

**EXAMINING THE ACTIONS OF DRUG COMPANIES
IN RAISING PRESCRIPTION DRUG PRICES**

HEARING
BEFORE THE
**COMMITTEE ON
OVERSIGHT AND REFORM**
HOUSE OF REPRESENTATIVES
ONE HUNDRED SIXTEENTH CONGRESS

FIRST SESSION

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JANUARY 29, 2019
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**EXAMINING THE ACTIONS OF DRUG COMPANIES
IN RAISING PRESCRIPTION DRUG PRICES**

Tuesday, January 29, 2019

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

The committee met, pursuant to notice, at 11:49 a.m., in room 2154, Rayburn House Office Building, Hon. Elijah Cummings (chairman of the committee) presiding.

Present: Representatives Cummings, Maloney, Norton, Clay, Lynch, Connolly, Krishnamoorthi, Raskin, Rouda, Hill, Wasserman Schultz, Sarbanes, Welch, Speier, Kelly, DeSaulnier, Khanna, Ocasio-Cortez, Pressley, Tlaib, Jordan, Amash, Massie, Meadows, Hice, Grothman, Comer, Cloud, Gibbs, Higgins, Norman, Roy, Miller, Green, and Armstrong.

Chairman CUMMINGS. Without objection, the chair is authorized to declare a recess at any time. Welcome to the first hearing of the Committee on Oversight and Reform for the 116th Congress. Before I begin, I want to thank Ranking Member Jordan and his staff for agreeing to accommodate this hearing. I know that we are taking a lot of time today, but I truly believe this is one of the most important issues facing our constituents, and it is one that demands immediate, immediate attention. I will now recognize myself for an opening statement.

Today we will examine the actions of drug companies in raising prescription drug prices in the United States, as well as the effects of these actions on the Federal and state budgets, and on American families.

Before we begin, I acknowledge that there is a lot going on right now here on Capitol Hill and across the country. Until last Friday, the Federal Government was in the midst of the longest shutdown in United States history. Hundreds of immigrant children and possibly many more are still separated from their families. The latest of President Trump's long-time advisors has been indicted on criminal charges.

But today, for our first hearing, I wanted to focus on one of the biggest problems facing American families across the country. The actions of drug companies that have been aggressively increasing prices on existing drugs and setting higher launch prices for new drugs, all while recording windfall profits.

Two weeks ago, the committee launched an investigation into the prescription drug prices to determine why drug companies are increasing prices so dramatically, how drug companies are using the proceeds, and what steps can be taken to reduce drug prices.

Our first witness today is not President Trump's personal lawyer, Michael Cohen. No, it is not Michael Cohen. It is not someone from

the White House or even someone from the Trump administration. Contrary to what some have claimed, that never was planned.

The first witness to testify before the Oversight Committee is Antoinette Worsham. Ms. Worsham is a working mother—listen up—whose daughter died, 22-year-old daughter died, tragically, when she could not afford to pay for the insulin she needed to treat her diabetes, and instead began to ration her medicine. It would have cost \$1,000 for three months of insulin. She died. And I know Ms. Worsham will share her story, and it is not easy to testify, but as I said to her, I thank her for taking her pain, turning it into her passion to do her purpose.

I also want to thank you for being here to share your family's story with us. You are not alone. Researchers at Yale University recently found that one in four patients with type 1 or type 2 diabetes, and I quote, "have reported using less insulin than prescribed," end of quote. So when you testify here today, you are representing thousands upon thousands of your fellow Americans who are suffering from the same worsening problem.

I also want to thank our other witnesses for being here with us today. We are grateful to have Dr. Catherine Georges of AARP to speak on behalf of America's seniors. And I want to thank all the members of—I asked my staff who were all those people in the red, and I am glad to see you all.

We also value the expert testimony of Dr. Gerry Anderson and Dr. Aaron Kesselheim, and Dr. Avik Roy, for being with us today.

I have been waiting a very long time to hold this hearing. For the past decade, I have been trying to investigate the actions of drug companies for all sorts of drugs, old and new, generic and brand name. We have seen time after time that drug companies make money hand over fist by raising the prices of their drugs, often without justification, and sometimes overnight, while patients are left holding the bill.

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

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

We all recognize that research and development efforts on groundbreaking medications have made immeasurable contributions to the health of Americans, including new treatments and cures for diseases that have affected people for centuries. But the bottom line is that the ongoing escalation of prices by drug companies is simply unsustainable.

This is a matter literally of life and death, and we have a duty to act now. Our constituents are demanding it, and I am grateful that we are finally starting down the road with this hearing.

Before I go on, I would like to enter in the record—yield to the—before I yield to Mr. Jordan, I would like to enter into the record

letters the committee has received in recent days from a variety of organizations, including the American Medical Association, the American Society of Health-System Pharmacists, and the Association for Accessible Medicines.

All of these groups have written to express their concerns about the impact of high prescription drug prices on their members and the American healthcare system. I ask unanimous consent that these letters be entered into the record. So ordered.

Chairman CUMMINGS. I now recognize—I am about to recognize the gentleman, Mr. Welch, but let me just say this. I talked about when I was in the hospital, Mr. Ranking Member, but when I was in the—I will never forget. On my third week, when I was about—when a lady that had been in the hospital with me, and she was an elderly lady, and she was about to get out of the hospital. And I said, “You leaving today?” She said, “Yes, I am leaving today. I said, Oh, Miss Mary, you should be happy that you are leaving today.” And then she started crying. This is at Johns Hopkins. I said, “Why are you crying?” She said, “I am crying because they had to treat me at Hopkins, but now when I am leaving, I can’t afford the cure. I can’t afford the medicine.” And so, I will never forget her, and we will fight for her.

Mr. Welch, I yield to you for two minutes.

Mr. WELCH. Thank you, Mr. Chairman. Mr. Chairman, Pharma justifies its highest prices in the world by perpetuating two myths: First, they warn in very solemn tones that if we negotiate prices, it will result in price fixing. Mr. Chairman, we already have price fixing. Pharma fixes the prices whenever they want, as high as they want, and as often as they want.

Second, Pharma claims that the high prices are essential to innovation. If that is so, Mr. Chairman, why is it, why is it that Pharma spends more on advertising than research? Why is it that Pharma spends more on stock buybacks than it does on research? And why is it that Pharma spends more on mergers and acquisitions than they do on research? And the sad truth is that Pharma, for all the good it does with life-extending and pain-relieving drugs—and my family has benefited from that—is holding all of our good constituents hostage to the universal desire each of us has to help a loved one through an illness or to cope with a chronic condition.

Mr. Chairman, consider some of the disgraceful tactics that Pharma has employed to fix high prices. Renting a patented drug to a Native American Tribe to assert sovereign immunity to block generic competition, imposing a gag rule on our local pharmacists so they can’t tell a customer that it is cheaper to pay cash than to pay the deductible. Evergreen, the practice of making the ever smallest cosmetic change to extend the patent monopoly. Paying generic manufacturers to keep their lower cost product off the market so they can extend their monopoly.

The maneuvers are endless, they are relentless, and they are unconscionable. And our mission, Mr. Chairman, both sides of the aisle, restore competition, restore transparency, and lower prices.

I yield back.

Chairman CUMMINGS. I want to thank the gentleman for his statement.

I yield to the distinguished ranking member of our committee, Mr. Jordan.

Mr. JORDAN. I thank you, Mr. Chairman. And I want to welcome our witnesses as well. I have had numerous conversations with Dr. Roy. Dr. Anderson has been in front of, in the previous Congress, the Subcommittee on Healthcare, has been in front of our committee. We appreciate you being here today with us.

And then, of course, Ms. Worsham, we appreciate you coming from the Buckeye state and what your family has been through. And we look forward to hearing from all of you here in just a few minutes.

There are few issues more in need of the committee's attention than this one. One thing that the chairman, President Trump, and I all have in common is that we are committed to finding reforms that will improve access and affordability with respect to prescription drugs. I hope that Chairman Cummings will view us as partners in this endeavor.

But I am concerned. I am concerned. Earlier this month, the majority launched an investigation into pharmaceutical companies' pricing models without minority consultation, and without any indication of their scope or plans other than saying that they would be dragging in pharmaceutical CEOs in the coming months for testimony. I feel this does not signal a willingness to find answers, but an attempt to score political points.

Democrats wrote to 12 pharmaceutical companies asking for detailed information about their pricing structures and supply chain management. Once again, it seems the Democrats are eager to blame the private sector when the answer, I think, is far more complicated. The greatest healthcare innovations in the last 100 years happened in America, and they happened not because of government dictates, but as a result of tireless individuals having the freedom to experiment and compete and improve all of our lives.

The problem is not that the free market has failed us; it is that government interventions in the market have distorted incentives, created barriers to competition, and left things in a mess. The Democrats' last grand idea for fixing healthcare, ObamaCare, was a colossal failure that we will be trying to repair for the foreseeable future.

We were told all kinds of things about ObamaCare. I call them the eight lies of ObamaCare. Like your plan, keep your plan. Remember that one? Like your doctor, keep your doctor. We were told premiums were going to decline. The President of the United States at the time told us premiums would decline, on average, \$2,500. We were told deductibles would decline. Remember this one? We were told the website was going to work. We were told the website was secure. We were told that these co-ops that were created, 22 of them, were going to be the grand all, be all, and yet every single one of them, with the exception of one, went bankrupt.

Rather than trying to pretend that more bureaucracy is the answer, we need to take a hard look at government's role in rising prices. We must rethink regulations distorting prices and ensure that adequate competition happens in the marketplace. We also need to reevaluate the manner and scope of the monopolies the

government grants to pharmaceutical companies in the form of patents and FDA exclusivities.

What was envisioned by our Founders as a limited guarantee to profit from your invention has been distorted into an evergreen right to broadly exclude others from selling similar drugs.

For the past two Congresses, I chaired the subcommittee with jurisdiction over healthcare. This is an important subject, and I look forward to digging into it. At the subcommittee, we did important work on waste, fraud, and abuse in public health programs like Medicaid and Medicare. This work should and must continue. And I hope, I hope that it can proceed on a bipartisan basis. We will never succeed in delivering reforms to the American people if all possible solutions are not on the table.

Mr. Chairman, I look forward to this hearing, and I hope that, going forward, we can work together to make progress on this important issue. I yield back.

Chairman CUMMINGS. I want to thank the ranking member for his statement. I guarantee you that we will act in a bipartisan way, because we have made a commitment to our constituents to address this problem. We don't want to see anybody else die needlessly. We don't want to see anybody else suffer. So I promise you, you have got my word on that.

All members will have 10 legislative days in which to submit opening statements for the record.

Today we welcome five witnesses to the committee. Ms. Antoinette Worsham is the mother of two insulin-dependent daughters who has traveled from Cincinnati, Ohio, to share her story with us.

Dr. Catherine Alicia Georges is the national volunteer president of the AARP, and a registered nurse who is the chair of the Nursing Department at Lehman College, the City University of New York. And Dr. Georges, I must tell you that having spent some time in the hospital, I have gained a new appreciation for nurses, and I am serious about that.

Dr. Aaron Kesselheim, an Associate Professor of Medicine at Harvard Medical School and a primary care physician at Brigham and Women's Hospital.

Dr. Gerard Anderson is a Professor of Health Policy and Management at Johns Hopkins University. Johns Hopkins is located smack-dab in the middle of my district. I am glad to have you here.

And Dr. Avik Roy is the president of the Foundation for Research on Equal Opportunity, a think tank that focuses on expanding opportunities for those with incomes below the U.S. median.

And pursuant to committee rules, all witnesses who appear before us today must be done under oath. I now ask each of you to stand and raise your right hand to take the oath.

Do you solemnly swear that the testimony you are about to give will be the truth, the whole truth, and nothing but the truth? Thank you very much. You may be seated.

Let the record reflect that each witness answered in the affirmative. I will now recognize each witness to present oral testimony. I remind you that your entire written testimony will be included in the hearing record. We, therefore, ask that you limit your testimony to approximately five minutes. You will each notice a clock

in front of you. After four minutes have elapsed, the green light will turn yellow, indicating that you have one minute. When the light turns red, five minutes have expired, and we ask that you conclude your statement.

I now recognize Ms. Worsham to begin oral testimony, and I thank you.

**STATEMENT OF ANTROINETTE WORSHAM, MOTHER OF TWO
INSULIN-DEPENDENT DAUGHTERS**

Ms. WORSHAM. Good morning, everyone. Thank you for having me today. Again, my name is Antroinette Worsham, and I am the mother of two type 1 diabetics. My older daughter, Antavia, was diagnosed at the age of 16 and only lived six years with this disease, due to the high cost of insulin. She started rationing her insulin in 2016 when she was kicked off of BCMH, Bureau for Children of Medical Handicaps. It's an Ohio program. She was kicked off due to her age. My son found her deceased in her bed one morning. She wasn't answering her phone. He went over to where she was living, and he found her. How detrimental is that to happen to anyone, especially a sibling, to find their sister passed away.

My youngest daughter, Antanique, she was diagnosed at the age of 12. She is now 18 years old. She attends the University of Toledo. She is studying law right now while battling type 1 diabetes. I fear the same is going to happen to her in two years. She'll be 21, and she'll get kicked off of BCMH as well.

I am wondering how pharmaceuticals think that college students are supposed to afford high drug costs on top of high tuition, room, and board. Healthcare is an essential right for U.S. Americans. We are asking for a change now. Type 1 diabetics need—they need insulin to live, or they will die like my daughter and other Americans have. We have seen it. Insulin is not a cure. It is definitely a life support.

High drug prices are forcing patients to be noncompliant. When type 1 diabetics ration their insulin or stop taking it, it causes them to go into DKA, which is diabetes ketoacidosis, and that is what happened to my daughter. I feel type 1 diabetics do not get the attention they deserve.

Many Americans are forced to purchase their insulin out of the country and are forced to buy from the black market, all so they can live a longer life. The rise of drug costs has impacted so many Americans, and again, we are demanding a change now. The copays, deductibles, and coinsurances are so high, that too has a huge impact on affordable insulin.

In 2018, in November, I protested outside of Sanofi, held in Boston, Mass, alongside Right Care Alliance Institute, demanding to lower their drug costs. Just this year, insulin manufacturers are still raising the cost. I have received so many calls and emails from type 1 diabetics needing help paying for their insulin. The insulin manufacturers are telling us that they have programs to offset the cost. One type 1 diabetic recently told me it could take two weeks for approval. Another one was told that he was over income restrictions. We, as consumers, are the reason businesses are successful, and we need to see affordable healthcare for all now, not just for

those living below or above poverty. What about the middle class as myself and as my daughter when she graduates school?

In conclusion, I am not an expert but a mother of two diabetics, two type 1 diabetics who is affected by the rising cost of insulin. Again, in two years, my daughter will be 21 and no longer be eligible for BCMH. I am crying out and asking Congress to review the pharmaceutical drug price gouging and make affordable healthcare for all. Antanique is a very smart young lady who is trying to be successful in the U.S., and feels it is hard dealing with chronic illness, on top of wondering if she can afford insulin as she ages into adulthood. Thank you very much.

Chairman CUMMINGS. Ms. Worsham, thank you very much. You've set a wonderful example. You were able to get yours in in less than five minutes.

Ms. WORSHAM. Thank you.

Chairman CUMMINGS. Thank you very much.

Ms. WORSHAM. You are welcome.

Chairman CUMMINGS. Dr. Georges.

**STATEMENT OF CATHERINE ALICIA GEORGES, ED.D., RN,
FAAN, NATIONAL VOLUNTEER PRESIDENT, AARP**

Ms. GEORGES. Good afternoon, Chairman Cummings, Ranking Member Jordan, and members of the committee. My name is Dr. Catherine Alicia Georges, and I am the national volunteer president for AARP, a nonpartisan, nonprofit, nationwide organization with nearly 38 million members in all 50 states, District of Columbia, and the U.S. territories.

For more than 40 years, I have been a nurse involved in academic nursing, both teaching, practicing, and developing courses. Thank you for the opportunity to talk about rising prescription drug prices and their impact on older Americans. Prescription drug prices are high priority for AARP and its members. Last year in AARP's 2018 voter issue survey, 92 percent of voters, age 50 and older, told us that candidates' positions on lowering drug costs was important to them with 74 percent saying very important. That is because older Americans struggle to afford needed and life-saving medications.

Most Medicare beneficiaries live on modest incomes with an annual median income of just over \$26,000, and one quarter of them have less than \$15,000 in savings. This is not a population that has the resources to absorb rapidly escalating drug prices. It is hardly surprising that our members consistently tell us that they cannot afford the medications they need, and are forced to make difficult choices as a result.

Take the story of Joyce Domintano, an AARP member from Florida, diagnosed with gastrointestinal cancer. Joan was prescribed Gleevec, one of the drugs this committee is investigating, 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 lives on a fixed income and simply cannot afford to drain her retirement savings to pay for medication.

No one should be asked to make that kind of choice. AARP has been tracking the prices of widely used prescription drugs since

2004. Our most recent prescription drug price watch report focused on brand name drugs and found that their retail price increased by an average of 8.4 percent in 2017, four times the rate of inflation. We also examined how drug company price increases add up over time, and found that annual costs of one brand name drug therapy, now around \$6,800, would have been just under \$2200 in 2017 if retail price changes had been limited to general inflation between 2006 and 2017.

The average annual price increases for these drugs has exceeded the corresponding rate of inflation every year. This problem goes beyond a few bad actors. Virtually all of the manufacturers we tracked have consistently raised their prices over the past 12 years. Our adults, older adults, are particularly vulnerable to these strains. Medicare part D enrollees take an average of 4.5 prescription drugs per month, and over two-thirds have two or more chronic conditions. High-end growing 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 recently seen massive increases in Medicare spending on drugs.

In conclusion, current prescription drug prices trends are simply not sustainable. Drug companies are still working very hard to try to shift the blame to others in the healthcare system, leaving them free to set incredibly high prices and increase them with little restraint. As a result, we Americans continue to pay the highest brand name drug prices in the world. It is long past time for Congress to take action to rein in high drug prices. Thoughtful efforts to help reduce prescription drug prices could save tens of billions of dollars for patients, taxpayers, and other healthcare systems. We will help ensure that all Americans have affordable access to the drugs they need to get and stay healthy. Thank you, and I look forward to your questions.

Chairman CUMMINGS. Dr. Kesselheim, you are recognized.

**STATEMENT OF DR. AARON S. KESSELHEIM, M.D., J.D., M.P.H.,
ASSOCIATE PROFESSOR OF MEDICINE, PROGRAM ON REGULATION,
THERAPEUTICS, AND LAW, HARVARD MEDICAL
SCHOOL**

Dr. KESSELHEIM. Okay. Thank you, Chairman Cummings, Ranking Member Jordan, and members of the committee. My name is Aaron Kesselheim, and I run the program on Regulation, Therapeutics, and Law at Brigham and Women's Hospital, one of the largest independent research groups in the country focused on pharmaceutical policy topics. And as you are aware, U.S. drug prices have risen rapidly over the last decade, and now exceed prices in comparable countries. The key policy dilemma is that although the drugs cost a lot to develop, increasing drugs prices can make important breakthroughs unaffordable to patients leading to bad consequences because you can't get benefits from a drug you can't afford. The main driver are brand name drugs which make up about 10 percent of descriptions, but over three-quarters of spending.

High prices arise from three complementary forces: First, the government gives patents and other market exclusivities to brand

name manufacturers, and lets them charge whatever the market will bear. Second, the purchasing market that is expected to provide a counterweight is extremely inefficient, since various laws and other factors prevent payers from effectively negotiating. And third, manufacturers often extend their exclusivity rights through value strategies and use their substantial lobbying power to block sensible political reforms.

I am going to try to address these three problems and talk about some solutions. During the drug's branding market exclusivity period, which lasts 12 to 14 years on average, 15 for first-in-class drugs, and even longer for biologic drugs, limits on public and private payers, prevent them from pushing back against the prices set by manufacturers. For example, Medicaid must cover all FDA approved drugs while part D plans have to cover all approved drugs in six protected drug classes. And it is hard to negotiate an effective price if an insurer must cover the drug.

Doctors and patients also suffer badly because many drugs are used for years without information about how well they work compared to other drugs or non-drug treatments.

The only type of competition that consistently and substantially lowers drug prices comes from interchangeable generic drugs that emerge after this market exclusivity period. However, this transition can be delayed and prolonged because manufacturers get dozens of additional patents on the use or formulations of their products. And this is part of the reason why older pharmaceutical products can suddenly become expensive if packaged in a new delivery device, such as with EpiPen for which the manufacturer raised the price from \$50 to \$600, even though epinephrine was isolated over 100 years ago.

Generic manufacturers can try to sue to cut through this thicket of patents, but the litigation can lead to settlements in which the generic manufacturer agrees to drop the lawsuit for some valuable consideration. These issues are addressable with rational policy-making that can get us back to a more optimal competitive marketplace, while still allowing drug manufacturers to earn reasonable profits on true innovation.

To improve competitive price negotiation during the market exclusivity period, we could authorize Medicare to create a program-wide formulary and negotiate drug prices. The process could be designed in way to maximize the chance that the final price falls within a particularly, widely accepted range of value for the money that approximates the benefit that the drugs provide to patients rather than whatever the manufacturer wants to charge, irrespective of the drug's actual value.

Other incremental steps that may not require legislation could also lead to some prices savings, and I have a memo listing some of them here, and also in my written statement.

Another major policy that should be enacted to help cut through are those that should help cut through the patent thickets that block timely or efficient entry to generic drugs. For example, whenever a new patent is listed with the FDA, it could be subject to automatic review by the Patent Trial and Appeals Board, an administrative body created by Congress in 2011. Many of those patents would be overturned.

We could also provide specific guidance to help the FTC exclude problematic brand generic legal settlements. The goal should be to ensure that manufacturers are not able to indefinitely extend their exclusivity periods beyond what the patent laws intended.

Changes made to rationalize U.S. drug prices along these lines will not substantially reduce drug innovation. First, studies show that most of the most important drug innovation occurs from publicly funded research paid for by the NIH and occurring in government or academic laboratories or startups spun out of these institutions before investments from manufacturers at a later stage. As long as the U.S. Government continues its decades-long commitment to investing in drug development through the NIH, there will be a consistent supply of potentially transformative approaches, targets, or even compounds.

Second, the recommendations will address the fact that the current system actually encourages the wrong kind of innovation because in the existing marketplace, the incentives are misaligned with patient or public health goals where even marginally effective drugs or incremental improvements can lead to outsized revenues. Substantial drug spending in the U.S. goes to many cost-effective products, and bringing U.S. drug prices closer in line to their actual clinical value means that in many cases, prices will be higher for drugs that offer substantial gains in clinical outcomes over existing treatments, and that is appropriate. But Medicare and Medicaid and other U.S. payers will be able to afford to cover such products for patients who need them if they aren't wasting vast sums of money on drugs that do not offer such advantages as they currently do.

I am glad that this hearing has been pulled together and is a great sign that Congress is moving in the direction of trying to engage these kinds of changes, and I'm happy to be here to share my thoughts and continue working with the legislators here to try to craft sensible solutions. Thank you very much.

Chairman CUMMINGS. Thank you.

Dr. Anderson.

STATEMENT OF GERARD F. ANDERSON, PH.D., PROFESSOR OF HEALTH POLICY AND MANAGEMENT, BLOOMBERG SCHOOL OF PUBLIC HEALTH, JOHNS HOPKINS UNIVERSITY

Mr. ANDERSON. Thank you, Chairman Cummings, Mr. Jordan, and members of the committee. When I testify, I try to—

Chairman CUMMINGS. Can't hear you.

Mr. ANDERSON. When I testify, I try to wear a tie that is related to my testimony. Today, it is Leonardo da Vinci's left-handed backward writing in Latin. I think that is pretty much appropriate for this hearing. It's a discussion of drug pricing to try and keep everything secret. I am a professor testifying on behalf of myself as a professor, not on behalf of Johns Hopkins University. At Johns Hopkins, I lead a team of about 20 faculty members from the Johns Hopkins Medical School, Public Health School, Business School and Hospital, studying a variety of drug pricing issues.

The reason why I'm so excited to testify today is that research that we try to do on many drug products requires confidential data. In my testimony, I will try to explain what we've learned from ex-

isting data, and then try to tell you where I think the oversight investigations are particularly important.

In my written testimony, I outline seven areas where I think the committee should pay attention. First of all, why do branded drug companies justify, and how do they justify their recent price increases? Why does it cost so much to develop a new drug? Why do PBMs, PBPs place the most expensive drug in preferred positions on formularies? Why do some blockbuster drugs also have an orphan designation? How do PDPs manipulate direct and indirect remuneration to increase cost in the Medicare program and to Medicare beneficiaries? How do drug companies attempt to influence the patient assistance programs that they finance financially? How do drug companies attempt to influence the patient advocacy groups that they support financially? Because I only have five minutes, however, I just want to focus on the first two.

In the U.S., branded drug companies are much more likely to increase prices than lower prices. According to a recent Associated Press analysis, drug companies announced 96 price increases for every price decline in 2018. In other countries, the prices of branded drugs tend to go down. According to economic theory, research is a fixed or sum cost and cannot be used to justify subsequent price increases. Once the drug company has spent the money to develop the drug, there are no additional research costs that can justify price increases.

The production costs of most drugs are relatively small, often pennies per pill. Inflation is still low, so most drug prices cannot be justified by higher production costs. The House Oversight Committee should ask the branded drug companies to explain why they have increased their prices.

The second question that I want to talk about is why does it cost so much to develop a new drug, and what's included in those research costs? Drug companies, as everybody said, justify their high prices based upon the amount of clinical research that they do. The problem is that we just don't know why it costs drug companies so much to conduct clinical research. A drug company says they spent X billion dollars on clinical research. It is important to know how much of that research cost is used to pay salaries of clinicians and researchers, purchasing equipment to conduct the research. Maybe some of that money that they call research is really not spent on things that you and I might call research.

Perhaps it's even more important to understand how other drug company research is actually financed. I think the model most of us would have in our heads is that there's a team of researchers working in the lab, developing new products, conducting experiments, doing clinical trials. While this is true for many drugs, it's also increasingly common for the initial drug research to be done in academic medical centers, places like Johns Hopkins or the Mayo Clinic, with funding from the National Institutes for Health. Drugs to treat hepatitis C are one of the major breakthroughs in recent years. Researchers at Emory University started working on that drug to treat hepatitis C with considerable funding from the National Institutes for Health.

Gilead, the company that bought the drug to the market, purchased the research from the academic medical centers, and then

Gilead immediately doubled the price the researchers were going to charge for the drug. The only reason why we have these facts is that the Senate Finance Committee conducted an investigation of the development of Gilead's drugs. Drug companies have teams that look for promising research. Often the drug companies are not doing that initial research themselves. The drug companies—the House Oversight Committee should examine what drug companies define as research costs, where the research was initially conducted, and who financed it. Thank you very much.

Chairman CUMMINGS. Thank you very much.
Dr. ROY.

**STATEMENT OF AVIK S.A. ROY, PRESIDENT, THE FOUNDATION
FOR RESEARCH ON EQUAL OPPORTUNITY**

Mr. ROY. Chairman Cummings, Ranking Member Jordan, and members of the House Oversight and Reform Committee, thanks for inviting me to speak with you today. I'm Avik Roy, and I'm the president of The Foundation for Research on Equal Opportunity, a nonpartisan, nonprofit think tank focused on expanding economic opportunity to those who least have it.

When we launched in 2016, our first white paper showed how universal coverage, done the right way, can advance both progressive and conservative values at the same time, expanding access while reducing Federal spending and burdensome regulations. As you know, reducing the cost of prescription drugs is critical to ensuring that healthcare is affordable for every American. In my following remarks, I am going to focus on two excuses we often hear about extremely high drug prices.

The first is that high prices aren't set by manufacturers, but rather by middlemen like pharmacy benefit managers; second, that rising prices are necessary to fund medical innovation; and finally, I will describe market-based principles that can help restore affordability to prescription drugs. Manufacturers have been advancing the theory that high drug prices aren't their fault. Instead, they argue, they're forced, quote unquote, "to charge higher prices to make up for rebates to PBMs." To use the technical term, that's balderdash. Nobody forces drug companies to charge high prices. Seventy-five years of Federal policy has made patients insensitive to the price of the drugs they consume. Patients don't always understand how their premiums keep rising on account of rising drug prices, especially in the employer-sponsored market. As a result, in the absence of competition, manufacturers often charge the highest prices they can.

Let me explain why drug makers voluntarily offer rebates to PBMs. Private insurers enlist PBMs because PBMs have shown themselves to be good at what's called formulary management. Let's say you're a type 2 diabetic, and you have the option of treating your condition with high cost brand drugs, or clinically equivalent low cost generic drugs. PBMs will structure the insurer's formulary such that if you choose the low cost generic drug, you'll have a 0 or \$5 copay. If you use the high cost drug, you might have a \$30 copay. In this way, PBMs help reduce the cost of prescription drugs.

Indeed, America leads the world in the use of low cost generics. Nearly 90 percent of all prescriptions written in the United States are for unbranded generic drugs. Drug makers get around the system by offering rebates to PBMs. Sometimes in exchange for the rebates, the PBMs put a high cost drug on the zero copay tier alongside the generics. This may sound good on the surface, but by needlessly increasing the use of high cost drugs, rebates drive up the cost of health insurance for everyone.

Drug makers also use rebates to suppress competition. Last October, Merck and Samsung announced that they would be abandoning Lusduna, their competitor to Sanofi's Lantus, even though they invested hundreds of millions of dollars in gaining FDA approval. A common practice in such situations is for the incumbent brand to offer deep rebates to the PBMs, effectively dumping their drug onto the market to wipe out new competitors.

PBMs genuinely add value in the way they manage drug formularies, but Congress should eliminate rebates to restore transparency and accountability to high drug prices.

An oft-repeated cliché is that high drug prices are necessary to fund medical innovation. One test of this cliché is to apply it to other sectors of the economy. You would never hear Sony or Vizio say that high television prices are necessary to fund innovation in the TV market. They know that if their TVs are too expensive, no one will buy them. In 1996, Biogen launched Avonex, a multiple sclerosis drug, for \$8700 a year. Twenty years later, they were charging \$81,000 a year, nearly 10 times more. Imagine if Sony charged you \$81,000 for a 20-year-old TV claiming that the high price was necessary for innovation. You would laugh them out of the room.

There are two giant holes in the high price for innovation theory. The first is that increasingly, the business model of drug makers is to focus on ultra rare orphan diseases where R&D costs are low due to the limited supply of patients for clinical trials, while still charging extreme prices edging toward \$1 million per patient per year.

The second is that virtually all of the increase in prescription drug spending comes from price hikes on older drugs like Avonex. If a patient with multiple sclerosis is well-controlled on Avonex, it's considered bad clinical practice to switch that patient to a different drug, even if that other drug is cheaper. Companies take advantage of patients with chronic disease dependence on their drugs to drastically increase the price of all their drugs year over year.

So what's the solution? I delve into this topic in my written testimony. The core idea is this: In areas where there is robust competition, especially with generic drugs, prices are extremely affordable, even in America. Where there are monopolies, legitimate or artificial, prices are high. In the past, Congress and the FDA have sometimes worsened the problem of artificial drug monopolies. This Congress has the opportunity to enact bipartisan reforms. I look forward to discussing these ideas with you in more detail. Thank you.

Chairman CUMMINGS. Thank you very much for your opening statements. Each member will now have five minutes to ask ques-

tions. I yield to the gentlelady from the District of Columbia, Ms. Norton.

Ms. NORTON. Thank you, Mr. Chairman. I take Dr. Roy's suggestions at heart, but what we have heard here today and some of them could have been—could be—would need Congress in order to go into effect, and none of us, all of us believe that competition is part and parcel of the problem.

I want to focus on patients. As you've heard so much about the industry, the excesses of the industry are legendary. One wonders why those excesses are given the profits that this industry makes continue. Now, the Federal Government spends almost \$100 billion on Medicare part D. That's a lot of money. You would think that would do it, unfortunately, and yet, we continue to hear that patients are hurt by the pharmaceutical sector.

Dr. Georges, to focus on patients for the moment, in light of all the money that's been spent by the Federal Government on Medicare part D, how does the price of a drug impact or affect seniors for their out-of-pocket for medications? Why so many complaints coming from seniors for what they pay out of pocket?

Ms. GEORGES. Congresswoman Norton, in 2015, seniors spent over \$27 billion in their out-of-pocket costs for their drugs. In my oral testimony, I referred to the fact that the average income of a Medicare beneficiary is only \$26,000. That's why the increase in drug prices have become unsustainable for this group of people.

Ms. NORTON. Well, breaking down your number that seniors spend, I have been given a number of at least \$2,000 out of pocket for drugs doubled in just four years from 2011 to 2015, that those who paid \$2,000 now, that number has been compared to what the average Medicare beneficiary earns as a median income at \$26,200, so you can imagine that much coming out of your—out of not your salary, out of your income.

Dr. Georges, you, perhaps, have a valuable perspective because you are a registered nurse, so what has been your experience of how these prices have affected seniors at this income level? Do they buy their drugs? How do they accommodate these drugs?

Ms. GEORGES. I'll give you a perfect example. One of my faculty members was on the line in a pharmacy this past week. One of her neighbors—they live in Harlem in New York City. One of her neighbors who is on a fixed income was talking to the pharmacist and saying I can't—this drug I won't have this month. It costs too much. I will only be able to take these drugs. As we said, what the effect is on our members and older Americans, they're making choices over should they ration, should they not adhere to treatment because they can no longer afford it?

Ms. NORTON. Dr. Georges, this is a problem that I see we have, the notion that people who worked all their lives have to perhaps decide whether they are going to live on an ongoing—based on the drug that they have taken. And I'm very concerned that the older we get, the worse it gets, that a quarter of older Americans, 65 to 69, need at least five prescription drugs, and half of those, 70 to 79. So when we talk about the cost of these drugs, they multiply as people get older. So we're pricing people out as they grow older, and we've got to understand this and make some accommodation to that. And I thank you, Mr. Chairman.

Chairman CUMMINGS. I yield to the ranking member.

Mr. JORDAN. I'm sorry. I yield the balance of my time to Congressman, Mr. Green.

Chairman CUMMINGS. I yield to Congressman Green.

Mr. GREEN. Thank you, Mr. Chairman and Ranking Member Jordan. Thank you for addressing this very important issue. First, I would like to take a second of my time and just share my credentials to speak on the subject. As an Army physician, I've been a medical provider in a 100 percent government system, and as a patient in the VA, I am in universal healthcare. As a civilian physician, I've seen patients in both for-profit and not-for-profit hospital systems. I even ran two free healthcare clinics in our state in Tennessee. I founded a healthcare company and served as its CEO, operating in 11 states and 52 hospitals, emergency medicine, the front lines of healthcare. And Mr. Chairman, I'm a cancer survivor. Like you, I've had to contemplate both my life and my death. I remember going from chemotherapy back to the Tennessee State Senate right from a treatment to cast a vote in the Tennessee State Senate. Very interesting times. I've been on both sides of the stethoscope.

The cost of pharmaceuticals are concerning, and certainly we need to look at some of the practices that are out there, but the concerns that we—that I have are really concerns that are more broad, that impact our entire healthcare system.

Let me put this into perspective. All of our pharmaceutical costs are around \$333 billion a year in a healthcare system that's \$3.5 trillion. That means pharmaceuticals are about nine percent of the total cost of healthcare. That doesn't mean just because it's nine percent, we shouldn't look into this issue. But the forces that are driving increased costs of pharmaceuticals are also the forces that are driving significant cost problems throughout healthcare. I'd say they are wreaking havoc on our healthcare system, and these problems are structural. The very infrastructure of our healthcare system is the problem.

For example, if you look at 100 percent government payer system, the demand will always exceed the supply. It's simple economics, and that's why in Canada, it takes six months to get an MRI. However, when government fixes the price below the market price, what happens is cost shifting. We cost shift to the third-party payers, and for non-paying patients, that cost shifting is even greater. And what then happens is the price for the payer increases, the cost for the payer increases so they have to increase their prices, which means fewer people can afford it, which means they have to raise their prices which means fewer people. It's the death spiral in healthcare in America right now. It's what's killing our system.

What happens is a huge gap between price and the actual charge to the patient or the payer. And if cost shifting produces—it produces this negotiation between the provider and the payer, and it winds up with a price that's different than what the cost and it makes for a significant complex problem that can't be fixed without structurally changing what we are doing in our healthcare system, and other structural issues, not just cost shifting, but things like reversed incentives, masked prices, governmental restrictions that prevent competition, no free market.

You ask, would a free market work in healthcare? Absolutely. Look at Lasik eye surgery. When it came out, it was thousands of dollars an eye. Now, I saw an ad the other day, Mr. Chairman, for 250 bucks for a Lasik eye procedure. That is because there's no—that cost shifting scenario with third-party payers doesn't exist. The ophthalmologists are competing for the dollar. Technology has gone up, and price has plummeted.

Those are the structural issues that are affecting all of healthcare, and they are clearly impacting the price of pharmaceuticals. If we don't—and there's lots of little issues that we can drill down on in pharmaceuticals, but if we don't fix those structural problems in our healthcare system, we can't fix this issue, either.

I do have a question for Mr. Roy, though. You mentioned monopolies that are created out there and that that's driving, the big driver in this cost issue. How is government creating those monopolies?

Mr. ANDERSON. So in my written testimony, I elaborate on this quite a bit. There are a lot of different policies that both Congress and the FDA and in the case of drug pricing instituted that established monopolies. One example is that the Biologics Price Competition Innovation Act of 2009, which was part of the Affordable Care Act, mandated that biologic drugs that have no intellectual property, be given 12 years of market exclusivity after FDA approval, despite the fact that they have no actual patents. For a small molecule drug, that's five years. There is an arbitrary difference that makes no sense, and that's a government-created monopoly, not one that private industry created, though private industry certainly advocated for it.

Mr. GREEN. I have some other questions, but I think I'm out of time, Mr. Chairman.

Chairman CUMMINGS. Thank you very much.

Mr. Lynch.

Mr. LYNCH. Thank you, Mr. Chairman. I want to thank all the witnesses for your willingness to come here and testify, especially you, Ms. Worsham. I really do appreciate your powerful testimony and really putting a human face and a human family behind this problem.

Mr. Chairman, as you know, we've been working on this issue for a long time, and the two systems that we deal with more often on this committee are the Federal Employees Health Benefit Plan, which I know, Mr. Anderson, you're familiar with, and the VA health plan. And the difference between the FEHBP, the Federal Employee Health Plan, is that they negotiate their drug prices through a pharmacy benefit manager. Theirs is CVS Caremark. But we just did—we just had a study done by the Teamsters Union and the SEIU, and one of the things that they discovered was unbelievable, in my estimation. They found that when a Federal employee goes in to buy their pharmaceuticals, they pay more than a person just walking off the street and—and signing up for a discount program with CVS that has no insurance, and that troubles me greatly.

So here you have a member of a—a healthcare plan that has 9 million participants, and they walk in with their insurance card,

and they pay more than the person who walks in off the street, God bless them, with no insurance and just signs up for the discount card. All right. That's a plan that's negotiated through a PBM, a pharmacist benefit manager.

Now, let me give you another example. I have three big VA hospitals in my district. We have a huge number of veterans in my district, and my veterans, when they go to the VA pharmacy program, they pay either \$8 or \$9, and they argue about what they should be paying, and they're not happy—they used to pay \$7.50, so they're not happy with me right now. Even if the drug cost 800 bucks, they pay \$9. They pay \$9 or \$8. They get to negotiate directly. The VA gets to negotiate directly with the drug manufacturers. Those are the two types of systems that we deal with here, so Mr. Anderson—Dr. Anderson, I'm sorry, and Dr. Kesselheim, help me with this. Would it not be better, you know, rather than getting very complicated and deep in the weeds, why don't we just let Medicare do for our senior citizens what the VA is doing for our veterans? Let the Medicare program negotiate directly, directly with the pharmaceutical companies. Would that—would that help? Help me out.

Mr. ANDERSON. So—it's a great question. So when you look at the VA, there is two things to notice. The first one is they have access to most every drug in America, whereas if you're a Medicare beneficiary or you're an FEHBP, you probably have access to about half the number of drugs on the formulary that the typical VA person has. So you have much better access as a Medicare—as a VA person.

Mr. LYNCH. Why is that, though?

Mr. ANDERSON. Because they essentially have put a lot more drugs on the formularies. They negotiate prices.

Mr. LYNCH. We can do the same thing, though, for—for Medicare.

Mr. ANDERSON. Yes, you could do that, absolutely, but—but we have—the programs that are the PBMs want to negotiate a much more restrictive set of—

Mr. LYNCH. Right, but what I'm saying is clear them out—

Mr. ANDERSON. Okay.

Mr. LYNCH [continuing]. and just allow Medicare to negotiate directly. It's simple. It's clear. Maybe it won't be \$8 or \$9. Maybe it will be 15 or 20, I don't know, but—but it just seems to me that the lack of—of transparency here. We can't even figure out what the insurance company—what the drug companies, what their costs are. We went to court with them. They would not tell us what it cost them to make their drugs because we wanted to give them a fair profit but not—not gouge senior citizens, and we—the judge ruled against us. We couldn't—we couldn't get that information as astounding as that seems, but please.

Mr. ANDERSON. So the other thing that you mentioned is that you can get a lower price when you actually pay cash than when you do it through your—through your plans, and the Congress last year passed allocation called the Gag Rule which essentially meant that the pharmacist could say to you as a patient, you pay—if you pay cash, you would pay less. So Congress actually did something

very important last year in passing the Gag Rule to make that a much better thing for the patient.

Mr. LYNCH. Thank you.

Chairman CUMMINGS. We're going to recess until 1:30. We have a vote. 1:30. All right. Thank you.

Chairman CUMMINGS. We are calling the committee back to order now.

Mr. Massie is recognized for five minutes.

Mr. MASSIE. Mr. Chairman, I want to thank you for having this meeting.

The drug pricing system is sick and it is failing. The prices are unnecessarily too high. But all doctors take an oath to first do no harm, and I think we have the same oath here in Congress. We should take it, if we don't. And I'm worried that we may have come up with a misdiagnosis or part of the situation is diagnosed improperly.

I want to read from the Constitution: The Congress shall have power to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.

So, you know, I challenge anybody to walk into a hospital and say, I only want the drugs and the medical devices and the procedures that were developed at the NIH and public institutions. Your lifespan would be cut by 10 years at least by just uttering those words. It's the patent system that incentivizes inventors, scientists, engineers, and doctors to come up with these life-extending, life-improving, life-saving drugs and medical devices.

So with that in mind, Avik Roy, Dr. Roy, I believe you and I overlapped at MIT, we just discovered. You were course seven and I was course six, molecular biology and electrical engineering. But I noticed in your written testimony, you talk about four—at least four different problems that we have trying to get generics to market after the patents have expired. A lot of people think patents are to blame for this, the high drug prices, but the patents are the incentive that cause people to develop new drugs and new medical devices.

So could you talk about the morass that companies encounter or some of the problems that we run into when they try to develop the generics after the patents have expired? Which by the way, our Founding Fathers never wanted a patent to go on forever. The charge to us in that phrase in the Constitution is for a limited period of time to promote, develop it, not forever and not for one minute, but for a period of time that's optimal. So can you talk about how they get bogged down after the patents expire?

Dr. ROY. Well, since we have three minutes and 45 seconds, I'll—

Mr. MASSIE. That's very generous.

Mr. ROY [continuing]. this very complex problem. And, again, I would encourage everyone to look at the written testimony which explores this question in a lot of detail.

One example that I will give that I think is of—that should be of urgent attention not just to this committee, but to Congress as a whole is the problem of so-called biosimilars. So there is a new wave of drugs that have been developed through recombinant DNA

and molecular biology technology that are not simple pills or simple molecules. They're protein therapeutics, often monoclonal antibodies, there are other drugs that have very complex molecular structures. And because they have complex molecular structures, the FDA and Congress have decided to regulate those drugs in a different way than traditional drugs. They're regulated through the Public Health Service Act and through the Biologics Competition Price and Innovation Act of 2009.

The bottom line is that this different set of regulations has meant that when those biologic drugs go off patent, the earliest biotech drugs now are starting to go off patent because they were developed 20, even 30 years ago. We're not seeing the same flood of generic competition that comes in and lowers the prices down to commodity prices, the way we saw, for example, when Lipitor, a best selling cholesterol lowering drug, went off patent a few years ago. We are not seeing that with biosimilars.

In fact, in Europe, there are about 50 biosimilars that have been approved by the European equivalent of FDA, but only about nine or 10 by the FDA. And, again, part of that is because the way Congress has authorized the FDA to regulate these drugs is very different. The FDA also historically has been slow in getting its act together in the way it regulates biosimilars.

But the end result is it is extremely expensive and extremely risky for competitors to develop these so-called biosimilar drugs. And when they even get approval from the FDA, as I noted in my opening testimony, sometimes they're withdrawn because the price they have to charge to justify their cost is too high. So this is a huge problem because, as a share of overall drug spending, biologic spending is rising. It's basically doubled in the last eight years and it's going to continue to rise as these biotech drugs become a bigger, bigger portion of the pie, and so addressing that problem is of urgent importance.

Mr. MASSIE. Can you talk about another one of the ways that these products don't come to market after the patent is expired? I noticed in your testimony, you mentioned off-patent drugs with specialized delivery devices.

Mr. ROY. Yes.

Mr. MASSIE. The EpiPen has about 25 cents of epinephrine in it, if you were a veterinarian and bought epinephrine.

Mr. ROY. Yes.

Mr. MASSIE. So why is it \$600? The EpiPen, the patent expired on it. And I think people have a misunderstanding that somehow that original EpiPen patent got extended. That's not the case. There's a new patent and then the regulatory morass, but can you talk about some of the other drugs or delivery devices?

Mr. ROY. Yes. As one of my colleagues noted, epinephrine was discovered over 100 years ago. And the key issue here is that the delivery device that Mylan developed has patents around it. And the FDA has required that any potential generic competitor exactly replicate Mylan's device. Well, if you exactly replicate Mylan's device, you're violating Mylan's patents around its device. When in fact what the FDA should do is say any other device which has the same clinical effect in a patient, with the same dosage and the same, you know, treatment of the disease, that should be allowed.

And the FDA, under Scott Gottlieb, I will say, has begun to do that, but, again, Congress could help the FDA by creating a statutory pathway for complex generics to be approved more rapidly.

Mr. MASSIE. Thank you for shedding light on that.

I yield back, Mr. Chairman.

Chairman CUMMINGS. Thank you very much.

Mr. CONNOLLY.

Mr. CONNOLLY. First of all, Ms. Worsham—I'm sorry. You think I'd know that by now.

Ms. Worsham, I want to join the chairman in expressing our deep condolences. I can't imagine, and like many of us in this room, I have close—people close to me who are diabetic and are insulin dependent. And the thought that they have to make that kind of terrible choice is just unacceptable, and I think highlights why we're here. At any rate, our hearts go out to you and your family.

Ms. WORSHAM. Thank you.

Mr. CONNOLLY. And hopefully—and I want to thank the chairman for having this hearing and the ranking member for joining with us.

This is an issue that touches every family. And in some ways, it's getting only worse. You know, we raise prices on drugs that have been around for a long time just because we can, and we maximize profit. And there's nothing wrong with profit, unless the choice is human health and safety versus and exorbitant profit I don't really need. And at some point, the ethics of that do come into play in terms of public policy, and thus this hearing. And I am so proud of the chairman for making this the first hearing of his chairmanship in the new majority. I think it really underscores the importance we put on this issue.

I'll put this question to the middle part of the panel. Why is there such a difference in drug pricing, same drug, between the United States and most other industrialized countries? What accounts for that price differential?

Dr. KESSELHEIM. Well, I think that there are a couple of different factors at play. In many other countries, there is a negotiation on behalf of the country to where the country is able to use its power as a monopsony buyer to try to, you know, whether—about whether or not the drug gets into the—is allowed to be on the country's formulary and allowed to be given to patients there.

I think that also a lot of other countries use evidence related to the comparative effectiveness and cost effectiveness of the drugs to determine—you know, to help negotiate, and through that negotiating process, determine a fair price for the drug depending on what it's value is. And so a lot of other countries use these value-based determinations to try to assess a fair price and to use that as a basis for the negotiating process. I think that both of those things contribute to the differences.

Mr. ANDERSON. Well, I think the most important thing to recognize is that, in the United States, once a drug is launched, the prices go up, and in other countries the prices go down. So what we now see is, for established drugs, there's a three to four to one difference between the price in the United States and the prices in other countries.

Mr. CONNOLLY. An example of what you're saying, Dr. Anderson, Humira.

Mr. ANDERSON. Correct. No. 1 seller in America.

Mr. CONNOLLY. No. 1 seller in America costs \$2,669 in this country, costs \$822 in Switzerland.

Mr. ANDERSON. Correct. And it might actually cost less than that in Switzerland. You don't always get all of the discounts reported.

Mr. CONNOLLY. We're talking about insulin. Insulin's been around since 1921. Can you think of any reason why the prices of insulin, a commonly used drug for 100 years, has skyrocketed so much?

Mr. ANDERSON. Well, I mean, it is—you know, the insulin that we use today is a little bit different than the insulin we used then. There have been some changes to the molecule over the time. But in general, a lot of the issue has to do with patents on—at least right now, patents on the delivery devices as opposed to the product itself. So, you know, if the pen clicks this way or clicks that way, then companies are able to get new patents on them that give them another 20 years and another 20 years. And because there's not good effective competition between drugs that have those kinds—when they have those kinds of patents, that it can make it difficult to try to bring in competitive products and to get true competition that leads to lower prices.

Mr. CONNOLLY. If Medicare were allowed to have that true competition, would it drive down prices significantly?

Dr. KESSELHEIM. I think it would drive down prices closer, again, to what the values of the drug really are and closer to what, you know, in other countries are able to negotiate, you know, to try to evaluate the utility of the drug for the patient. I think that we could use those kinds of strategies to try to get a fairer price that still provides sufficient profits for the manufacturer but is a fairer reflection of the drug's value.

Mr. CONNOLLY. Thank you, Mr. Chairman.

Chairman CUMMINGS. Thank you very much.

Mr. Meadows.

Mr. MEADOWS. Thank you, Mr. Chairman, for calling this hearing. And I have a personal note that I wanted to convey to you from the President of the United States. He wanted to make sure that you knew that on this particular subject, not only is he serious, but he's serious about working in a bipartisan way to lower prescription drug prices. And when I spoke to him last night, he wanted to make sure that I conveyed that to you.

Chairman CUMMINGS. Would the gentleman yield just for 30 seconds?

Mr. MEADOWS. Sure.

Chairman CUMMINGS. I just want you to convey back to the President that we are willing, ready, and able to work with him to get it done. And thank you.

Mr. MEADOWS. I thank you, Mr. Chairman.

Dr. Roy, let me come to you. Obviously, the Trump administration has made some recommendations in terms of whether it be the percent of commission paid to physicians on prescriptions or a comparable amount that can be charged based on either the EU or

other areas. What kind of effect do you think that those two Trump administration proposals would have on drug prices?

Mr. ROY. So you're referring, just for everyone else's interest and knowledge, to some of the reforms that the President and Secretary Azar have proposed for the Medicare part B program—

Mr. MEADOWS. Part B, that's correct.

Mr. ROY [continuing]. which is physician administered drugs and drugs that are usually delivered through intravenous infusions and injectables.

Mr. MEADOWS. Right.

Mr. ROY. The one big distortion that was introduced by the Medicare Modernization Act was the so-called ASP plus 6 where doctors get a 6 percent commission. That incentivized the use of higher priced drugs and not low cost generics. And so that's an example of where a reform system that the administration has proposed and is modeling and demonstrating through CMMI would be very helpful in aligning doctors' economic interests with giving patients the lowest cost drug, which is not the case today, an important area of market distortion as you imply.

The second piece, in terms of having an international benchmark to compare Medicare part B prices and align Medicare part B prices to that, we just published a paper at my think tank, at freopp.org, that argues that the 15 countries that are in the international benchmark that the Trump administration proposed are the wrong countries to compare to the United States, because they don't necessarily have market-based approaches to either health insurance or prescription drug prices.

Mr. MEADOWS. Which countries would best be in that pool of—

Mr. ROY. So we suggested—I'll emphasize, the countries that we think are the most worth benchmarking Medicare part B to are Switzerland, the Netherlands, Singapore, and Denmark. Those are the countries that either have more market-based health insurance systems, like Switzerland and Netherlands, or in the case of, for example, Denmark, they have unregulated drug prices. Companies can charge whatever they want, just like they can in the United States, but the difference is, in Denmark, the insurers or the insurer offers a specific price that's aligned to the lowest cost drug in a particular category, that if you choose that lowest cost drug as a patient, the drug is free, you are subsidized by the government. If you choose a higher cost drug, you have to pay that difference out of pocket. And what that has done is created a market-based incentive for drug companies to charge a low price.

Mr. MEADOWS. Sure.

Mr. ROY. In fact, Denmark has the lowest prices for prescription drug spending in all of Europe using that model.

Mr. MEADOWS. It's amazing how the free market will put pressure on profits and corporations.

So, Dr. Anderson, let me come to you, because one of the areas that I'm concerned about is the difference and everybody saying, well, if we just get the government involved, everything will work out. But I went to my local pharmacist and I looked at one particular drug, and there's four different prices. There's a cash price, there's a Medicaid price, there's a Medicare price, and there's a private insurer price. And they're not anywhere close. In fact, the

Medicaid price was higher than the other prices when we looked at that.

And so that would not necessarily suggest that government intervention is going to lower prescription drug prices. So how do we reconcile that, Dr. Anderson?

Mr. ANDERSON. You do have a whole variety of different prices out there.

Mr. MEADOWS. And why? I mean, I would assume that the risk associated with getting a patent, manufacturing, it does not normally look at the end consumer on—it doesn't cost more to produce a drug for a Medicaid patient, does it?

Mr. ANDERSON. No. It is the exact same cost of production and exact same research, but it's different market powers. And some places have more market power than others to negotiate prices.

Mr. MEADOWS. Yes, I thought that was the case, but I started looking at that and that's not actually necessarily always the case. And, quite frankly, when you look at—we're talking about negotiating—some of the big private companies that provide insurance have a whole lot more market power in terms of the number of people that they protect than some of the other programs. And so there's not a linear correlation that I can find.

Mr. ANDERSON. No, there isn't, but essentially—and I think a lot of it is because the PBMs and the PDPs are keeping a lot of those profits into the system, so that's why you see these large differentials.

Mr. MEADOWS. So you would recommend getting rid of PBMs and PDMs?

Mr. ANDERSON. I think either getting rid of them or, more importantly, changing the incentives that they have so that they don't have incentives to fight over the rebates that lead to higher list prices.

Mr. MEADOWS. I yield back.

Mr. CUMMINGS. Thank you, very much.

Mr. KRISHNAMOORTHY.

Mr. KRISHNAMOORTHY. Thank you, Mr. Chairman, and thank you for your leadership on this very important issue. This is like the first time we've had kind of a rather informed free-wheeling discussion on both sides of the aisle on this issue. And thank you for your leadership.

I think that most of us would agree that patents and other intellectual property protections can play an important role in incentivizing innovation and helping companies recoup the sizable investments they make in developing new drugs. However, when these protections are too generous, they can restrict competition and ultimately harm consumers. One area of particular concern is biologics, which are pharmaceutical products made from living organisms. Biologics currently represent only two percent of all prescriptions, but they account for 26 percent of total consumer spending. By 2025, over 70 percent of drug approvals are expected to be biologics.

Since a living organism cannot be patented, manufacturers of these biologics are granted an exclusivity period which currently lasts for 12 years. Now that Democrats and Republicans alike are making drug prices a priority, shortening this exclusivity period is

one of several options under consideration. However, the recently signed U.S.-Mexico-Canada Agreement, the USMCA, the renegotiated version of NAFTA, includes a provision that would sync up exclusivity periods across all three countries. This would mean that no single country could shorten this period, this exclusivity period, without the approval of the other two countries. We should not allow this treaty or any other treaty to prevent us in Congress from taking action to lower drug prices and making it easier for affordable biosimilars to come to market.

So I have a question for Dr. Georges of the AARP. Ma'am, you wrote a letter to the U.S. Trade Representative Lighthizer expressing concern over any provision in the renegotiated NAFTA, that is the USMCA, that could limit the market or lower the exclusivity period. And so can you talk a little bit about why you wrote that letter?

Ms. GEORGES. Well, I—I don't have in front of me all the details of the letter. But I will say to you that one of things that we in AARP are concerned about is the length of exclusivity, you know, for these high priced biologics. And in that one of the things that we're now looking at and will be able to spend more time is looking at this whole NAFTA-2 agreement. We are going through an analysis now through AARP and taking a look at that.

Mr. KRISHNAMOORTHY. Thank you.

Dr. Kesselheim, what would be the impact of locking the U.S. into a certain exclusivity period for biologics? And how would it limit our ability to address the issue of high prices in these—in this class of pharmaceuticals?

Dr. KESSELHEIM. Well, I mean, I think it would be a problem because one of the—the reason that that 12-year exclusivity period was set originally is because there was some thought about how long it might take manufacturers to recoup the cost of development for their biologic products. And if it turns out that over time we had miscalculated on that and it should actually be shorter than that, then doing that kind of locking in the United States policy in that way would be a bad idea in—without allowing us to have the flexibility to make changes.

Although I do want to point out that there are dozens and dozens of patents covering biologic products in addition to that exclusivity period that the BPCIA provides and, in fact, some of those patents have gotten in the way of getting lower cost—potentially lower cost biosimilar products on the market. I still think it would be a bad idea to lock the United States in in that way to be unable to adjust that number in the future.

Mr. KRISHNAMOORTHY. Dr. Anderson, can you comment on that?

Mr. ANDERSON. So I think the key thing is one is the international, but more importantly is domestic. And domestically, we essentially have allowed them to have a whole series of patents that we can't even find if you wanted to. For small molecule drugs, you can go on the FDA site and you can find it. For biologics, you can't go on the FDA site and find all the patents. And so if I'm a drug company that wants to develop a biologic, I can't find all the patents, I'm probably going to go up against one of those drugs—those patents and I'm going to run into a problem. So I'm not even going to start the activity.

On a reimbursement side, the biologics have a different set of codes than the biosimilars do. So you can't interchange them, whereas for generic drugs you can. So we've made it much harder to, essentially, copy the biologics and maybe biosimilars.

Mr. KRISHNAMOORTHY. Got it. Thank you so much.

Thank you, Chairman.

Chairman CUMMINGS. Thank you very much.

Mr. HICE.

Mr. HICE. I thank the chairman.

You know, it seems like we're hearing a lot these days, probably more than we have in quite a while, from many on the other side of the aisle that the answer to rising drug costs is more government involvement. I strongly disagree with that. Case in point would just simply be the so-called Affordable Care Act was signed into law about 10 years. And since that time, we've seen drug costs skyrocket in excess of 40 percent, despite the fact that President Obama over and over, as has already been cited today, said if you like your plan, you can keep your plan, all this kind of stuff. We're still seeing the out-of-pocket costs skyrocket, as well as the cost of drugs themselves.

So, Dr. Roy, let me begin with you. Can you please explain the connection between higher drug costs and ObamaCare in particular?

Mr. ROY. There are two particular policies—well, there's three particular policies, I'd say, in the Affordable Care Act that have driven up, in my view, prescription drug pricing and spending. The first is what we mentioned before, the BPCI Act, which regulates biosimilars, and how, as a result, biosimilars have not been getting out of the market.

The second is the changes to Medicare part D, which reduced the amount of cost sharing in the Medicare part D program, the so-called coverage gap or donut hole. While there are meritorious reasons to want to reduce out-of-pocket spending for seniors, the end result of that left lower price sensitivity was massive price increases by manufacturers because they knew that seniors wouldn't care whether the prices were high or low, the taxpayer was on the hook for those extra prices. So we've seen Medicare part D spending skyrocket as a result.

The third area is in the Affordable Care Act exchanges where there are mandates that have been—that were issued by the Obama Administration to require that plans participating in those changes cover a bunch of drugs, branded drugs, even if those branded drugs had no economic value, that is to say they were generic drugs that could do the job just fine. That's resulted in a higher than necessary pharmacy cost in Affordable Care Act based plans.

Mr. HICE. So based on what you're saying, let me just throw out a somewhat loaded but sound like a simple question. Would the repeal of ObamaCare lower drug costs for Americans?

Mr. ROY. It would lower overall prescription drug spending. It may, in certain cases, raise out-of-pocket spending for some individuals who are buying Affordable Care Act subsidized insurance plans, but overall spending would go down.

Mr. HICE. Again, it just seems to me there's a whole lot more involved to this whole thing of rising drug costs than what meets the eye. It is a complicated issue and there's a lot of factors involved. It's certainly more than just greed of the pharmaceutical companies; there are a lot of factors.

Dr. Anderson, let me go to you. Can you provide a basic brief overview of the drug supply chain? And specifically what I want to know is who pays what price at what point in the chain. Is there any way to do that briefly?

Mr. ANDERSON. I will do my best.

Mr. HICE. Okay.

Mr. ANDERSON. So it essentially starts with the drug company announcing a price, called the list price, and then they negotiate with the PBM over the price that they actually—the PBM will pay for the drug. And it could be all of that price or most commonly a significant reduction of that price. Then the PBM keeps some of that money, but not all of it. And we don't know how much of that money they in fact keep, because that's all confidential. Then it goes to the pharmacy, and they buy the drug essentially from the PBM and they get a price for it. Again, we don't know what that price is. And then the consumer goes to the pharmacy and buys the drug.

They pay the price based upon the list price, the price that the drug company originally set, and that's why the major reason why the prices for consumers have gone up, because those list prices keep going up. The reason why the list price is going up is because the PBMs are saying if you give us a higher list price, we will more likely put your drug on a formulary.

Mr. HICE. And then you add into that, as I understand it, the rebates. So the rebates have—when you factor the rebates in, the cost of the drugs have somewhat been kept under control to the consumer. Is that an accurate statement?

Mr. ANDERSON. Well, they could be, but we don't know exactly how much because we don't know how much the PBMs are keeping and how much the drug companies are getting and how much the consumer is paying. So we just don't know that information. So we think that's true, but we don't know.

Mr. HICE. Thank you.

Thank you, Mr. Chairman. I yield back.

Chairman CUMMINGS. Thank you very much.

Mr. ROUDA.

Mr. ROUDA. Thank you, Mr. Chairman. And thanks to all of you for providing testimony here today.

Drug pricing is the largest driver of healthcare costs in our country. We spent over \$333 billion last year on drugs, of which the Federal Government, through Medicare, Medicaid, and VA spent approximately \$150 billion. And while I recognize that it often takes years of research and development to bring new drugs to market, we cannot have Americans rationing or abandoning life-saving medication due to the bureaucracy, inefficiencies, and greed.

Patients can't reap the benefits of pharmaceutical innovation if they're forced to choose between their drugs or rent. A hardworking American shouldn't pay the highest price for healthcare in the world and receive, for some, inadequate care at best. Like most

things in life, the reality of drug prices is always more complicated than the sound bites we hear. List prices get all the attention, but they don't really tell the full story. The real cost to patients is opaque to even the most seasoned health policy expert such as yourselves. It might as well be a foreign language to patients.

We deserve and we ought to demand transparency through the entire drug supply chain, the manufacturing process, the R&D, and the rest of the entire healthcare system. That includes the true prices other stakeholders pay and charge for the healthcare they provide. The rebates thrown around the system to hide the truth need to be presented as well. Hospitals, device companies, doctors, pharmacy, benefit managers, insurers, transportation providers, billing managers, everyone needs to provide transparency and accountability.

And, yes, drug companies need to be held accountable too for their role in our increasing costs and the massive spikes in drug prices. We shouldn't allow companies to abruptly raise the price of a drug when that drug has been on the market for years, especially when there's been no innovation, no R&D to justify a new price for an existing medicine.

Bad actors that hinder competition shouldn't be able to delay patient access to generic and biosimilar medicines by slowing down the generic approval process. And it's, of course, understandable that these companies want to reap a profit from their innovation. However, it's unjustifiable to cutoff patients from the care they so much deserve.

I believe we can find a balance between protecting IP and access to care. We can start by maintaining rational IP standards, ending market abuses, and providing more innovation and competition. And with that, I'd like to focus my time on how certain pharmaceutical companies are gaming our patent system to prevent competition and maintain high prices.

Dr. Kesselheim, I know you have a lot of experience in this area, and I'm hopeful that we can get from you testimony on specific companies, specific examples where we have seen a specific drug or a specific company gaming the patent process to extend their control and opportunity to really gouge the public to make these types of profits that we're so concerned about.

Dr. KESSELHEIM. Sure. And I provided some of those examples in my written testimony, but, you know, there are a number of examples where companies are able to use, you know, the patent system and weak or inappropriately granted patents to extend the market exclusivity of their products. They can—for example, there were—there's examples of companies that have patented single isomer versions of their product and then sold those single isomer versions as new brand-name products, even though they're not, you know, clinically any different from the original product. But in shifting their promotion to the new product as the older product's going generic, have shifted the market in a way that they're using that product, et cetera, even pulled the old product off the market.

As we talked about before, there are ways that companies can patent aspects of new formulations of their product or uses of their product, and in doing that try to prevent generic manufacturers from coming on the market. And, ultimately, if the generic manu-

facturers then sue to try to get those patents thrown out of court, then the brand-name company can offer consideration to the manufacturer to settle those claims and to keep—to prop up those weak patents.

Mr. ROUDA. So what are the two or three things you would change if you could to address this issue?

Dr. KESSELHEIM. Sure. I mean, I think that there are a couple of things that you can do. I mean, we can reexamine, you know, how the U.S. Patent and Trademark Office grants patents in these cases, what the rules are about how one obtains, you know, a patent on a pharmaceutical product and what is novel and nonobvious and how the rules are applied to pharmaceutical products. I think that we can do a more—we can have more systemic reexamination of those patents by administrative bodies like the Patent Trial and Appeals Board, and we can make it harder for companies to list certain noninnovative, you know, slightly incrementally changed patents with the FDA in order to put a block on generic entry.

So I think that we can act at the level of the patent office, we can act at the level of reexamination, or we can act at the level of the FDA listing process.

Mr. ROUDA. Thank you very much. I yield back.

Mr. CUMMINGS. Thank you.

Mr. COMER.

Mr. COMER. Thank you, Mr. Chairman.

Mr. Meadows and Mr. Hice touched on the subject of more government intervention in all of this. I want to add to the conversation and talk a little bit about the consequences of more government involvement in healthcare.

A recent proposal of Medicare for All is likely to devolve into complete government control of our healthcare. What effect would a government-run system like Medicare for All have on prescription drug prices?

Mr. ROY. Well, we have some example—I assume this question is directed at me?

Mr. COMER. Yes, Dr. Roy.

Mr. ROY. We have some examples actually within the Medicare program itself, which is the irony. When people talk about Medicare for All, they generally mean fee for service, public option, quote/unquote, government part A, part B Medicare. They don't mean Medicare Advantage, the part of Medicare that's administered by private plans. And the reason I bring that up is because Medicare part C, the Medicare Advantage program, actually does a much better job of delivering the Medicare benefit at a lower cost to both seniors and the government, and with additional benefits at times, relative to Medicare part A and part B combined.

So that's one example of many I could offer of how private insurers are delivering coverage more efficiently than the Federal Government does in the Medicare program. That's why I've advocated for universal coverage on a private basis where private insurers are shopping their plans to individuals purchasing health insurance as we do for any other form of insurance. If we had that kind of a system, we'd have less spending, more choice, and higher quality.

Mr. COMER. Okay. Let's stay on part D, but let me ask this question of Dr. Anderson. You know, politically in this environment, ev-

everyone is frustrated with the rising cost of drug prices, myself included. I can assure you that. But the proposal for the HHS Secretary to negotiate prices for part D drugs is—you know, it's very popular, but practically speaking, how would HHS manage that task?

Mr. ANDERSON. So that would be a challenge, in my opinion, to negotiate the prices for every single drug. So what you would have to do is at least start out negotiating the prices for a limited set of drugs. And the ones that I would start on are the drugs where Medicare pays 80 percent of the cost, which are the most expensive drugs, because the way the Medicare part D program was set up, once you enter the catastrophic phase of Medicare, Medicare pays 80 percent of the cost and can't negotiate anything. And so that's where I would start the negotiation and then move in—and if that works, expand it beyond that amount.

Mr. COMER. Dr. Roy, and this is a proposal that a lot of people on the left keep talking about that it sounds great. Again, there are consequences. One of the good things the drug companies do is research and development. If the government continues to go on the path of taking over medicine and specifically prescription drugs, what effect will that have on research and development? I mean, is the government going to successfully invest in research and development? And how efficient is that? And what will the drug companies do from this point on with respect to research and development?

Mr. ROY. Let me just answer quickly in terms of your last question, because the Centers for Medicare and Medicaid innovation actually rolled out a demonstration project just last week to allow for private insurers to negotiate that 80 percent catastrophic part D benefit on behalf of Medicare is something I suspect would be very impactful. CBO has scored, by the way, the government taking over part D is not saving any money relative to what PBMs negotiate on behalf of Medicare.

To your question about R&D and how that could be affected if the government took over R&D, we actually have experience with that. So academic medical centers, the National Institutes for Health do conduct clinical trials using NIH money appropriated by Congress, and those clinical trials almost always fail to have the rigor and technical standards necessary to get a drug over the finish line in terms of FDA approval, because the FDA standards are so specific and the data that they need is so specific in order to ensure that a drug is efficacious and safe.

So I have zero confidence that government-run clinical trials or government-sponsored clinical trials will have those technical standards that private companies have delivered up to this point.

Mr. COMER. Thank you, Mr. Chairman. I yield back.

Chairman CUMMINGS. Thank you very much.

We're going to go to Ms. Hill, but before we go there, as I'm listening to all of this, I just want to remind all of our witnesses and to all of us, I want to know some solutions. I have a fear that we will talk and talk and talk and talk, and people will die while we're talking and it will only get worse. So I just want to just keep that, I mean, as you're answering questions, help us to figure out where do we go from here. Because I don't—I just think the urgency—we

can debate and debate and debate and nothing happens, and I think that's what America is kind of upset about right now. Okay?

All right. Ms. Hill.

Ms. HILL. Thank you, Mr. Chairman. And I want to thank you for focusing the committee's first hearing this Congress, the first hearing of my congressional career, on the escalating cost of prescription drugs. I'm also very excited about how much common ground we have with our Republican colleagues on this issue. It makes me very hopeful that we might be able to make some real progress on this issue that affects every single American. And I completely agree with your desire to focus on real solutions.

I'd like to talk about one issue in particular, one area in particular. As the gentleman from Kentucky mentioned, the argument that we always hear when we talk about lowering drug prices is that drug companies need high prices in order to recoup their investments and develop the next breakthrough cure. But the fact is drug companies spend a lot more on other expenses, like marketing and payments to shareholders, than they do on research and development.

First, we know that drug companies spend billions of dollars to advertise their drugs to consumers. We've all seen the fun commercials on television. And we are one of only two countries that allow this. I was shocked to learn that drug companies spend \$5.6 billion on direct-to-consumer advertising in 2016. That's a number, 5.6 billion, that's hard to forget, given the recent conversations.

Pfizer alone spent \$1.19 billion. What's more, drug companies are allowed to take a tax deduction for the money they spend on this type of advertising, which is particularly horrifying to me.

So, Dr. Kesselheim, as a practicing physician, has it been your experience that direct-to-consumer advertising improves health outcomes?

Dr. KESSELHEIM. Well, I mean, I think that it is the case often that people will come in to my office and say, oh, you know, I saw this drug on television, I saw that drug on television. And I think it is the case that direct-to-consumer advertising drives prescribing of higher cost products, because generic drugs generally don't advertise. And so all we see on television are advertisements for the highest cost brand-name products. Usually drugs that are really good also don't need to be advertised, so it also potentially can be for drugs that don't offer, you know, substantial improvement over what's already available.

So the existence and the prevalence of direct-to-consumer advertising definitely increases pharmaceutical spending by driving patients and physicians toward higher—

Ms. HILL. Thank you. I appreciate it.

And, Dr. Georges, let me turn to you now. In response to a request for information issued by HHS, AARP said the following, and I quote, given that the effects of DTC advertising, direct-to-consumer advertising, are still subject to debate, we strongly encourage HHS to also consider studying the effects of DTC on consumer choice, cost, and clinical outcomes in order to determine whether the potential benefits of DTC advertising outweigh its potential harms.

What does AARP view as the potential harms of direct-to-consumer advertising?

Ms. GEORGES. Well, AARP is concerned that the price of the drug is never advertised. So that alone gives our members, the older American is not sure of what it is that may be a cost to them, again because the drugs that—the information that comes through to DTC may not be clear enough for our consumers to really understand what may be the potential effects or side effects of the drug. And so we think transparency, transparency is the key in the DTC.

Ms. HILL. Thank you. I appreciate that.

Another area where drug companies spend a lot of money is that they spend hundreds of millions of dollars in payments to physicians and hospitals. From 2013 to 2016, drug companies made a total of \$9.1 billion in disclosed payments to doctors and hospitals. AstraZeneca alone spent \$189 million.

Dr. Kesselheim, in your view, what is the objective of these payments?

Dr. KESSELHEIM. Well, there is a lot of different reasons why drug companies might have financial relationships with physicians. You know, there is a lot of research that physicians can conduct in partnership with pharmaceutical manufacturers, but it is also the case that pharmaceutical manufacturers spend billions and billions of dollars advertising their drugs to physicians, you know, through speakers bureaus and providing food and providing, you know, money for attending CME courses. And there is, you know, decades and decades of research showing that those kinds of promotional relationships also drive prescribing of high cost drugs and increased spending—

Ms. HILL. Thank you.

And just because we're almost out of time, I just want to close this out by asking Dr. Anderson, in your opinion, is this any relationship between the price of a drug and the amount a company spent on research and development?

Dr. KESSELHEIM. We can find no evidence that that is true.

Ms. HILL. Thank you so much. I yield back.

Chairman CUMMINGS. Thank you very much.

Ladies and gentlemen, we have four votes on the floor. I hate to tell you this, witnesses, but we're going to be gone for about close to an hour because we have four votes. It may be a little less than that.

But to the committee, 15 minutes after the last vote, in other words the last minute of the vote, we'll be back here and we'll finish up this hearing. And I don't expect any more interruptions after that. Just hang with us. This is a very important hearing. We're here to save lives and make people's lives better.

With that, we recess.

[Recess.]

Chairman CUMMINGS. Mr. Gibbs.

Mr. GIBBS. Thank you. Thank you, Mr. Chairman, and thank you for the witnesses for sticking around.

I think we can all agree that we have lots of challenges overall, and I think Representative Green earlier today talked about the structural changes in his comments and questions, and he's absolutely right.

And I've got a couple tracks I want to go down. One is I'm really concerned about research and development. You know, there's no doubt that the pharmaceutical drugs are extending people's lives, quality of life. I think we're all in agreement. The United States, of all the total dollars spent on R&D for pharmaceuticals, 2-1/2 years, about 52 percent. I was surprised the next country is Japan at 16 percent, and then everybody else is down below 10 percent. Canada is only at one percent.

And I asked Dr. Roy at the break, because he had to leave, and he agreed with those numbers because we're a big country, you know, blah, blah, blah. And I said, the next question is how about, are we over 50 percent of developing these drugs, and he said the biologics, we are at the beginning, but then it takes—they're usually smaller companies and they end up having to get venture capital, a lot of Switzerland and Japanese companies, but we're still the innovators.

So I guess my comment I just want to make on this, and you can tell me if you disagree or agree, but we've got to make sure we don't go down the path where we disincentivize R&D, because we will see life expectancies, quality of life, because we're doing so much stuff with drugs now, preventing surgeries and everything else. And that's my big concern. You see these countries that have a centralized governing system. They're not really doing much R&D. And so I don't know if you—Dr. Anderson, if you want to comment on that, my synopsis of that.

Mr. ANDERSON. I think—in terms of the data, I think you're absolutely correct. And I would agree with Dr. Roy and you that those numbers are pretty much correct, most of it. Now, a lot of that is because the research and development starts with the NIH in the United States. I mean, we probably also spend 50 percent or more of the R&D funded by the government, and so—and also, the best scientists tend to be in the United States. So that's where the research is going to be developed, because that's where the infrastructure is.

Mr. GIBBS. I think you said—I think it was you that said in your earlier testimony that it takes the private capital money to get more across the board, to move it on, right?

Mr. ANDERSON. Correct. So, essentially, what often happens now is it starts at a place like Johns Hopkins or Harvard or something. They develop the thing mostly funded by NIH, and then venture capital jumps in when they see an opportunity, when something pretty cool happens. And they put in another \$200 million or something like that. And then if it really turns out to be a drug that they think—the big drug companies think makes sense, then they come in and they pay a lot of money for that.

So the researcher does very well who develops that, but the question is, is it the research that the drug company is doing or are they essentially buying the research?

Mr. GIBBS. I just want to be careful. You concur with me that we need to be careful whatever we do in the regulatory aspect that we don't disincentivize the incentive to develop drugs?

Mr. ANDERSON. As a researcher, we definitely want that. I think what we're concerned about is, once you develop the drug and you've gotten your patent time, that should be enough.

Mr. GIBBS. Yes.

Mr. ANDERSON. And what we're seeing is all these games to keep that patent alive.

Mr. GIBBS. I want to get into the games a little bit. Orphan drugs. You know, I've had constituents come in and they've got some disease, a problem that's not common, and they're orphan drugs. And then my understanding is we have a provision and policy to help the pharmaceutical companies with that, as long as it's under 200,000 people. And then my understanding, over 200,000, some of these drugs can be used for both, and they go back to orphan waiver or whatever you want to call it, so that's one issue, right.

Another issue I have is the risk evaluation mitigation strategy, REMS, can act to restrict getting generics—generic drugs on the market. Is that correct?

Mr. ANDERSON. So let me do the orphans and then the REMS.

Mr. GIBBS. Okay.

Mr. ANDERSON. So the orphans—if I look at the top 10 best-selling drugs in America, six of them have orphan status, including the top three. In no way would you consider any of those to be orphans. They have, through a loophole or through something that was unintended in the Orphan Drug Act, have now developed an orphan on the side, and that gives them a lot of power with pharmacies and with PBMs. And so that's the problem.

With respect to REMS, REMS is to make sure that the drug is safe, and that's very important. The FDA does a reasonably nice job of doing that. What's happened with respect to research and development is they've taken the REMS idea, and what they have done is say, I'm not going to sell that product to a generic drug company, and therefore, you can't get it because of this REMS rule.

Mr. GIBBS. Okay. And I'm just about out of time, but the PBMs. In Ohio, we've got CVS is buying—they just bought a local family of pharmacies, about 20 stores. They've finally given up. I worked with them for 20 years, and articles about what's happening in Ohio with the Medicaid program, so I think there's lots of problems with how the PBMs are operating. So if we address the orphan issue, the REMS, and the PBMs, we'd make a lot of progress, I think, without overregulating and not disincentivizing and let the market function.

Mr. ANDERSON. That would be a huge undertaking, and it would be great.

Mr. GIBBS. Okay. I yield back.

Chairman CUMMINGS. Ms. Wasserman Schultz.

Ms. WASSERMAN SCHULTZ. Thank you, Mr. Chairman.

Ms. Worsham, I really want to thank you for your courage and your leadership that you displayed today in being here on behalf of your daughters and on behalf of, really, all patients everywhere.

Type 1 diabetes is a devastating disease, and it's one that has an astonishing, really dizzying number of complications that individuals deal with throughout their lives, and it is their medication, their insulin, that keeps them alive. And what the travesty is that we're dealing with here is that just like not having health insurance, the very fact of someone not having health insurance is a cause of death. Not having health insurance can kill you. Having your prescription drugs be too costly by itself can kill you. And I'm

so sorry for your loss, and it just makes it that much more important that you're here today to illustrate and put a human face on the impact of these high cost drugs.

Another human face that I can put on is the number of times that—you know, obviously I represent the state of Florida. We have a disproportionate number, the highest percentage per capita population of elderly in the country, and I have stood behind seniors in my district who I watched have five prescriptions come to the counter and they can only take three home, or they ask the pharmacist to—I've witnessed this. This is not second-and third-hand stories. Or they ask the pharmacist to score their pills, because they want to break them in half so they can double the length of time that the prescription lasts because it's unaffordable.

And as Ms. Worsham has pointed out, previously, the cost of insulin could be \$1,000 per month when you're considering all the supplies that it takes for a diabetic patient to survive. My daughter's best friend since she was four years old has Type 1 diabetes. Her younger brother, four years later, was diagnosed with Type 1 diabetes. Imagine a family dealing with two children with Type 1 diabetes.

These price increases continue despite little evidence that the products themselves are changing. For example, insulin has not changed much since its development in 1921, yet in a five-year period, the cost of insulin has almost doubled. We don't see the same price hikes for an iPad from one year to the next, for a pen from one year to the next, for this bottle of iced tea from one year to the next, because it's just not that many changes, like there hasn't been that many changes for insulin. So why the astronomical price increases?

And even more alarming is that you have just three firms—Eli Lilly, Novo Nordisk, and Sanofi-Aventis—account for the entire diabetes market in the U.S., and 90 percent of the market around the globe—around the globe. I want to know, how can drug companies justify price increases for products like insulin with minimal modifications to the medications themselves?

Dr. Anderson, isn't that just that they are padding their price to pad their bottom line?

Mr. ANDERSON. So as I said in my opening statement, you know, it's not the prices of the products that they're buying are going up. It's not—once you've developed the research, there is no additional cost, because you're not doing any additional research. So there is no real justification that I can see for raising your price repeatedly over time. It just—you know, but that's something that this committee should take a look at and ask the drug companies, why have you done this? I can't do that. You have that ability.

Ms. WASSERMAN SCHULTZ. That's right. I've just not heard any practical, legitimate, detailed explanation today about what the possibility is that would be justifiable for these kinds of price increases.

Another question I wanted to ask you, Dr. Anderson, is drug companies are also setting higher and higher launch prices for their new drugs. One study looked at a launch price for 58 cancer drugs approved between 1995 and 2013. I'm a breast cancer survivor, so it's a little personal for me. And they found that drug com-

panies increased launch prices by 10 percent annually or an average of \$8,500 per year, even after taking into account inflation and the estimated survival benefits of the drugs.

So in your opinion, why are drug companies setting astronomical launch prices for new prescription drugs?

Mr. ANDERSON. Well, now you get into the issue of Medicare part B, and Medicare part B, as we heard, pays the physician an initial 6 percent of the cost of the drug. So if you have two drugs, one which costs \$10,000 and one which costs \$100,000, and you get 6 percent of that difference, you'd rather have the \$6,000 than the \$600. And so we have a system set up to encourage the drug companies to raise their prices so that the physicians who prescribe the drug make more money.

Ms. WASSERMAN SCHULTZ. Revolting.

I yield back. Thank you, Mr. Chairman.

Chairman CUMMINGS. Doctor, how do you deal with that? Dr. Roy, I mean, is that your answer?

Mr. ANDERSON. So, essentially, it's better than it was before. Before, the drug company would set a very high price and the doctor would essentially make the difference between the high price and the price that they could get it. So they limited that profit to 6 percent. And now I think it's time to go down and say no profit, because there's no other doctor that gets paid additional money when they prescribe something.

Chairman CUMMINGS. Thank you.

Questions, Mr. Grothman?

Mr. GROTHMAN. Okay. A couple of questions. I noticed recently that the number of generics that are being approved by the FDA each year has gone up. I think in the first—in the most recent calendar year, it jumped up to 791. Just a few years ago, were going up about 500 a year. I know a lot of that—I don't know if a lot of it's coincidence, but I know President Trump promised to stand for the pharmaceuticals and get more of these generics approved.

Could you comment on the increase in the number of generics that have been approved recently by the FDA, and does that have an effect on the overall cost approach in this country?

We'll take you, Dr. Anderson. We'll start with you, either one of you.

Mr. ANDERSON. So the answer, it's great that we have more and more generics because generics are absolutely much less expensive than the brands. What we now have to do, and I don't want to bash the PBMs all day, but essentially the brands are now paying the PBMs to keep the brand on the formulary and to give it a very favorable placement. So we have to take that into account now, so we—it's great that we have the generics available; we just need to have them on the formularies in a very good placement.

Mr. GROTHMAN. It's important, though, that we keep the turnout of new generics up. That overall helps society, right?

Mr. ANDERSON. That absolutely does, and there's a whole set of things that are making it hard to do so the way the drug companies operate. So we—the key thing—

Mr. GROTHMAN. It's gone up, though, significantly. And like I said, under this administration's first year, it was 970, I think, and

the recent background was only 500 a year. So something good is going on over there.

Mr. ANDERSON. Something great is going on there. And one of the things I testified about three years ago is to do expedited review of these drugs, because where there's no competition, this was sort of the anti-Martin Shkreli thing that we talked about in this committee about three years ago, and that was to make sure that generics could be into the market when there was no competition, and the FDA has followed up on that.

Mr. GROTHMAN. Okay. I'll give you kind of a related thing. We have these biosimilars. Okay. I want to talk about them a little bit. I know some states have passed legislation kind of restricting the degree to which biosimilars can be used. I know my own state of Wisconsin passed legislation last year signed by former Governor Walker to facilitate dispensing and substitution of biosimilar products at the pharmacy.

First of all, I'd like to know, do you know about how many biosimilars we have in the United States approved, and could you comment, is this a good trend as we make it easier to prescribe the biosimilars?

Mr. ANDERSON. So I think, unfortunately, we only have three or four biosimilars that are active on the market right now, and in Europe, they have almost 50. So I think we have a serious problem with getting the biosimilars, first of all, out in the market, and then when we get them out in the market, for the drug—for the PBMs to put them in favorable placement. So I think you've got two problems here.

Mr. GROTHMAN. Do you agree with that, Dr. Kesselheim?

Dr. KESSELHEIM. So the FDA has approved about 12 or 13 biosimilars, but only, as Dr. Anderson said, only about three or four are out on the market, and that's because a lot of the other biosimilars are being backed up as a result of litigation over the patents on them and settlements between the brand name and the biosimilar manufacturer that are keeping the biosimilars on the market. But I do think that getting biosimilars out on the market will help reduce prices a little bit.

Again, there's evidence that they are able to reduce prices in Europe. I don't think you're going to see biosimilars reduce prices as much as we see generic drugs reduce prices because they're not interchangeable in the same way, at least not yet.

Mr. GROTHMAN. Just like I said, in Wisconsin, they're pushing to allow pharmacists to sell more biosimilars, and I understand in other countries—in other states around the country they're going the opposite way, you know, making it more difficult for pharmacists to prescribe them. I wonder if you would comment on the political pressures, you know, why some politicians like in Wisconsin are pushing more, why some would be lobbying against allowing pharmacists to sell more biosimilars.

Dr. KESSELHEIM. Well, I mean, I think that part of what's going on in other states is there is concern about automatically substituting biosimilars in the same way that we automatically substitute small molecule generic drugs, because there are concerns about whether or not that's safe for patients to go in that direction.

Mr. GROTHMAN. Okay. You're being very kind. Just one other comment. Somebody said we all agree that more—more pharmaceuticals are—are good for our health. I'm not sure that our—our life expectancy compared to Europe is that high. I'm not sure that necessarily spending all this money is causing us to live longer. So that's not an automatic assumption, but thanks much.

Chairman CUMMINGS. Thank you very much.

Mr. Sarbanes.

Mr. SARBANES. Thank you, Mr. Chairman. And I want to thank the witnesses for being here today and staying as long as you have.

Ms. Worsham, first of all, thank you for being here. You've taken the pain you've experienced, and as many have said, channeled it to a crusade on behalf of others, and we thank you for that. I'm curious. Do you feel like the pharmaceutical companies, the industry has too much influence up here in Washington over how the policy gets made because of the money and special interests peddling, and all the rest of it that they get to do? I want to get your perspective on that.

Ms. WORSHAM. Again, just being a T1D mom, I'm not an expert in that area, but again, I'm just asking for a change.

Mr. SARBANES. Yes.

Ms. WORSHAM. Help, help Americans live, you know, a healthy, longer life by reducing the cost of prescription drugs, by price transparency. Let us see what's going on behind—behind closed doors. Why are the drugs so expensive? Knowing one does not bring in that annual salary of how much a drug cost. I personally don't myself, even though I have a degree, I still don't make that much money. Just again, help us, you know.

Mr. SARBANES. And we're going to try to do that. One of the reasons it is difficult to do that is because these industries have a lot of influence on how policy gets made, and when they see these changes coming down the road, they—they rev up that influence machine, and it has an impact.

And I want to just give some statistics to the committee and to you that I think reflect this. According to the Center for Responsive Politics, the pharmaceutical industry spent more on lobbying than anyone else, any other industry last year, \$280 million. In the 2018 election cycle, the industry donated over \$41 million to Federal candidates and committees. Big Pharma had over 1,400, 1,400 lobbyists last year, according to the Center for Responsive Politics. So that's three lobbyists for each Member of the House. And they're doing their best to protect the interest of their clients. I mean, I don't blame them. That's what they do, but that's not helping the public interest out at all.

And so I don't think it's any surprise that it's taken so long for us to get this right, because when we go to try to fix the law, that influence gets in the way and the money gets in the way. And I think many of our constituents would say that, too often, Congress is leaning in the direction of the big money and the special interests and away from the interests of the broad public. So we need to do something about it.

And it's not because people are bad people. People serve here, want to do the right thing. But if you develop as an institution certain dependencies on money and influence, then it's just human na-

ture that you'll start leaning in that direction. So we need to try to address that and break those dependencies. And you may know, the Democrats are leading an effort here in the House to try to strengthen our democratic institutions and make them more resilient to the money and the special interests so that we can carry out the will of the public. And I'm just curious. Do you think we're on the right track with that? Do you think that's a good approach, to try and reduce the influence that comes from that money that the special interests have, the pharmaceutical industry has, and try to lift up the influence and the voice of everyday Americans like yourself?

Ms. WORSHAM. I do agree. I believe that bringing this to the forefront is the start. At least it's on the table and we're able to see what's going on. Now it's time to—to go another step and to enforce price transparency. It's time to see, you know, who's getting paid, who can be cut out, the middleman, so that we can save more lives.

Mr. SARBANES. Thank you for your testimony today. Rest assured we're going to keep doing our best—

Ms. WORSHAM. Thank you.

Mr. SARBANES [continuing]. to try to deliver the right results and solutions for people like yourself.

Thank you, and I yield back.

Chairman CUMMINGS. Mr. Roy.

Mr. Roy of Texas. Thank you, Mr. Chairman.

I want to say thank you to Ms. Worsham. Thank you for coming here and telling us that personal story and putting a face on something I know is very close and personal to you, so thank you for taking the time to do that.

To all the witnesses, I'm sorry I don't get to question Dr. Roy. We live a couple miles apart in Austin, Texas. He might, you know, could be my twin brother except, you know, he's not. But he's a good friend, and so I wish we could have gone back and forth.

This is an issue that's important to me. It's very personal. I, like my colleague who just explained is a breast cancer survivor, I'm a survivor of Hodgkin's lymphoma. Seven years ago last week I was finishing chemotherapy at M.D. Anderson, and I've been cancer free for seven years. I was the beneficiary of a great trial drug at the time that, brentuximab, which goes in and targets the cancer cells and injects antibodies and the poison—rather than carpet-bombing your body with poison.

I say that only to say that—and I think, I assume everybody here agrees—you know, we want to make sure that we have an environment where pharmaceutical companies are able to still go out and engage and do what they do to create the drugs that are making our lives a heck of a lot better, whether it's the Neulasta shots that were helping my white blood cell counts or any of the improvements in drugs that are helping people's lives.

I've got a few questions, if you don't mind, for Dr. Georges. Can I ask you how many members AARP has? I have 38 million. Is that a rough estimate?

Ms. GEORGES. Yes, it is, sir.

Mr. ROY OF TEXAS. Thank you, ma'am. And am I correct that AARP as an organization was—opposed the passage of the AHCA a couple years ago, the proposal to replace ObamaCare, arguing

that it would make older Americans have higher premiums and smaller tax credits. Is that fair, did you all oppose that?

Ms. GEORGES. Sir, what we were very clear on is that it included an age tax, and we were concerned that older Americans should not be taxed because of their age. And so, of course, that is why we did not support it.

Mr. ROY OF TEXAS. Thank you for that. Just a question. Can you confirm that AARP has made approximately \$4.5 billion in revenue since 2009, the rough time since ObamaCare was passed?

Ms. GEORGES. I can't confirm it. I don't have anything in front of me, but it is public information, anything that you would like to see on the 990's that are filed with the IRS.

Mr. ROY OF TEXAS. Okay. Thank you. And would you be aware that—if you go back to 2011, the information I have is that AARP made \$458 million in health insurance revenue and it would rank its organization as the sixth most profitable health insurer. Do you know what that would look like in 2018 data?

Ms. GEORGES. Well, first of all, AARP is not a health insurer.

Mr. ROY OF TEXAS. Right. But if you compared it to it in terms of the amount of revenue it provides, and I'll get to that here in a second, but if that \$458 million number—I'd like to see the updated 2018 number, if we can.

According to reports, AARP makes a large royalty percentage from United Healthcare, which sells AARP-branded Medigap plans. In a 2011 House Ways and Means report, AARP received 4.95 percent of revenue off Medigap coverage. So essentially we're looking at a 4.95 percent royalty for every Medigap policy they sold to seniors. Is that accurate, and is that still the case?

Ms. GEORGES. I do not have those figures in front of me, Mr. Roy, but again, our information about our relationship with UnitedHealth is public information.

Mr. ROY OF TEXAS. Okay. And then are you aware that ObamaCare exempted Medigap insurance plans from its reforms, including preexisting conditions, leaving about 8 million people in that gap? Is that an accurate statement?

Ms. GEORGES. I cannot comment on that.

Mr. ROY OF TEXAS. Okay. And then is it accurate to say that—that the AARP in 2016 lobbied, I believe the number was somewhere around 77 bills it lobbied, and not one of those is in favor of Medigap reform?

Ms. GEORGES. I don't have that exact number—

Mr. ROY OF TEXAS. Okay.

Ms. GEORGES [continuing]. about the Medigap.

Mr. ROY OF TEXAS. Okay. Well, I think one of the reasons I'm raising these questions, and we can look at it, is just a concern about the extent to which we have a lot of conversations in this body about preexisting conditions, and what we're talking about here is a significant gap, and with respect to the Medigap coverage. And if you look at it and you say, well, what has AARP been doing with the amount of money it's made over the last decade and how that might have been used, I believe AARP was said to have said it would like to send every dime it has in order to make sure people are covered. There's a pretty big hole there with a significant num-

ber of people who are left in that gap in the preexisting existing conditions coverage.

So if we're talking about that, I'd just like to have a little bit more understanding about the profits that AARP is making in its engagement in the healthcare arena and what that means for that particular population.

That's all I have, Mr. Chairman. Thank you.

Chairman CUMMINGS. Thank you very much.

Before I go to Mr. Welch, I understand, Ms. Worsham, that you have to catch a plane. Let me take a moment to—I know every member of this committee would repeat the very words I'm about to say to you. Are you listening?

I thank you so much for taking your pain and turning it into a passion to do your purpose. Pain, passion, purpose. As I said to you a little bit earlier, the idea that \$333 a month could have saved the life of your 22-year-old is incredible. And I can't imagine as a father, my kids, to imagine one of them leaving this earth because of \$333 a month.

And some people could just go out and, after mourning and after going through difficult moments of grief, could just stand on the sidelines and do nothing. But you've taken your pain and you brought it here, and I promise you we will do everything in our power. You hear a lot of people talking up here about a lot of things. Some of you—I know—I'm sure you spent a moment asking, what does this have to do with my daughter? My daughter's not here. She's not here anymore. She was 22 years old. And I know that every birthday that comes along you mourn. Every Christmas you mourn. Every time you hear about somebody having a baby, you say, oh, my daughter might have been having my grandchild by now.

We understand, and we feel your pain, and so I just want to thank you for coming. And the thing, you know, that really gets me, Ms. Worsham, is when you told me that you've got another daughter that could face the very same thing. But I'm going to do everything in my power, and we will do everything in our power to make sure that we save her life. We do not know what gifts your daughter who passed would have brought. She had gifts to bring, but those gifts got snuffed out. And so now we must concentrate on the living, and I promise you, I promise you, we'll give it everything we've got, okay?

Ms. WORSHAM. Thank you.

Chairman CUMMINGS. You may leave if you need to. I don't want you to miss your plane. No, I don't want you to do that. And I know that the chairman who was from Ohio, he had to leave for a minute, would agree with me. We want you to get back to Ohio, all right?

Ms. WORSHAM. Thank you.

Chairman CUMMINGS. May God bless you.

Ms. WORSHAM. Thank you. Likewise.

Chairman CUMMINGS. Mr. Welch.

Mr. WELCH. Thank you. Mr. Chairman, you did speak for all of us. And, Ms. Worsham, thank you.

Ms. WORSHAM. Thank you.

Mr. WELCH. We'll let you get a minute to gather yourself and make that plane.

Ms. WORSHAM. Thank you. I just want to say thank you to everyone. I just want to say thank you to everyone. I know there's rules and there's regulations and there's policies, but we want to save more lives. It can be done, and you are the people to make it happen. I'm just a voice for people, as well as having another daughter who is enduring the same thing, and she's scared. And me speaking is making her scared. But just figure out how we as American people can live longer and healthier lives. That's all we need to figure out.

Mr. WELCH. Thank you.

Ms. WORSHAM. God bless you all.

Chairman CUMMINGS. God bless you.

Mr. Welch?

Mr. WELCH. Thank you. First of all, Mr. Chairman, thank you very much for this hearing. And, Ranking Member Jordan, thank you as well.

I just want to make a quick observation. There's two issues that we've been talking about. One is about trying to bring down the cost of prescription drugs that are high because of a broken down market. A subtext here has been relitigating some of the disputes we've had about ObamaCare, and that will continue, but my hope is that we'll be able to work together, Mr. Chairman and Mr. Ranking Member, on these broken market elements that have been brought up by both people on both sides of the aisle, because what's happening with Pharma is that, you've explained very well and Dr. Roy explained, the market is broken and is being exploited by those who are in a position to raise prices without any restraint.

Just a couple of things. I want to just reiterate—it's late—on some of the things we can do to bring down prices that don't in any way affect innovation. One, stop evergreening. Any disagreement there? No. 2, stop pay-for delay. Any dispute there? No. 3, stop this bogus transfer of a patent to a Native American tribe so they can assert sovereign immunity. Any problem there? No. 4, stop this abuse of the redistribution network so that generics don't get access to the product in order to come up with a generic alternative, something that Mr. Gibbs talked about. Any disagreement there?

Next, getting rid of this exploitation of the orphan designation that results in the congressional grant and incentive for orphan drugs to be used for non-orphan drugs. Any reservation about us acting on that? And then finally, what about price negotiation, letting the purchaser who buys wholesale not have to continue to pay retail? Any problem with that?

All right. Now, transparency. I want to go to the PBM. The PBM creates a formulary, and that's a list of drugs that are preferred, correct? Is there any transparency about what drugs are in that formulary? I'll start with you, Dr. Anderson.

Mr. ANDERSON. No, there is not. I mean, well, we know after the fact which drugs are in the formulary. So if you go on the Medicare website and you look at a PDP, you can see what they are. You don't have any idea why those were chosen.

Mr. WELCH. Let me interrupt here, because one of the concerns people have raised, Pharma companies have raised about price ne-

gotiation, including a formulary, is that that would limit access. But isn't it the case that if you have a formulary that is determined by a PBM and their interest is maximizing their profits, the prospect of their formulary limiting access far exceeds the public interest formulary?

Mr. ANDERSON. Well, I think what you've got to look at is the VA formulary which negotiates prices. And you compare it to the typical Medicare formulary which has the PBM or PDP involved, and they're about half as large as the VA formularies. So the VA formularies has more options, twice as many options, as the typical Medicare beneficiary has.

Mr. WELCH. That's great.

Dr. Kesselheim, how about you?

Mr. KESSELHEIM. Yes. I think that more—I mean, I think that getting on the right page about what the formulary should be and which drugs should be on the formulary and which drugs, you know, perform the best and why drugs should be on there and not be on there, I think that that's—that is the kinds—those are the kinds of decisions and issues that PBMs look at, and I think that that's also something that government payers when they set the formularies like the VA also look at.

Mr. WELCH. All right. Then the final question. Is there any other government that you're aware of that doesn't play a role in protecting consumers, taxpayers, and employers from the pricing practices of the pharmaceutical industry?

Dr. KESSELHEIM. I know in other countries the government is involved in determining what is a—what is a reasonable price, and actually, throughout Medicare too, I mean, without—throughout all of Medicare, Medicare sets a reasonable price or negotiates a reasonable price for all services, physician services, x-rays, all services, colonoscopies. Drugs is the only part that they don't actually do that.

So even within our government, our government is involved in setting prices for everything. Nobody talks about like, you know, R&D deficits in colonoscopies or whatever, right. So I think that it's both not only in other countries, but actually in ours too.

Mr. WELCH. Well, I thank you. My time is up, but I want to compliment the panel on an excellent presentation.

Chairman CUMMINGS. Mr. DeSaulnier.

Mr. DESAULNIER. Thank you, Mr. Chairman. Thank you, Mr. Ranking Member, for this hearing. Sorry. I think for all of us, we wanted to be here for this hearing and this amazing panel.

So Mr. Welch did the really detailed stuff. I'd like to talk about three areas that are much broader but have historical context. So it all is based on how the culture has changed. There's a wonderful book from 2008 by Melody Petersen, I think, *Our Daily Meds*. And in that book she describes how the culture of the pharmaceutical industry changed from the fifties and sixties where it used to be a researcher became the CEO. A physician was—physicians were on the board of directors if they were publicly traded.

And then her history shows that, like a lot of investments in our country, when venture capitalists came in, and I'm not against venture capitalists, but the rate of return was expected to be higher, and it's changed, and then we went into the marketing. So we

haven't always allowed this level of marketing. It used to be illegal to do television ads. I think New Zealand and we are the only two countries, and Canada has it, so we know that they spend billions of dollars on that.

If that was redirected back into a portion of research and development, it would still attract a return on investment, and it seems like this is just marketing. I had a bill when I was in the legislature that was copied on a successful bill in Washington state, where in Washington they had the state health officer and the Washington—University of Washington post on a website what their interpretation of the accuracy of TV ads for pharmaceuticals were. I couldn't get that passed even in a democratically controlled statehouse in California because of the influence of the pharmaceutical industry.

So transparency, strikes me, would be helpful here both for the physicians but for the customers. Dr. Kesselheim, could you talk about transparency both from a physician standpoint, but also from a client standpoint?

And the other part of my comments here is personal. I have a form of noncurable leukemia. Fortunately, 15 years ago, medical researchers in the Department of Defense and at NIH came up with treatments, so I take a pill every day and it keeps me alive, and it costs about \$10,000 a month, and I have good health insurance. It's not because I'm a Member of Congress, I should add. So it's both personal—and trying to negotiate with my physician and my oncologist understanding why these things were happening was a challenge for me.

So how do we help the client and the physician and still attract a reasonable rate of investment that I think is exaggerated right at this point?

Dr. KESSELHEIM. Well, I mean, I think that certainly the pharmaceutical industry has been among the most profitable industries in the United States, you know, throughout the last few decades. And so the rate of return they're getting is quite—has been quite sufficient.

But I mean, I think your point on transparency is well taken. I think that the most important thing that patients and physicians need is transparency about how their drug works and what they expect to see with their drug, what side effects they expect to see with their drug. Why their drug costs so much is another aspect of transparency. And I think that that's what this committee is doing by trying to get information from the pharmaceutical industry and try to answer these questions as to why drugs are priced the way they are and why drugs increase in price, and, you know, how these decisions are made, and then that can help us figure out how to, you know, try to, you know, ensure that there is appropriate—you know, the appropriate competition and appropriate markets and that the decisions are made in the appropriate way, and where they aren't, then there are ways maybe that Congress can get involved.

Mr. DESAULNIER. So what's the rate of return, you think, in the sweet spot if you were—if you were a market enthusiast like Dr. Roe? I want private sector investment, but I don't want it so extreme, especially when I know, for instance, my medication, the

most of that work was done with public taxpayer dollars. So I have asked this and have worked with the National Academy of Science and others to try to figure out what's a reasonable rate of return to get investors to invest, because we want them to do that but not so much that they obscure the efficiency of a marketplace, a mixed marketplace.

And then last, it strikes me that we didn't always like—we didn't always allow stock buybacks. We could at least in this field, say, restrict it so that at least a portion of it goes back to research and development.

Dr. KESSELHEIM. Right. I mean, I think, you know, so the large pharmaceutical companies make about, you know, a 20, 22 percent profit margin as opposed to the average Fortune 500 company makes more like a 7 percent profit margin. So again, I think it is an open question as to what exactly the right rate of return should be. I think that ultimately what we should be doing is asking about where the return should go. And right now, the pharmaceutical market is set up such that, you know, small changes, not valuable products can get out in the market and can—and pharmaceutical manufacturers can make more money in selling those products because there's less risk in the development of them. And we want to try to incentivize the pharmaceutical manufacturers and venture capitalists and whoever is investing to invest in the products that we need the most for patients in the public health.

Currently in our system, in our broken system, we don't really do that because it's so—it can be so easy to just make a small tweak to an already existing molecule and make outsize profits on that.

Mr. DESAULNIER. And just to conclude—thanks for the indulgence, Mr. Chairman—in my case, I'm told that my disease, which is the most common blood cancer, they have field trials right now that can cure it, but the market, it sort of seems to be counterintuitive. If somebody's making \$10,000 a month off of keeping me alive but not curing it, why would be the incentive to cure it? So anyways, thank you.

Thank you, Mr. Chairman.

Mr. ANDERSON. Hopefully it's a different company that will come up with that.

Mr. DESAULNIER. I'm hoping for that.

Chairman CUMMINGS. Mr. Khanna.

Mr. KHANNA. Yes. Thank you, Mr. Chairman. Thank you for your moral leadership and having this panel. I'm pleased to follow Representative DeSaulnier and his powerful personal story and sharing that.

My colleague, Representative Comer, said earlier today that he's concerned that government would have more of a role in medicine, and his concern is that if government has more of a role in medicine, it may hurt, as he put it, our innovation. I'm hoping, Dr. Kesselheim, that you can put him at ease with facts, because as I understand it, my colleague, if he cares about innovation, should actually be cheering for government to have a bigger role.

I know you're familiar with the study that shows that between 2010 and 2016, of every drug, all 210 drugs that were approved by the FDA were funded by the NIH or public money. Dr. Kesselheim,

can you speak, because you're such an expert in this area, about the role of public dollars in innovation and your judgment about whether the public investment is more responsible for innovation or the private pharmaceutical companies?

Dr. KESSELHEIM. Well, I mean, so the study that you're referring to is an important one, and it showed that all drugs that come out of the market in some way can be linked to NIH-funded research that helped, you know, understand the enzymatic pathway or understand the mechanism of action of the drug, you know, and do some of this basic research and this translational research that occurs in the laboratories. And I think that that's an incredibly important role that the U.S. Government plays in funding that research, and that helps float all boats. All drugs come out of those.

There are some drugs in which the U.S. Government investment even goes further, and there's development and isolation of the compound by NIH-funded research. Usually, though, at some point in this translational process, the pharmaceutical manufacturers get involved as well at a later stage and then a lot of—there's a lot of investment in the pharmaceutical manufacturers as well for a number of products at the later—at a later stage as well. I think the most important thing is both to make sure—to understand that the—that the public investment, you know, expands throughout the entire pharmaceutical space, but also that the—that private industry plays an important role as well, and we need to make sure that there is appropriate balance between the two and recognition of the public role, particularly as it relates—and we did the study showing particularly as it relates to transformative drugs and the most important new drugs that it tends to be public funding that takes those products, you know, all or sort of much of the way through the development.

Mr. KHANNA. Would it be fair to say that most of the foundational research is being done with public dollars and that—I mean, this is just sort of common sense. If you know the people who go to their M.D., Ph.D.s and want to win Nobel prizes, they tend to go to universities, not becoming general counsels or vice presidents at pharmaceutical companies. I mean, is that not your experience?

Dr. KESSELHEIM. Yes. And actually, I think that's happening more and more. It used to be the case that a lot of large pharmaceutical companies had really big research arms. But in recent years, a lot of those companies have divested from those research arms and instead are looking for the research that's coming out of the academic settings.

And I want also to bring back to what other people have said earlier in this hearing about the need for a financial incentive. And actually, a lot of these people at Harvard and at Johns Hopkins, you know, a lot of these scientists go to work every day, and their incentive is to try to cure disease and to make people better and to progress—and to, you know, develop the progress of science and, you know, they're not thinking about whether or not they can become a billionaire or whatever. That's the incentive.

Mr. KHANNA. What an odd concept, right? I mean, like Members of Congress, I mean, don't you think here most people would think they don't want to make just a billion dollars, they're in it for the

public good? What an odd concept that someone else may have a similar view.

Let me just digress one comment that Dr. Roy made and then have the panel address it. I was a little perplexed because Dr. Roy said that the FDA comes up with these difficult standards and that government then is unable to meet those standards. It's like saying a high school calculus teacher is capable of making a high school exam but wouldn't be capable of passing that exam. How can government be competent enough to come up with the standards and then you're arguing that government isn't competent to meet those standards? Was it something I was missing in that argument or is it just defies common sense?

Dr. KESSELHEIM. I mean, you know, the FDA is doing its best to try to make sure that when drugs are approved, they're as safe and as reliable as possible. And, in fact, the FDA is the fastest drug regulatory agency in the world. So to—you know, I think that—I don't think that it's right to blame the FDA. The FDA is there to help and is actually helping drugs get to the market but want to make sure that when those drugs get to the market, that patients and physicians can rely on them being interchangeable and can rely—you know, to rely on them to help the conditions that they need.

Mr. KHANNA. Thank you. I see my time has expired.

Chairman CUMMINGS. Thank you.

Ms. Ocasio-Cortez.

Ms. OCASIO-CORTEZ. Thank you, Mr. Chairman, and thank you all as our panelists here for lending your expertise and your insight to help us better legislate, and especially thank you to Dr. Georges as a professor at Lehman College for representing the Bronx so well here in this body.

I have a question I wanted to continue a little bit on my colleague from California's line of questioning about public investments in research and development. You know, I guess you would say that this is—would it be correct, Dr. Kesselheim, to characterize the NIH money that is being used in development and research as an early investment?

Mr. KESSELHEIM. Yes.

Ms. OCASIO-CORTEZ. So the public is acting as an early investor in the production of these—in the production of these drugs. Is the public receiving any sort of direct return on that investment from the highly profitable drugs that are developed from that research?

Mr. KESSELHEIM. No. In most cases, there is—when those products are eventually handed off to a for-profit company, there aren't licensing deals that bring money back into the coffers of the NIH. That usually doesn't happen.

Ms. OCASIO-CORTEZ. So the public is acting as early investor, putting tons of money into the development of drugs that then become privatized, and then they receive no return on the investment that they have made?

Mr. KESSELHEIM. Right.

Ms. OCASIO-CORTEZ. Dr. Anderson, I have a question. Since you studied comparative insurance systems, are there models where the public—where the public does receive returns on investments in other insurance—in other insurance models across the world?

Mr. ANDERSON. There are a few, but they're relatively uncommon.

Ms. OCASIO-CORTEZ. And how does that tend to work?

Mr. ANDERSON. So, essentially, if the places at the U.K. or some place like that have invested money in it, they will get some rate of return on those investments, but that, again, is relatively uncommon.

Ms. OCASIO-CORTEZ. I also have one question for Dr. Georges, and please stop me if my—if I'm going out of the scope of your expertise. As a nurse, in your experience as a nurse, do you have knowledge of the VA, general knowledge of the VA and how the VA works?

Ms. GEORGES. I have some knowledge.

Ms. OCASIO-CORTEZ. And in your experience, is the VA as a public owned and operated—operation, rather, are the drug prices in the VA lower or higher or the same as what we see—

Ms. GEORGES. Well, that I can't speak to. I don't have that kind of knowledge.

Dr. KESSELHEIM. They tend to be much lower than in other places in the country.

Mr. ANDERSON. About 31 percent lower than what Medicare pays.

Ms. OCASIO-CORTEZ. So the VA tends to be lower. And can you explain why, anyone on the panel, why that is?

Dr. KESSELHEIM. Well, in part because the VA gets some automatic statutory rebates based on the drugs that it buys, but also because the VA negotiates on behalf of all of the members of the VA and is able to use its marketing power to try to negotiate that. And also because it takes a very thoughtful approach to developing its formulary and can use inclusion on its formulary as another way of trying to negotiate a fair price for the product.

Ms. OCASIO-CORTEZ. So you would—so you would say, and am I correct in saying, that the VA is using collective bargaining power in the market to lower the price of drugs as a counter to some of the for-profit or profit motive pressures, upward pressures from the cost of pharmaceuticals?

Dr. KESSELHEIM. Right. Yes.

Ms. OCASIO-CORTEZ. Okay. Great. And I guess one last question in my remaining time. If you all could ask us, you know, to act, as Members of Congress, and do one thing, one action, what would that action be?

Mr. ANDERSON. So I think, for me, it's external reference prices, and that's something that President Trump has proposed in Medicare part B, to pay 126 percent of what the other countries do. I'm not sure I would agree with the countries that he chose, but essentially to pay 123 percent. If right now, you know, in the Medicare part D, which is most of the money, we pay about three to four times what other countries pay for the same drugs. I don't think we can bring it down to what they pay or 126 percent of it, but we can bring it down a lot.

Dr. KESSELHEIM. I tend to think external reference pricing is not a good idea, and I think that what we should do is actually get our own house in order and negotiate and try to evaluate the value and comparative and cost effectiveness of drugs better in the U.S. and

try to determine what the right prices for U.S. patients, rather than relying on what the prices are in other countries. But so if I could say one thing that we could do, I think it would be to, again, try to develop a system where the government could try to identify what the fair price is for a drug and what are reasonable prices for the drug based on the value that the drug provides to patients and then use that to negotiate with the pharmaceutical manufacturer to try to get a more effective price that we provide.

Ms. GEORGES. We in AARP would like you to have HHS be allowed to negotiate lower drug prices on behalf of Medicare beneficiaries.

Ms. OCASIO-CORTEZ. Thank you. Thank you all so much.

Mr. Chair, I yield my time.

Chairman CUMMINGS. Thank you very much. Thank you.

Ms. Pressley.

Ms. PRESSLEY. All right. Thank you, Mr. Chairman. It is a testament to you, Mr. Chairman, that the first matter on our docket, the priority of this committee was to lift up lived experiences, the struggles, the perspectives, or the expertise of real people. Although Ms. Worsham had to leave for her flight, I do very much appreciate your centering our first hearing squarely on her lived experiences and struggles.

Yesterday, a number of my colleagues, in fact, Rep. Tlaib and some others, we had a conference convening on the state of mamas, and based on Ms. Worsham's testimony, it is a reminder that there are many mamas that are worried about their babies. And we mourn the loss of Antavia. And there are millions more like her whose health is threatened and whose lives hang in the balance because of a tiered for-profit healthcare system because of greed. We have the right to healthcare, to afford life-saving medications. To remain alive, it seems, is up for debate.

This is the Oversight and Reform Committee. Our chairman reminds us that we are here to seek the truth. Today we have heard it. And one of the most common hardships that we've heard throughout the recent shutdown of the Federal Government is that so many people are already living in the margins and on the precipice because of the fight for a living wage, because of stagnant wages and rising rental costs. They're already struggling to meet basic needs. And on top of that, cannot afford insulin, EpiPens, blood pressure medication.

What we need is a complete reframe of our infrastructure, and we need to commit to more than just health insurance but true healthcare, and that includes access to affordable life-saving medications. But until that day, I look to this panel for your continued expertise and your insight and observations. The gentlelady of New York asked my question, which was to seek your prescription other than our brewing transparency and rooting out the pervasive greed which is in abundance in this industry. There's no denying that.

So if, indeed, the role of this committee is to root out the truth, soon enough, we'll know whether or not we are willing to do the bold work necessary to realize—to live out our truths, our ideals as a Nation.

Ms. PRESSLEY. So my question, since we heard from patients, and we talked about the companies, the drug companies, is I want

to talk about the impact on providers. And in turn, what is that impact on patient care? I represent the Massachusetts 7th. There are 15 community health centers in my state. There are 52 community health centers. And so they serve the most vulnerable, low-income, communities of color. And so, I was wondering if you could speak about what that impact is. And we will start with Dr. Kesselheim, who is in my district. I thank you very much for your incredible issues. And so could you speak to the impact on providers?

Dr. KESSELHEIM. Sure. I mean, I think that it is a really important issue. I think, unfortunately, providers don't know enough about the costs of the drugs that they prescribe. But in many cases, you know, the drugs that they might prescribe, and they set a treatment plan for a patient, and then the patient goes to formulary and the drugs are unexpectedly high, the prices of the drugs are unexpectedly high, and the patient is not able to fill the prescription, and then as a provider, you're stuck, and you need to then work again with the patient on a different mechanism to try to treat their condition. And that can make things very difficult for the patients who you're trying to take care of.

Ms. PRESSLEY. And since they are serving our most vulnerable is this exacerbating and contributing to existing health disparities? And also, is it resulting in reduced staffing levels, which is also impacting patient care?

Dr. KESSELHEIM. Absolutely it does. I mean, it takes time, it takes additional nurses, it takes additional pharmacists onsite at these places to try to deal with all these issues, and to try to understand, why this drug costs this much? And how are we going to get this patient the drugs that they need? What systems are there that we can rely on? What backups to those backup systems? And it is a very complicated and very challenging process for patients and then providers are doing the best they can to help patients through that.

Mr. ANDERSON. Let me tell you a story about Maryland hospitals, we have a rate-setting commission. We can't grow more than three percent per year in Maryland in terms of hospital spending. And as a result of that, when the drug companies increase their prices by eight or 10 percent, we have to find some other way to live within that three percent. So we have to let off nurses, or we have to do something else in Maryland in places like Johns Hopkins in order to combat the higher prices for pharmaceuticals.

Ms. PRESSLEY. Thank you. I now have a question for you, Dr. Georges. Could you just speak to any—sort of antidotally, to any other, what you've seen on the front lines in terms of tough choices that older Americans are making?

Ms. GEORGES. Yes. What older Americans are doing are making choices between food and drugs. And that's a shame. They've lived long, they've worked hard and that's—the price is unsustainable, the drug prices. As Dr. Kesselheim also said, one of the issues that we find then, add nonadherence to the medical regime setup, which, in turn, slows down any recovery, any restoration or any maintenance of their health. So what we're doing is we're looking at choices: Do I live in a more healthy life? Do I need to eat? Who's

going to pay my rent? And those are unacceptable for us in America today. We cannot continue these unsustainable prices.

Ms. PRESSLEY. Something I heard, I'm sure you've experienced this, but in my district, that not only were people scoring medications, but they were also sharing medications, which is incredibly dangerous. Is that something that you're hearing as well?

Ms. GEORGES. Right. And what people are doing not knowing, because they are not the physician, they are not the primary care provider, so they don't know for sure that the medication they are going to share is really—has the efficacy that the physician is expecting for that patient. But people are desperate.

Chairman CUMMINGS. Thank you very much.

Ms. PRESSLEY. Thank you.

Chairman CUMMINGS. Ms. Tlaib.

Ms. TLAIB. Thank you so much, Mr. Chairman. I would like to thank you so much for your leadership, leadership with compassion. And to repeat what my colleague from California said, your moral leadership. This is so critically important. As you know, I think all of us, as we were hearing rumors about the possibility of Mr. Cohen testifying before us, I've got to tell you, it was incredible that our first person to speak before this, my first official committee hearing, is to have a mother like myself, Ms. Worsham, who is facing such a crisis right now in regards to access to insulin for her only living child.

According to the report from the Centers for Disease Control and Prevention as of 2015, more than 100 million Americans had diabetes or prediabetes. And the American Diabetes Association says that about 1.25 million people have type 1 diabetes. And there are over 400,000 adults, Mr. Chairman, 21 years old and older that live in Wayne County, Michigan in my district, that are high risk for diabetes. And in Detroit, the number is over 150,000.

People with type 1 diabetes, therefore, depend on insulin to live. I'm so sorry to see Ms. Worsham leave and I wanted to talk to her more, but for those that are here, thank you. I just wanted you to know that when I read that three companies, Norvo Nordisk, Eli Lilly, and Sanofi-Aventis, hold 99 percent of the global market for insulin, and there is no generic version. We've seen insulin prices nearly triple from 2002 to 2013 and drug companies have continued to raise prices since then.

Dr. Anderson, I know that you work with your colleague at Hopkins, Dr. Jeremy Greene, who has done a lot of work in this area. In your opinion, why have drug companies taken this dramatic price increase for insulin? I know my colleague from Boston pretty much called it corporate greed. That would be my answer. But I'm here to learn, and possibly maybe you have a different answer, but I'd enjoy to know what that is.

Mr. ANDERSON. So you have a market of 112.5 million people, and you want to continue that market. And, you know, if the drug becomes a generic, you lose that market. So you're going to do everything you can in your power as a drug company to continue that market, and they do patent things, they do orphan drug activities. They do a whole variety of things that the Congress could stop them from doing, if they took appropriate action. So there's a number of things that you could choose to do, if you did, and make

those drugs for diabetes available much—in the generic form and much quicker.

Ms. TLAIB. One of the things—I have the 13th congressional district in Michigan, third poorest congressional district, very diverse. The majority of my residents being Black Americans in this country, and which we know research shows over and over again that almost twice as likely to be diagnosed with diabetes. Dr. Kesselheim, you're a primary care physician, I believe, correct? How are the high insulin prices affecting the patients that you treat, in particular, patients that come from communities of color?

Dr. KESSELHEIM. Yes, it's a really important issue. More and more people are struggling with the prices. And I think the story you heard from Ms. Worsham is terrible and heartbreaking, but it's repeated in many different practices where people are noticing that patients are struggling with the prices of insulin.

I would point out that we actually have a study out this week in JAMA where we looked at a health system that substituted older human insulins for the newer versions, and found that patients did just as well and spent a lot less money. And it just kind of shows you that substituting older products that maybe aren't in vogue because they don't have all the bells and whistles of the new products, but they work just as well clinically, could be a really good alternative.

And I know that there was a bill in Congress last year about setting up a government system to produce insulin for patients who need them and then to sell it at cost. And if there was a system in place, to try to fill that market niche of these potentially older products, that might work just as well, but could be available at a cheaper price, I think a lot of patients would benefit from it and a lot of physicians would use it because they are observing what you're saying, which is this, you know, issue where a lot of people are struggling with the cost of the product.

Ms. TLAIB. Thank you so much. This is a question that's a little different, but, you know, this is the first time that I'm hearing that there's tax deductions for ads run on TV for drugs. I'm a little taken aback by that. Do you know what the rate there is? How much can we save by taking away that tax deduction?

Mr. ANDERSON. I do not know, but we can find that out for you.

Dr. KESSELHEIM. Absolutely.

Ms. TLAIB. Thank you, Chairman. I yield my time.

Chairman CUMMINGS. Thank you very much.

As we go to Ms. Maloney, I want to thank our freshmen for embracing Ms. Worsham. I thank you. I—if my knee wasn't bad, I would have been down there. But thank you, because so often, people see government as distant from them, and when they feel that you have the humility to touch them, and that they can touch you, it makes a big difference.

With that, Mrs. Maloney.

Mrs. MALONEY. Thank you so much, and I share your same sentiment. It was really wonderful to see the enthusiasm, and the warmth, and the caring of our new freshmen, and for staying and participating and being so supportive to Ms. Worsham. And I want to thank you, Mr. Chairman, for calling this incredibly important hearing, and all of our panelists, especially Dr. Georges, who is

from the great city of New York, which I have the honor of representing a portion of it. And we're very proud of your professional career and your testimony today.

I found Mrs. Worsham's testimony really a national scandal that a child could die because they could not afford the insulin, or they did not get the insulin they needed, particularly since it's been around for 100 years. And the creator, Dr. Frederick Banting, he sold it for \$1, because he wanted it to be affordable. And I want to go to your point that you made, Dr. Kesselheim, that we should go back to the original products, they work. Maybe they are not as good as the new brand names, but if you can't afford the brand names, then it could save lives.

This past weekend, I was at a conference at Mount Sinai with doctors in my district, and they told me that insulin is not available, the generic insulin. And they say it works, they want it, they want access to it. It's not available in New York City. The only place they can find nearby selling it is Walmart. They are selling insulin. But all of the pharmacies are not selling it. And the doctors aren't prescribing it. Now you could argue the new brand is better, but if you can't afford the new brand, the old brand works, just the point that you said. So how can we get the insulin that works and is affordable, the generic brand, out there to the people in the pharmacies? And Dr. Kesselheim or Dr. Anderson, if you could both answer that.

To me, I find it scandalous that the generic is available, but people can't get access to it. And the doctors in New York are saying, Can you tell us how we can get it? Is it affordable? We want the generic, but the drugstores are not selling it. Can we require them to sell it? How can we get this lifesaving insulin out in an affordable way to people that need it?

Dr. KESSELHEIM. So I would say not only that, the study that I was just talking about that came out in JAMA today shows that the older insulin actually does work just as well.

Mrs. MALONEY. That's what the doctors were saying, so why isn't it available?

Dr. KESSELHEIM. It's not. So one of the reasons it's not available is that people aren't producing it and making it as available. And so as I just had said a few minutes ago, one of the things that the government could do is try to step in and produce the product itself, given the fact that this is such a widespread problem and a major public health crisis, this market failure where there isn't enough product of this—of this sort of older—

Mrs. MALONEY. Dr. Anderson.

Dr. KESSELHEIM [continuing]. off patent being available, maybe that's one mechanism to try to address the issue.

Mr. ANDERSON. Another mechanism we have is really a private sector response, and that's something that we are doing with a number of hospitals, and it's called Civica Rx, and what it is is a nonprofit drug company that's being established, started at Intermountain Healthcare, but about 10—1,000 hospitals who have joined up, and they are going to start making things like the insulin out there to compete against it. Because the problem that you have right now is that if you competed against it, somebody will lower the price and your initial investment doesn't make sense. But

if you can get a guaranteed market by these hospitals, they will make the drug.

Mrs. MALONEY. Well, according to this article in The New York Times on the insulin wars, it says the three drug companies are now under a lawsuit because of price fixing, running the prices up, not making affordable drugs available. This is outrageous that this is allowed to happen in this country. And I hope the chairman will call all three of them in for a hearing to testify on why they are not making insulin available at an affordable price. And this goes on. What is going on, it sounds like the wild west. There are no rules, no regulations. They can raise prices higher than the hospitals can. They can do whatever they want, these drug companies. And I haven't heard any type of responsibility. Can you give me some understanding on why three drug companies can fix prices, take off affordable items that can save lives? Doctors, all three doctors? Does anyone have any answer to that?

Chairman CUMMINGS. This is her last question to you. Does anyone have an answer to that?

Dr. KESSELHEIM. It shouldn't be—I mean, again, this is something the FTC should look into if there is evidence of—you know, you can see actually if you look at the historical insulin prices from the three companies, that they do kind of go up in lockstep over time. And so, you know, I think that's something for the committee to look into.

Mrs. MALONEY. Now another question, when you were testifying that PBM that they came out with their formulas, and they're formulating things that they put out there, why can't you require that insulin be part of those formulating things that they put out, doctors?

Mr. ANDERSON. Well, they are part of it, but—

Mrs. MALONEY. But not the generic.

Mr. ANDERSON. Not the generic. So—

Mrs. MALONEY. But can't we require them that the generics be part of it?

Mr. ANDERSON. You could.

Chairman CUMMINGS. Thank you very much.

Mrs. MALONEY. Thank you. I yield back.

Chairman CUMMINGS. Ranking Member Jordan.

Mr. JORDAN. Dr. Anderson, are prescription drug costs are too high?

Mr. ANDERSON. I think from affordability point of view, yes. The fact that Ms. Worsham and others can't afford those drugs—

Mr. JORDAN. How about healthcare costs in general? Are they too high?

Mr. ANDERSON. Yes, they are.

Mr. JORDAN. And have they trended—like, if you look at the last decade, is the trend up on both prescription drug costs and overall healthcare costs, insurance costs, hospital costs? Are they all turning up?

Mr. ANDERSON. Unfortunately, they are all going up.

Mr. JORDAN. All trending up.

What was the single biggest change to the American healthcare system over the last decade?

Mr. ANDERSON. Probably the Affordable Care Act.

Mr. JORDAN. Probably the Affordable—I would probably get rid of the word “probably.” I would say the Affordable Care Act, right? And yet, every single thing in healthcare continues to go up?

Mr. ANDERSON. Correct. And it was going up before. We were number 1 in terms of—

Mr. JORDAN. I’m asking about before. I am asking in the last day—how long ago was the Affordable Care Act passed?

Mr. ANDERSON. It was passed in 2010.

Mr. JORDAN. I believe it was March 2010. Is that right?

Mr. ANDERSON. Yes.

Mr. JORDAN. March 2010. So nine years ago, and everything continues to go up. How can that be?

Mr. ANDERSON. Well, what I look at and I wrote a paper that just came out in the Journal of Health Affairs and looked at what’s the trend over last 10 years.

Mr. JORDAN. No. I mean, how can that be in light of what we were—

Mr. ANDERSON. Let me explain.

Mr. JORDAN [continuing]. in light of what we were told, Dr. Anderson, because we were told this was the cat’s meow, this was the end-all, be-all, greatest thing in history. How can they all—everything in healthcare continued—the price continued to go up. When we were told they were all going to go down. Premiums were going to decline, Dr. Anderson.

Mr. ANDERSON. I hear you.

Mr. JORDAN. You liked your plan, you were going to get to keep your plan, Dr. Anderson.

Mr. ANDERSON. And I have.

Mr. JORDAN. If you liked your doctor, a doctor like Mr. Kesselheim—Dr. Kesselheim, excuse me, you were going to get to keep your doctor.

Mr. ANDERSON. So let me explain what I see is the major trend over the last 10 years, and that is, the private sector prices have increased about twice as fast as the public sector prices. So in 2010, the Medicare program and what the private sector paid for hospitals, and physicians, and drugs was about the same. Now, the private sector is paying 50 percent more on average than what the—

Mr. JORDAN. Because the market’s all messed up, right?

Mr. ANDERSON. But it’s the private sector market where the prices are going up.

Mr. JORDAN. So Dr. Anderson, do you know the name Jonathan Gruber?

Mr. ANDERSON. Sure.

Mr. JORDAN. And do you remember Mr. Gruber, what he was called when it came to the Affordable Care Act, the ObamaCare? Do you know what Mr. Gruber’s title was?

Mr. ANDERSON. He was an independent consultant. He—

Mr. JORDAN. I’m talking about what The New York Times called him. The New York Times called him the architect of ObamaCare. And why is Dr. Gruber somewhat famous, particularly around the Halls of Congress? Any recollection?

Mr. ANDERSON. I think you’d have to answer that question.

Mr. JORDAN. Well, because he was caught on tape lying to us. Actually he was caught on tape telling the truth about the fact that he lied to us, right? He is the one who said, Oh, you can pull it over on the American people. We can't tell the American people the truth about ObamaCare. So might that have something to do with the high cost of medicine today? The high cost of insurance? And as we are talking about this hearing today, the high cost of prescription drugs?

Mr. ANDERSON. Well, except that in 2009, we were also the most expensive country in the world. So it's no different. So I wrote this paper back in 2003, we were the most expensive. I rewrote the paper—

Mr. JORDAN. Are you advocating, Doctor, a bigger role for government in all of healthcare? Mr. Khanna talked about the role that government plays in development of drugs at the NIH just a few minutes ago. Do you advocate a bigger role for government in all aspects of healthcare?

Mr. ANDERSON. I think there is certain places where the private sector works well, and there are certain prices where the public sector works well. And I think we just have to take a look at where we are getting the best value for our dollar.

Mr. JORDAN. And so you would say—well, I don't want to put words in your mouth, but you would say maybe when it comes to quality of the research done, it's—that's where government involvement is good, but maybe not in access, maybe not in affordability, maybe not in other areas. Where would you draw the line?

Mr. ANDERSON. Well, I think affordability. As I said, the private sector is paying 50 percent more for the same services the public sector is. So in terms of affordability, I would give the points to the public sector, not—

Mr. JORDAN. Doctor, do you support single payer?

Mr. ANDERSON. No.

Mr. JORDAN. Dr. Kesselheim, do you support single payer?

Dr. KESSELHEIM. I think—I mean, yes, I think that there's—

Mr. JORDAN. Do you want the government to run it all?

Dr. KESSELHEIM. Well, no. As Dr. Anderson was saying, I think that there is some role for private sector in different parts of it, but I do think that in the case of pharmaceuticals, we could be getting—we could be using government negotiation to get better prices for the part that the government pays for right now.

Mr. JORDAN. Yes, but that's not—but you said you support single payer, but then you just limited it to prescription drug and buying negotiations—

Dr. KESSELHEIM. So the question today is about prescription drugs, and are we getting the best value for our money for prescription drugs? And I think that clearly the government is not, because the government doesn't use its power to pay the appropriate price for the drugs that it's buying. So in that sense, I think that we should be using the power of Medicare to try to evaluate what the right price is for the products that the government is buying.

So I do think that that—in terms of other parts of the healthcare sector, that's not my area of expertise, but I think that there is a role for a government option that people can use.

Mr. ANDERSON. In terms of—public option makes way more sense to me than single payer, allowing people to buy into Medicare if they so choose.

Mr. JORDAN. Dr. Georges, I'm sorry I didn't get to you, but my time is out, but thank you for coming and to all our witnesses.

Chairman CUMMINGS. I want to thank all of our witnesses for being here today. As I said a little bit earlier, my major concern is that we will debate, and debate, and debate and end up doing nothing. One of my colleagues, Mr. Delaney, has a saying that I wish I had invented it. He says, "the cost of doing nothing is never nothing." The fact is that people are dying.

The story that Ms. Worsham told is being repeated over, and over, and over, and over, and over again, but still we debate. I think Mr. Welch laid out a number of things that we need to be doing, and you all have laid them out. The question is will we do them? We have to do them. You know, when I think about listening to things about Affordable Care Act, you know, today's hearing offered the committee a meaningful opportunity to examine issues that are affecting millions of American families each and every day. It's unfortunate that my Republican colleagues are using this time to instead continue their extreme partisan attacks against the Affordable Care Act.

The ACA expanded coverage for nearly 20 million Americans through Medicaid expansion in exchanges. To that extent, the greatest spending on healthcare can be attributed to the healthcare law. It is because more Americans have been able to access high quality affordable healthcare than ever before.

But I take you back to the story that I told from the beginning, the lady who said I can get the operation at Hopkins, but I can't afford the cure. That makes absolutely no sense, none. Can get the operation, the surgery, but can't afford the medicine, you know, you have to have followup, am I right, Docs? You have to have followup, Madam, Dr. Georges, you know that. No followup, what good is the operation? As a matter of fact, you might be worse off. So we have—you've heard the questions, you've given your best. And now we've got to move forward with it. We want to try to pull the curtains back on Dr. Georges why these—the costs are going up. Trying to pull the curtains back on, is it really R&D that these profits are being used for, is it buybacks? And then we went to know how we get to the bottom line to reducing the price of this medicine.

I'll never forget Shkreli, Shkreli—yes, he came in here, and after jacking up prices sky high, and he basically as he's walking out the room after he refused, he took the Fifth, if I recall correctly, and called us imbeciles. That's what he said. He called us imbeciles. And yet, and still, he was responsible because of what he did or failed to do for a lot of people dying. And I guess that's what I want us to keep in mind, the bottom line, that people are suffering.

I mean, think about what Ms. Worsham said, for \$333 a month, \$333 a month, if her daughter had \$333 a month to pay for that insulin, she'd still be alive. That's a 22-year old. I mean, just think about that. This is America, this is United States of America, and I am convinced that we are better than that. And what we have to do now is synchronize our conscience with our conduct. We have

got to have synchronization. One side talking about, Oh, I don't like this, I don't like that. Okay, if you don't like it, work out something that does work, and we do it in a bipartisan way, but we've got to do something. And this is bigger than us. This is bigger than us. And it's not about us. It's about generations yet unborn.

You heard DeSaulnier talk about he had a situation, a cancer situation where I assume at one point it may have been a fatal situation, but now apparently, it's chronic. Why? Because of research, because of medicine. And he said—you hear what he said? Was it \$10,000 a month, was it a month? He can afford the \$10,000 a month, I guess. \$10,000 a month, just to stay alive. There's something wrong with that. Part B, when we talk about the President's proposal, I'm hoping that we can get that done, I'm hoping we can do a Medicare negotiation. We need it do probably a combination of things. But the American people are watching this right now, they are watching us right now trying to figure out how I'm going to make it? How am I going to be there for my daughter's wedding? How am I going to celebrate my next birthday? Am I going to be here for two more Christmases because they cannot get the medicine, cannot afford it? And so, I am determined and I'm going to paint Ms. Worsham's face in the DNA of every cell in my brain to try to make sure that her other daughter who's facing the same thing does not die.

And with that, we call this hearing to an end. Thank you.

[Whereupon, at 5:09 p.m., the committee was adjourned.]

