challenges between EHR vendors and payers who are not using the same syntax. We therefore support a testing period after the initial publication of the NCPDP RTBT

standard to ensure seamless translation between the two different syntaxes and that any RTBT can provide physicians with accurate and complete prescription drug formulary and pricing data across all payers and patients.

a. **Follow-up: Are there any laws, regulations, electronic health record contracts, or other agreements that stand in the way of developers of these programs from sharing this information with physicians?**

As described above, current CMS regulations only require Part D plans to support a single RTBT that is required to integrate with only one physician EHR/e-prescribing system. As such, physicians and their EHR vendors could presumably need to support a different RTBT for every Part D plan to have access to prescription benefit information for every patient treated by the practice. Thus, while not a barrier for developers, the AMA is concerned about adding unnecessary administrative burden and costs to physician practices.

We are not aware of any legal or regulatory barriers to the provision of patient-specific formulary data, out-of-pocket costs, and therapeutic alternatives to physicians in their EHRs. These data are already provided to pharmacies in claim adjudication and should therefore be readily available to be disclosed in physician EHR systems. Additionally, several of the currently available proprietary RTBTs already offer this information to physicians in their EHRs, although we must again stress that these tools are of limited utility to physicians because they do not cover all payers or patients.

However, we have heard anecdotally from some industry stakeholders that the restrictions and protections in contracts and trade agreements between pharmacy benefit managers (PBMs) and pharmacies prohibit the disclosure of the amount paid by the PBM to the pharmacy for a patient's medication, as this would reveal proprietary contract information. We find this claim troubling at a time when our nation is transitioning to value-based care (VBC) and risk-based payment models. Under these newer payment systems, physicians are held accountable for the total costs of a patient's health care, including prescription drugs. Without access to a drug's overall costs, including the plan's responsibility, the physician will not be able to accurately assess true treatment costs. This will serve as a significant barrier to physicians' success in VBC arrangements. For a RTBT to be successful, it must not only provide information for every patient in a physician's care, regardless of PBM or other payer, but also report complete pricing data, including both patient and payer responsibilities for a particular drug. It is imperative that RTBTs display complete drug pricing data to physicians to support our nation's move to VBC. Without this capability, the full value of RTBTs will not be realized.

The Honorable John Shimkus

1. **Given that most of the witnesses on the panel have referenced the role of creating value in the health care supply chain, please comment on: Existing areas where Congress or the Administration may have needlessly added to the cost that patients or the government pays for a particular product, service, or intervention. For example, do you have recommendations on how reforms to existing laws like Stark and the Anti-Kickback Statute could accelerate value-based contracting within Medicare and Medicare Advantage?**

The Honorable Frank Pallone
August 9, 2019

The health care system is moving to a world that pays health professionals to manage episodes of patient care in a more comprehensive way. However, this approach to payment can run afoul of the fraud and abuse laws. For example, even if the primary purpose of an arrangement is to improve patients' health outcomes, as long as one purpose of the arrangement's payments is to induce future referrals, the arrangement may violate the fraud and abuse laws (e.g., an arrangement that pays for a nurse coordinator to coordinate a recently discharged patient's care among a hospital, physician specialists, and a primary care physician may induce future referrals to the primary care physician to avoid an unnecessary readmission to the hospital).

Fostering the shift to alternative payment models (APMs) has necessitated reviewing and, in some situations, updating fraud and abuse laws to ensure that they do not unduly impede the development of value-based payment. Through specific statutory authority, both the CMS and the Office of Inspector General (OIG) have deemed it necessary to waive the requirements of certain fraud and abuse laws to test the viability of innovative models that reward value and outcomes.

Outside of those models, however, the fraud and abuse laws may still pose barriers to initiatives that align payment with quality and improve care coordination. Tying compensation to the value of care provided, equipping providers with tools to improve care, and investing in tools to clinically and financially integrate all may run afoul of these laws. For example, the Stark law impedes sharing needed resources between multiple physicians caring for the patient which prohibits physicians from coordinating care on behalf of their patients. Instead, the patient, in addition to dealing with the physical and emotional aspects of a disease or condition, must also attempt to coordinate their own care in a fragmented and siloed system. Placing the obligation on the patient to know how to properly manage follow-up care without the assistance of their physician or care coordinator may have a negative impact on patient care and the physician-patient relationship.

With value-based contracting, the anti-kickback statute potentially prevents health industry companies from providing health care providers with a bundle of services to achieve a specific clinical outcome and from paying a rebate if the outcome was not achieved. For example, it may make perfect clinical and logical sense to bundle services such as technology, consulting, training, and patient monitoring that cover the different ways in which a company may contract with health professionals. Discounts in connection with a bundled sale, however, do not qualify under existing safe harbors because safe harbor protection only exists for services, which are reimbursed by the same federal health care program using the same methodology, which could exclude the type of value-based service bundle that a company wishes to offer in the example.

Moreover, the existing warranties safe harbor limits any warranty to the cost of the item itself. Thus, the current safe harbor does not cover, for example, payment for corrective services if the targeted clinical outcome under a value-based contract is not achieved. Nor does the existing safe harbor allow manufacturers flexibility in determining the types of warranties that could be offered for products that do not work as specified (e.g., reimbursement of copayments or new products in exchange for damaged or defective products).

To ensure that value-based reforms benefit patients and protect taxpayers, the AMA has urged Congress and the Administration to create a Stark exception and anti-kickback safe harbor to facilitate coordinated care and promote well-designed APMs. This exception should be broad, covering both the development and operation of a model to allow physicians to transition to an APM model, and provide adequate protection for the entire care delivery process to include downstream care partners, entities, and manufacturers who are linking outcomes and value to the services or products provided.

The Honorable Frank Pallone
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2. How do we ensure that these value-based reforms benefit patients and protect taxpayers?

The reforms outlined above along with the recommendations that the AMA has advanced to support competition, transparency, and reduction in administrative burdens, will drive value, costs savings and improved outcomes. How? Patients will receive medically appropriate medication when their conditions are less acute or advanced; patients will receive care in lower cost sites of care as medication adherence should correlate with reduction in emergency department visits and hospitalizations; care coordination costs will be reduced and clinical staff will be able to provide medical care instead of complete paperwork; and, duplication and redundancies will also be substantially reduced.

In addition to the broader value the policies AMA is advocating will bring, the AMA believes in the context of value-based pricing of pharmaceuticals, "value" should be regarded as a comprehensive assessment of a range of factors that truly determine a product's value to the marketplace, including patients. In addition to strong consideration of clinical outcomes as an indicator of value, the AMA encourages a value assessment that also weighs factors such as cost, comparative effectiveness research, toxicity/side effects, novelty, budgetary impacts, incremental cost-effectiveness, and impacts on patients such as long-term benefits, patient individual budget, impact on caregivers, variation of clinical response in different patient populations, and the ability of patients to return to work.

A comprehensive review of all factors relevant to determining a drug product's true value will help assure patient affordability, limit system-wide budgetary impact, and determine appropriate payment amounts for those products that incentivize innovation by pharmaceutical manufacturers, ensure that patients have access to the critical drug product they need, and avoid situations where a product's success justifies a price that patients and the system simply cannot afford. Importantly, value-based prices of pharmaceuticals should be determined by objective, independent entities. Ultimately, initiatives to determine value-based pricing for pharmaceuticals should aim to ensure patient access to necessary prescription drugs and allow for patient variation and physician discretion.

The AMA recognizes that the concept of "value-based pricing" can mean different things to different players in the pharmaceutical marketplace. The AMA is concerned about conversations surrounding "value-based pricing" that really mean payment contracts negotiated on clinical outcomes only, without consideration of other important factors that impact the true value of a drug to the marketplace. Value-based prices of pharmaceuticals should be evidence-based and be the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, post-marketing safety and efficacy data, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes. As such, clinical outcomes are an incredibly important piece of the value equation when discussing payment policies for pharmaceuticals. However, the AMA believes strongly that a number of other factors need to be considered in concert in order to determine the true "value" of a drug to physicians, patients, and the health care system and to arrive at an appropriate, value-based price for the product in question. Furthermore, it is not clear that purchasing contracts based on outcomes alone are achieving any measurable savings for those payers that have entered in to them, showing the need for additional transparency in this space.

In fact, in the case of products that successfully demonstrate clinical effectiveness, outcomes-based pricing could even be used to justify extremely high prices. Even for pharmaceuticals that do not meet outcomes metrics and warrant the payment of retrospective rebates, such outcomes-based contracts do not result in a lower list price for the drug in question. Importantly, patients do not reap the rewards of reduced out-of-pocket costs under outcomes-based contracts: patients incur costs at the point-of-sale, and outcomes-based contracts are not structured in a way to enable patients to enjoy savings up front. Overall, the AMA believes that federal drug payment policies should be structured so that federal health programs do not pay the full amount for drugs that are not clinically effective for patients.

Richard Ashworth

Attachments—Additional Questions for the Record

Subcommittee on Health
Hearing on
"Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"
May 9, 2019

Richard Ashworth

The Honorable Michael C. Burgess, M.D.

1. Something I find particularly concerning about our drug supply chain is the possibility of drug shortages. These can occur because of natural disasters, manufacturing issues, or business decisions. What are each of your respective companies doing to prevent drug shortages?

Walgreens keeps our patients' health and well-being at the forefront of dealing with drug shortages. Under such circumstances, we work with our manufacturer and supplier partners to directly communicate as to the incidence, nature and breadth of any pending drug shortage and ways to initiate rapid reaction and mitigation strategies.

Walgreens utilizes our extensive network of stores to balance inventory and better mitigate supply issues from region to region. This involves frequent communication between our local and central teams, inventory coordination, and travel and distribution logistics to ensure timely arrival and availability of product. We also work closely and proactively with our patients and their physicians to create mitigation plans and recommend alternatives to help prevent any interruption in therapy.

The recent shortage for Angiotensin II Receptor Blockers (ARBs) to treat high blood pressure made this scenario all-too-real for our patients, and it presented an increasingly difficult challenge as more and more ARB lots became affected as well as other alternative therapies. We successfully explored and activated all available secondary sources to maximize our ARB supply, and we helped our patient's continue on their therapy without interruption.

Additionally, the potential for vaccine shortages is an ever-present challenge, as disease prevention and outbreak management create urgency. As part of our regular forecasting and planning, Walgreens utilizes logistics, surveillance and data to more accurately distribute product to areas where the potential for shortages are greatest.

Richard Ashworth

The Honorable John Shimkus

1. Given that most of the witnesses on the panel have referenced the role of creating value in the health care supply chain, please comment on: Existing areas where Congress or the Administration may have needlessly added to the cost that patients or the government pays for a particular product, service, or intervention. For example, do you have recommendations on how reforms to existing laws like Stark and the Anti-Kickback Statute could accelerate value-based contracting within Medicare and Medicare Advantage?

The U.S. healthcare system is transforming from one that incentivizes volume to an integrated system focused on value. Addressing barriers to this transformation requires far more work than simply re-ordering the way we pay for and deliver care. Alternative value arrangements and other activities that improve outcomes and save money should be encouraged by eliminating barriers.

The Anti-Kickback Statute (AKS) and the Physician Self-Referral or "Stark Law" should be examined by Congress with the goal of removing or reforming barriers to allow for new and innovative patient-centered value arrangements that can deliver on the promise of improved outcomes and cost savings, while also protecting against fraud. We welcome the opportunity to work with the Subcommittee on specific reforms in these areas.

2. How do we ensure that these value-based reforms benefit patients and protect taxpayers?

From the perspective of a pharmacy and healthcare company, Walgreens believes to truly change the current system, patient-level information related to pricing must be absolutely transparent, democratized and open source. This concept can be best envisioned through the complete restructuring of the pharmacy claims process to make it more transparent and non-monetized.

This can be achieved with the creation of open-source drug benefit design standards to establish a digital gateway that gives patients, prescribers and pharmacists a faster and easier way to search and compare drug prices, as well as provide key benefit design information (e.g., therapeutic alternatives) at the individual patient level. An open-source benefit design would encourage the private sector to bring innovation and rapid adoption of digital engagement to the government market. Additionally, it would ensure price and benefit data are shared across the patient's care team with easier, open access—versus how it is currently with data closely held and managed by health plans and PBMs as proprietary. Finally, a standardized open-source benefit design would ensure patient privacy is protected under the existing framework of HIPAA.

Richard Ashworth

The Honorable Gus M. Bilirakis

1. In your experience, what are the major disruptors to medication adherence?

The simple answer is cost. Out-of-pocket prescription drug cost is a key predictor of medication adherence. According to a recent IQVIA study, patients abandoned 21 percent of all prescriptions for branded drugs processed by pharmacies in the United States in the fourth quarter of 2017.[1] Another often-cited study found that prescriptions with copayments between $40 and $50 and those greater than $50 were almost 3.5 times to nearly 5 times more likely, respectively, to be abandoned by patients than prescriptions without copayments.[2] Finally, a study conducted by Walgreens found that patient OOP cost is the most significant predictor of abandonment and primary medication non-adherence.[3] Specifically, the study found the abandonment rate for Zostavax increased when copays were above $15, and increased substantially when copays were above $50.[4]

Medication non-adherence is a widespread problem among Americans taking prescription medications, and is a growing concern because of mounting evidence of its prevalence and association with adverse outcomes and higher costs of care. Up to one-half of the 187 million Americans taking prescription drugs do not take their medications as prescribed.[5] According to a study by the Network for Excellence in Health Innovation (NEHI), the costs of medication non-adherence are enormous, estimated at nearly $300 billion annually.[6] Medication non-adherence costs over $100 billion a year in excess hospitalizations; non-adherent diabetes and heart disease patients have significantly higher mortality rates; approximately 90,000 hypertensive patients die prematurely every year because of poor medication adherence; and 25 percent of all emergency room visits are the result of non-adherent asthma patients.[7]

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[1] IQVIA Institute for Human Data Science, *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*, April 2018.
[2] Shrank WH, Choudhry NK, Fischer MA, Avorn J, Powell M, Schneeweiss S, et al. The Epidemiology of Prescriptions Abandoned at the Pharmacy. Ann Intern Med. 2010.
[3] Akinbosoye OE, Taitel MS, Grana J, and Macpherson C. Factors Associated with Zostavax Abandonment. Am J Pharm Benefits. 2016.
[4] Ibid. Patient abandonment was 1.66 times higher at copay levels between $15-$34.99, and 3.27 times higher at copay levels between $50-$64.99.
[5] National Council on Patient Information and Education. "Accelerating Progress in Prescription Medicine Adherence: The Adherence Action Agenda. A National Action Plan to Address America's 'Other Drug Problem.'" October 2013.
[6] Network for Excellence in Health Innovation, "Bend the Curve: A Health Care Leader's Guide to High Value Health Care." 2011.
[7] Ibid.

Richard Ashworth

As the Subcommittee on Health examines ways to lower drug prices and increase transparency, it should give great weight to the dynamic effects that medication adherence has across the health care system for both patients and spending. Walgreens stands ready to assist in this effort with the medication and healthcare expertise that only a company like ours can possess.

Leigh Purvis

Attachments—Additional Questions for the Record

Subcommittee on Health
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Leigh Purvis

The Honorable Michael C. Burgess, M.D.

1. Something I find particularly concerning about our drug supply chain is the possibility of drug shortages. These can occur because of natural disasters, manufacturing issues, or business decisions. What are each of your respective companies doing to prevent drug shortages?

2. Yesterday, the Administration released a rule requiring manufacturers to include drug prices in direct-to-consumer (DTC) advertisements. This would shine a light on manufacturer drug pricing strategies and provide consumers more information about their prescription drug options. What would the effect of this type of price transparency have on Blue Cross Blue Shield and the overall market?

The Honorable John Shimkus

1. Given that most of the witnesses on the panel have referenced the role of creating value in the health care supply chain, please comment on: Existing areas where Congress or the Administration may have needlessly added to the cost that patients or the government pays for a particular product, service, or intervention. For example, do you have recommendations on how reforms to existing laws like Stark and the Anti-Kickback Statute could accelerate value-based contracting within Medicare and Medicare Advantage?

2. How do we ensure that these value-based reforms benefit patients and protect taxpayers?

Leigh Purvis's Response:

AARP supports efforts to move towards value-based care, including aligning the price of a drug with the value that it provides rather than continuing to allow drug manufacturers to set prices on

the basis of what the market will bear. While AARP broadly supports the concepts behind value-based purchasing arrangements, we also recognize that implementation may be challenging.

For example, AARP is aware that there is no universal definition of value, nor is there consensus on the standards and data that should be used when evaluating the value of prescription drugs. AARP is also concerned by research indicating that there is little evidence that value-based purchasing results in lower spending or better quality for patients.[1] As such, we urge Congress to carefully consider the use of value-based purchasing tools and ensure that they are only utilized when there is strong clinical evidence to support their use.

AARP also urges that any value-based purchasing arrangements share savings with beneficiaries directly, such as automatically reducing cost-sharing for beneficiaries who are taking the affected drugs.

In addition, AARP strongly believes that robust consumer safeguards must be included in efforts to pursue value-based purchasing arrangements for prescription drugs. Appeals processes should be transparent, easy-to-understand, and fair in order for them to function as a true recourse for enrollees. Congress should also regularly revisit and modify processes as needed to ensure appropriate beneficiary access.

We also recommend that Congress establish a transparent, comprehensive, and publicly available monitoring process for any value-based purchasing agreements. As part of the monitoring process, AARP encourages Congress to identify formal procedures for regularly engaging and involving beneficiaries and their advocates, including tools such as patient experience surveys and focus groups.

Further, given that value-based purchasing agreements are intended to help reduce prescription drug and taxpayer spending, AARP believes that any new prescription drug payment model should allow for lower reimbursement for drugs that are less effective than comparable drugs. In addition, higher reimbursement should be based on clear and convincing evidence that a drug is significantly more effective.

AARP also remains mindful that value-based purchasing agreements remain in their infancy and that meaningful savings could take years or decades to materialize.[2] Consequently, AARP continues to believe that additional administrative and legislative reforms are needed in order to reduce drug costs for beneficiaries and taxpayer-funded public programs. Such reforms could include secretarial negotiation, allowing for the safe importation of prescription drugs from Canada and other select nations, and curtailing anti-competitive behaviors that deter generic entry into the market.

The Honorable Gus M. Bilirakis

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[1] E. Seeley and A. S. Kesselheim, *Outcomes-Based Pharmaceutical Contracts: An Answer to High U.S. Drug Spending?* The Commonwealth Fund, September 2017.
[2] N. Bisserbe, "For new Trump Drug Plan, a Cautionary Tale in Italy," Wall Street Journal, April 17, 2018.

Leigh Purvis

1. With Florida's traditionally higher senior and Veteran populations, lowering prescription drug prices is very important to me.

    - To that end, Florida recently passed a law to allow for prescription drug importation. Can you discuss the benefits and risks of prescription drug importation-assuming Federal approval, what can Florida do to best position itself for success?

Leigh Purvis's Response:

AARP supports the safe, legal importation of less expensive prescription drugs from Canada and other countries as one step that will help lower costs and add competitive pressure on drug makers to lower the prices they set in the U.S.

According to Food and Drug Administration (FDA), the US imports more than 40 percent of its finished drugs and 80 percent of its active pharmaceutical ingredients.[3] In addition, FDA has repeatedly and safely imported drugs from other countries in response to US drug shortages.[4] Further, the agency recently proposed a single global development program that would allow for simultaneous drug approvals by multiple regulators,[5] an extremely strong indication that other countries have equally safe regulatory systems.

AARP is also mindful that most of the concerns about drug importation are based on individuals who purchased drugs from questionable websites. Florida's new law would ensure that FDA is appropriately engaged in the importation process and could actually help reduce such events by ensuring that struggling patients can purchase less expensive but equally safe and effective imported drugs at their usual pharmacy.

AARP strongly supported bipartisan legislation in Florida, Colorado, Maine, and Vermont to allow importation in those states. We believe it is critical that states that pass such legislation work closely with FDA to ensure that these laws can take effect in a manner that safely achieves the savings that were intended and makes prescription drugs more affordable and accessible to older Americans.

Finally, AARP is aware that the FDA has long had the authority to approve importation plans but only done so under limited circumstances. Consequently, we were pleased that the Trump Administration has agreed that lower priced drugs can be safely imported and that the FDA should use its full authority under law to help American consumers.

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[3] https://www.fda.gov/vaccines-blood-biologics/international-activities/foreign-inspectional-collaborations
[4] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm292658.htm
[5] https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/advancing-toward-goal-global-approval-generic-drugs-fda-proposes-critical-first-steps-harmonize

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