Hearing on The Cost of Rising Prescription Drug Prices

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTEENTH CONGRESS

FIRST SESSION

February 12, 2019

Serial No. 116-4

COMMITTEE ON WAYS AND MEANS RICHARD E. NEAL, Massachusetts, *Chairman*	
JOHN LEWIS, Georgia LLOYD DOGGETT, Texas MIKE THOMPSON, California JOHN B. LARSON, Connecticut EARL BLUMENAUER, Oregon RON KIND, Wisconsin BILL PASCRELL, JR., New Jersey DANNY DAVIS, Illinois LINDA SÁNCHEZ, California BRIAN HIGGINS, New York TERRI SEWELL, Alabama SUZAN DELBENE, Washington JUDY CHU, California GWENDOLYNNE MOORE, Wisconsin DAN KILDEE, Michigan BRENDAN BOYLE, Pennsylvania DON BEYER, Virginia DWIGHT EVANS, Pennsylvania BRAD SCHNEIDER, Illinois TOM SUOZZI, New York JIMMY PANETTA, California STEPHANIE MURPHY, Florida JIMMY GOMEZ, California STEVEN HORSFORD, Nevada	KEVIN BRADY, Texas DEVIN NUNES, California VERN BUCHANAN, Florida ADRIAN SMITH, Nebraska KENNY MARCHANT, Texas TOM REED, New York MIKE KELLY, Pennsylvania GEORGE HOLDING, North Carolina JASON T. SMITH, Missouri TOM RICE, South Carolina DAVID SCHWEIKERT, Arizona JACKIE WALORSKI, Indiana DARIN LAHOOD, Illinois BRAD R. WENSTRUP, Ohio JODEY ARRINGTON, Texas DREW FERGUSON, Georgia RON ESTES, Kansas
BRANDON CASEY, *Staff Director* GARY J. ANDRES, *Minority Chief Counsel*	

HOUSE COMMITTEE ON WAYS & MEANS
CHAIRMAN RICHARD E. NEAL

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

FOR IMMEDIATE RELEASE CONTACT: (202) 225-3625

February 5, 2019

No. FC-4

Chairman Neal Announces a Hearing on The Cost of Rising Prescription Drug Prices

House Ways and Means Chairman Richard E. Neal announced today that the Committee will hold a hearing, entitled "The Cost of Rising Prescription Drug Prices," on Tuesday, February 12, at 10:00 a.m. in room 1100 Longworth House Office Building.

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit written comments for the hearing record must follow the appropriate link on the hearing page of the Committee website

and complete the informational forms. From the Committee homepage, http://waysandmeans.house.gov, select "Hearings." Select the hearing for which you would like to make a submission, and click on the link entitled, "Click here to provide a submission for the record." Once you have followed the online instructions, submit all requested information. ATTACH your submission as a Word document, in compliance with the formatting requirements listed below, **by the close of business on Tuesday, February 26, 2019.** For questions, or if you encounter technical problems, please call (202) 225-3625.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but reserves the right to format it according to guidelines. Any submission provided to the Committee by a witness, any materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

All submissions and supplementary materials must be submitted in a single document via email, provided in Word format and must not exceed a total of 10 pages. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

All submissions must include a list of all clients, persons and/or organizations on whose behalf the witness appears. The name, company, address, telephone, and fax numbers of each witness must be included in the body of the email. Please exclude any personal identifiable information in the attached submission.

Failure to follow the formatting requirements may result in the exclusion of a submission. All submissions for the record are final.

The Committee seeks to make its facilities accessible to persons with disabilities. If you require special accommodations, please call (202) 225-3625 in advance of the event (four business days' notice is requested). Questions regarding special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Note: All Committee advisories and news releases are available at http://www.waysandmeans.house.gov/

###

WITNESSES

Ola Ojewumi
Founder, Project ASCEND
Witness Statement

Mark E. Miller, PhD
Executive Vice President of Health Care, Arnold Ventures
Witness Statement

Rachel Sachs
Associate Professor of Law, Washington University
Witness statement

Ala Reuther
Legislative Consultant, UAW Retiree Medical Benefits Trust
Witness statement

Joseph R. Antos PhD
Wilson H. Taylor Scholar in Health Care and Retirement Policy, American Enterprise Institute
Witness statement

Hearing on The Cost of Rising Prescription Drug Prices

U.S. House of Representatives,
Subcommittee on Health,
Committee on Ways and Means,
Washington, D.C

The committee met, pursuant to call, at 10:03 a.m., in Room 1100, Longworth House Office Building, Hon. Richard E. Neal [chairman of the committee] presiding.

Chairman Neal. The committee will now come to order.

I want to say good morning to all, welcome our witnesses and audience members, and thank all of you for being here.

Before I begin, I want to take a moment to extend condolences to the families of John Dingell and Walter Jones. Debbie Dingell has served with us for a considerable period of time.

For those of us who served with John Dingell, myself included for more than 15 years, we know about his love and affection for this country. Today's hearing is a fitting one to pay tribute to him in the sense that during his decades of service, among many other things, he worked to ensure that Americans had access to safe, high quality medication. It was a privilege to have been in his company.

John was aware of the availability of safe, high quality medication and knowing that it would mean nothing if Americans are forced to choose between refilling their prescription and paying their rent or putting food on the table. Americans, of course, are fed up with the rising price of drugs as more and more people simply cannot afford life-saving medications.

Let me also call attention to one of the most decent human beings that I have ever served with, and that was Walter Jones. In terms of the timeline, I also served with his dad for 4 years. They were impeccably kind and decent people, and in the case of Walter, a man of extraordinary conscience.

I know from a series of private meetings that we had with him as we tried to express the frustration that we all felt about the war in Iraq that Walter Jones was a leader on that front and regretted every day here the vote that he had cast. And I must tell you, it was always done with a mark of great sincerity.

Whenever you saw him, you could always tell that he was entirely reflective and

mindful of the consequence of having the privilege of serving in this institution.

Back to the issue of healthcare and innovation. We know that it is part of the fabric of my home State of Massachusetts, and medical research has opened the door to numerous breakthroughs. The high cost of this innovation often gets excessively passed on to the consumer.

Let me tell you about Jocelyn, who lives in Springfield, Massachusetts, my district. She was given a prescription for a drug but cannot afford the $600 a month price tag. There is no other drug that works for her health situation, and it has caused her to go into severe depression because there is nothing that she can do to manage her situation.

One of the challenges we face is understanding the underlying problem. The drug companies point to the PBMs, who point to the insurance companies, who point to the hospitals. The one group that is not the problem but is the biggest victim is, indeed, the patients.

This, we know, is not a Democratic or Republican issue. It crosses the political spectrum. In fact, the President noted the other night during the State of the Union address his continued concern about the intent of drug prices. If we are all on the same page on this, there clearly is a problem.

Recently, the Republican Governor of Massachusetts, Charlie Baker, has expressed his concern in a substantial op-ed piece in the Boston Globe. On my part, I have already started to kick the discussion going forward with Secretary Azar. I intend to keep that line of communication open so that we can find a realistic, sustainable outcome.

We have five excellent witnesses here today. The main message I want to drive home to my colleagues, including the takeaway, that in these next few hours there is no single solution. The problem is complex, and Congress will need a multipronged approach to address it. We will need to change policies and incentives in the FDA, CMS,

and potentially even look to the Tax Code. We need to change incentives within the system. At the heart of this, remember, it is the patient who needs relief.

I am certain with the information we learn today, coupled with continued and thoughtful discussion that we have tried hard to embrace, that we can craft policies that will bring down or at least stabilize the cost of drug prices. Americans are desperate for a solution to help them afford the quality, life-saving medications they need and deserve. We have that responsibility to act.

And now let me recognize the ranking member, Mr. Brady, for an opening statement.

[The statement of Chairman Neal follows:]

Mr. Brady. Thank you, Chairman Neal, for calling this important hearing today.

This is our second committee hearing in this Congress dedicated to healthcare, and we Republicans welcome that. It has been a year since the healthcare laws have been rewritten, and healthcare still remains the number one worry for families and workers across the country.

As we all know, it is the rising out-of-pocket healthcare costs that frustrate individuals and local businesses. High premiums, skyrocketing deductibles, and less power over healthcare bills haunt middle class families and workers. Medicaid is putting tremendous financial pressure on our States. And Medicare, this important program which provides healthcare to 50 million Americans, is going broke sooner than expected. The status quo is failing. We must do better.

Our focus today is on getting the cost of prescription drug prices down. I am pleased that our Democrat colleagues are willing to work together with Republicans in Congress and the administration on this issue.

Republicans on this committee believe Congress must work together to lower out-of-pocket healthcare costs for Americans. We can do so by cracking down on overpriced drugs, empowering patients to choose the most affordable medicines for them, and eliminating incentives in Medicare that reward bad actors and lead to higher prices. We have all heard horror stories of someone going to the pharmacy on their way home from work, and all of a sudden, it seems like the price tag for their drug jumped overnight.

Why is this happening? What is broken in the government-regulated market for medicine that allows for the seemingly annual price hikes on products, many of which have been available for years?

I am hopeful that our witnesses today can give us an answer and offer proposals and policies we should consider to remedy these frustrating problems.

Healthcare and drug prices are too big of an issue to go at it alone. We must collaborate to drive these costs down. This Congress, let's work together as Republicans and Democrats to lower drug prices. We stand ready to work together on a bipartisan basis to do so.

One thing needs to be stated clearly as we start this work: To protect the hope of future medical breakthroughs, Republicans reject Washington price controls that could limit Americans' access to life-saving medicines that many families are counting on.

When Washington negotiates in government-run healthcare programs taxpayers often end up bearing the cost, while Americans can be denied access to the most innovative breakthrough medicines available to others in the private market. We must avoid policies that jeopardize the valuable innovation of our researchers, pharmacists, and medical professionals. We have to get the incentives right to lower costs while we accelerate new advances in medicine, which isn't easy. We must give patients much more power to choose the care and the medicines right for them, not what is right for Washington.

Medicare part B and part D are due for needed reforms, and we want to work together with our Democrat colleagues to bring these bipartisan reforms across the finish line.

The best reforms we can implement are ones that will truly empower patients, ones that can unleash the same market forces that have found a way to reward the companies that have innovated the technologies in our cell phones but ensure its prices lower year over year.

While I know a small fraction are demanding that Democrats push through government control of every aspect of Americans' lives, we ask that you instead work with us to tackle what we think are problems that can be successfully addressed.

We want to push for solutions that work for patients. We want to work with all of our colleagues on the other side of the dais to lower healthcare costs. Today, let's show the American people we are ready to do just that.

Thank you, Chairman Neal.

[The statement of Mr. Brady follows:]

Chairman Neal. Thank you, Mr. Brady.

And without objection, all members' opening statements will be made part of the record.

Now let me turn to the witness introductions.

First, I would like to welcome Odunola Ojewumi. She is a founder of a nonprofit organization called Project ASCEND,

a disability rights activist, and a cancer survivor.

Next is Mark Miller, Ph.D., who is executive vice president of health care at Arnold Ventures, where he works to improve the value of healthcare. Dr. Miller was formerly the Executive Director of the Medicare Payment Advisory Commission, MedPAC, and is a nationally renowned expert in Medicare payment policies.

Welcome back to the committee. We are glad to have you here in your new capacity.

Rachel Sachs is an associate professor of law at Washington University. She is an expert on health policy and drug law with particular focus on the nexus of innovation and patient care.

Alan Reuther, an old friend, is a legislative consultant for the International Union of the Automobile Workers, or the UAW, and their Retiree Medical Benefits Trust. It provides healthcare benefits to 656,000 retired members of the UAW, including General Motors, Ford, and Chrysler.

Welcome back to the committee, Mr. Reuther.

And finally Joe Antos, Ph.D., is a Wilson Taylor Resident Scholar in Health Care and Retirement Policy at the American Enterprise Institute, where his research focuses on the economics of health policy, including health expenditures, the Affordable Care Act, and Medicare.

We welcome you back as well, Dr. Antos.

Each of your statements will be made part of the record in its entirety, and I would ask that you summarize your testimony in 5 minutes or less. And to help you with that time, there is a timing light on your table. When you have 1 minute left, the light will switch from green to yellow and then finally to red when 5 minutes are up.

The chair would now recognize Ms. Ojewumi. Please begin.

STATEMENT OF OLA OJEWUMI, FOUNDER OF PROJECT ASCEND AND PATIENT, BELTSVILLE, MD

Ms. Ojewumi. Good morning, Chairman Neal, Ranking Member Brady, and distinguished members of this committee. Thank you for the opportunity to testify today. My name is Ola Ojewumi, and I am honored to speak in front of you all today.

I run a small education nonprofit that provides college scholarships to disabled students. I am a disabilities rights activist, and I am here on behalf of Families USA, a nonprofit, nonpartisan consumer advocacy organization that has worked since 1982 to promote high quality affordable healthcare for all in this country.

At age 9, I was diagnosed with a severe heart condition. Two years later, I became the recipient of a heart and kidney transplant. I lived a relatively healthy life for 10 years or so, but at age 24, I was treated for cancer at the Johns Hopkins Kimmel Cancer Center.

Thankfully, by then the Affordable Care Act had been enacted, so I was able to stay on my parents' health insurance and afford the treatment that I needed to recover. I am 28 now and living cancer-free.

Now, in the movies and on television those that recover from organ transplants or cancer tend to bounce back quickly. They never have to receive treatment again. In reality, organ transplant patients have to take medication for the rest of their lives.

In order to keep my transplanted heart pumping and my kidney functioning, I will be on immunosuppressive therapy for the rest of my life, until the day that I die. Without insurance, that medication costs $2,000 for 30 days.

The past few years have proven that affordable prescription medication is a thing of the past. You can see this for yourself in the rise in the cost of insulin, EpiPens, and HIV

drugs.

I have been affected by this. Though it sounds like my list of medical problems couldn't get any longer, they have grown over the years. I have a unique muscular disorder, mitochondrial disease, that has made me a wheelchair user, and I also have a rare autoimmune disease that I had treated with surgery less than 2 months ago.

Right now, I have excellent health insurance through my employer, but the costs add up quickly, and insurance doesn't cover everything that I need. I take 22 pills a day including, an antirejection drug.

In 2014, my health insurance refused to cover a supplemental compound to treat my muscular disease, which has put me in a wheelchair. Monthly, I pay $200 out of pocket, and that is with great health insurance. So for the past 4 years, I haven't taken the medication because my insurance has chosen not to cover it, and I can't afford it.

Taken all together, I pay $3,000 a year in copays, and if I were to fill all of my prescriptions, I would be spending over $10,000 a year out of pocket.

This isn't the only hurdle I have experienced in trying to get care. I have faced delays in approval for medical equipment, including a motorized wheelchair. It took 7 years for insurance companies to approve a new chair. My former copay 7 years ago was $50. This year it was $900. All of this is with excellent health insurance.

The cost of my care has, in part, meant that I continue to live at home with my parents because it is simply just too expensive to afford to live on my own. The rise in costs of formerly affordable medical equipment and drugs is not coincidental or a result of the free market system. It is corporate greed bred from a lack of regulation of prescription drugs.

Congress has the power to stop this by changing public policy. Drug makers are granted the authority to drive up the costs of drugs to unaffordable and astronomical rates

with the consent of the state. Inaction on the part of lawmakers is what has led to this crisis. Drug manufacturers are preying on the needs of the most vulnerable population, the disabled and chronically ill.

If you care about the well-being of your fellow man, it is not only your civic duty, but simply just the right thing to do. The disabled community isn't asking for your pity. We are asking for compassion and commonsense policymaking.

Though you may not see us in you, you all will become one of us. Everyone eventually becomes disabled as they enter their senior years. The only difference is my issues happened to me in my youth. I am you, and you are me.

I would like to thank you so much for this opportunity to speak.

[The statement of Ms. Ojewumi follows:]

Chairman Neal. Thank you.

And, Dr. Miller, would you proceed?

STATEMENT OF MARK E. MILLER, PH.D., EXECUTIVE VICE PRESIDENT OF HEALTH CARE, ARNOLD VENTURES

Mr. Miller. Chairman Neil, Ranking Member Brady, distinguished members of the committee, I am Mark Miller, vice president of health care at Arnold Ventures. I appreciate you asking us here to testify today.

Arnold Ventures is a philanthropy dedicated to reforming dysfunctional markets and programs to ensure a better return on investment for the people who they serve and the people who pay for them. We work to develop evidence and ideas to improve public policy. We strongly believe in markets, but we also believe in evidence-based intervention when markets fail.

Our health objective is to lower costs and increase value for businesses, governments, and patients. We focus broadly on the problem, including targeting excessive hospital and physician prices, surprise out-of-network billing, excessive drug prices, reducing unsafe care, and finding better ways to manage care for the chronically ill.

Today, I will discuss drug spending and possible solutions to control that spending. In all instances, the objective is to protect innovation but to reduce the cost to the taxpayer and the patient.

There are strong reasons for this committee to act. We spent $470 billion on drugs in 2016, and that number is projected to grow 24 percent in 2020. In Medicare part D we spend $100 billion after rebates. The catastrophic portion of that program, which is financed 80 percent by the taxpayer, is growing at a rate of 17 percent annually, and this is

because of higher-priced drugs.

In Medicare part B we spend $30 billion. That spend has doubled since 2010, and most of that growth is due to higher-priced drugs. In Medicaid we spend $30 billion, and there has been a 50 percent increase since 2011.

The current debt held by the Federal Government is equal to something like 77 percent of the size of the economy. The prices of Hep C drugs are often unaffordable to States for their Medicaid and their prison population. One in four Americans choose not to fill a prescription because of the cost, and a recent Federal Reserve report indicates that 40 percent of American families can't produce $400 in an emergency situation.

So what are some directions for reform in Medicare? Consistent with MedPAC recommendations and proposals included in the last two administrations' budgets, the committee could consider a series of reforms to Medicare part D's payment structure that will increase pressure on the plans to more aggressively negotiate drug prices, for example, by requiring the plans to pick up 80 percent rather than 15 percent of the catastrophic drug costs. Concurrently, this policy could enhance beneficiary protections when they reach the catastrophic cap.

The committee could consider changing the sunshine legislation to report contributions to patient groups and could consider potentially applying the Medicaid-level rebate for the low income population in the Medicare program.

But there are drugs where there is no competition, and the PBMs have little leverage to lower prices in Medicare, and you should consider for a narrow set of drugs that are expensive and don't have competition using such tools as reference pricing, pricing to the clinical value of the drug, or binding arbitration. Authorizing the Medicare program to use its market power to address these situations would allow you to address situations where manufacturers set excessive prices in the absence of competition.

Turning to Medicare part B, consider replacing the percentage reimbursement model with a flat fee model to eliminate the incentive to prescribe higher-cost drugs. Other options include creating an inflation rebate or empowering physicians to form purchasing groups and negotiate better prices. Finally, you could consider lowering the payment benchmark altogether by using an international price index like that proposed by the administration recently.

But any changes in Medicare alone will be insufficient. Manufacturers benefit from taxpayer-funded NIH research and from government-granted monopolies. Naturally they devote substantial resources to protecting those monopolies. Those monopolies were granted by the government, and it is the government's responsibility to intervene on behalf of taxpayers when the market fails.

A comprehensive legislative package would also include policies such as CREATES and pay for delay. These will help control public program costs and have a collateral effect of reducing commercial sector drug costs.

In closing, there are additional policies and ideas detailed in the testimony. Most importantly, Arnold Ventures and its grantees stand ready to assist you or your staff on any of these ideas.

I would like to thank you for your attention. I look forward to your questions.

[The statement of Mr. Miller follows:]

Chairman Neal. Thank you.

Attorney Sachs, would you proceed?

STATEMENT OF RACHEL SACHS, ASSOCIATE PROFESSOR OF LAW, WASHINGTON UNIVERSITY IN ST. LOUIS, MO

Ms. Sachs. Chairman Neal, Ranking Member Brady, and members of the House Ways and Means Committee, my name is Rachel Sachs, and I am an associate professor of law at Washington University in St. Louis, where my research focuses on innovation and access to new pharmaceuticals. Thank you for the opportunity today to testify about the high prices of prescription drugs, the impact those prices have on patients and our public payers, and how this committee might help solve these problems.

Today, prescription drug prices in the United States are high and rising. Individual drug prices are rising. In 2018, there were 96 price increases on existing drugs for every price decrease.

Systemwide, spending is also rising. Between 2007 and 2016, part D spending rose from $46.2 billion to $99.5 billion. Part B spending rose from $15.4 billion in 2009 to $29.1 billion in 2016.

In the long term, these trends are not sustainable for our public payers. But in the short term, these trends are intolerable for patients. As we have heard, about one in four people taking prescription drugs have difficulty forwarding their medication, and they may respond by rationing doses or delaying filling prescriptions. Patients have died as a result of these choices.

This committee has an important role to play in responding to the problem of high drug prices, particularly in three key areas: lowering patients' out-of-pocket costs, fixing

misaligned incentives, and reducing overall pharmaceutical spending.

First, lowering patients' out-of-pocket costs will both relieve the financial pressures facing many patients and address the health consequences that come with those pressures. As the National Academies has recommended, Congress could limit patients' cost sharing for particular classes of drugs where adherence could reduce the cost of care. As MedPAC has proposed, Congress might eliminate part D beneficiary cost sharing above a particular threshold, and Congress might cap Medicare beneficiaries' out-of-pocket spending on prescription drugs on a per-month basis, similar to what a recently bill proposed.

These proposals would assist the millions of Medicare beneficiaries who have difficulty affording their medication. But reducing patients' out-of-pocket costs in isolation may increase burdens on other patients and on Medicare. Reforms to patients' out-of-pocket costs should be paired with other reforms which would lower prices more directly.

Second, both Medicare part B and part D have misaligned incentives, which drive up both the cost of individual prescription drugs and overall spending.

As the previous two administrations have proposed, Congress should reform part B's ASP-Plus-6 reimbursement system which financially rewards physicians for prescribing more expensive drugs.

Congress might require pharmaceutical companies to reimburse Medicare part B and part D when the price of their drug rises faster than a specified threshold, perhaps through extending Medicaid's inflation-adjusted claw back or through a tax.

As the National Academies has recommended, Congress could remove the tax deductibility of direct-to-consumer advertising of prescription drugs.

And Congress could remove existing sensitives for PBMs to place drugs with high

list prices and large rebates in preferred placements on formularies.

Third, particularly for specialty drugs in both part B around part D that have little or no competition, the committee ought to consider reforms that would strengthen Medicare's negotiating position or shift payments from higher cost systems to lower cost ones. Congress should give part D the authority to negotiate directly prescription drug prices, coupled with the authority to enforce lower prices in those situations.

Three sets of policies the committee ought to consider are binding arbitration, value-based pricing, benchmarking reimbursement to the clinical value of the drug, and external reference pricing based on an external reference basket of prices in other countries.

Congress should also give part B the authority to negotiate for lower prices. And Congress might consider applying Medicaid payment rates for low income subsidy beneficiaries rather than part D rates.

Congress has a critical role to play in solving the problem of high drug prices. This committee in particular can help lower patients' out-of-pocket costs, fix these misaligned incentives, and reduce pharmaceutical prices. There are additional proposals detailed in my testimony as well.

Chairman Neal, Ranking Member Brady, members of the committee, I applaud your leadership in focusing on this very important issue, and I look forward to answering your questions.

[The statement of Ms. Sachs follows:]

Chairman Neal. Thank you, Attorney Sachs.

Mr. Reuther, would you proceed please?

STATEMENT OF ALAN REUTHER, LEGISLATIVE CONSULTANT, UAW RETIREE MEDICAL BENEFITS TRUST, AUSTIN, TX

Mr. Reuther. Chairman Neal, Ranking Member Brady, members of the committee, my name is Alan Reuther. I am the legislative consultant for the UAW Retiree Medical Benefits Trust. We appreciate the opportunity to testify today on the cost of rising prescription drug prices.

The Trust provides healthcare benefits for 656,000 retired UAW members, along with their dependents. It is one of the largest nongovernmental retiree healthcare plans in the United States.

About 80 percent of our members are enrolled in Medicare. Nearly all of them are in a standalone employer group waiver Medicare part D plan maintained by the Trust.

Last year the total health care expenditures for the Trust were $4.2 billion. Of that, $2 billion, almost half, was spent for prescription drugs.

Like most healthcare plans, the Trust's spending on prescription drugs has been increasing rapidly in recently years, rising almost 58 percent from 2013 to 2018. This reduces the resources available to address other healthcare priorities for our members. For this reason, we strongly urge this committee and Congress as a whole to take actions to restrain the skyrocketing costs of prescription drugs.

I would like to talk first about insulin prices. In recent years, the Trust's single largest drug spend has been for insulin products. In 2018, we spent $235 million on insulin. Spending on insulin increased by 51 percent between 2013 and 2017. This was

despite the fact that insulin usage declined by 4 percent during that period.

The average price of insulin in the United States nearly tripled between 2002 and 2013. Between 2012 and 2016, the average price increased 15 to 17 percent per year. In stark contrast, European countries have been able to cap or even push down the prices for insulin.

In the long term, the Trust believes the solution to the problem posed by high insulin prices is to foster greater competition among the manufacturers. To do this, we urge Congress and the administration to speed up the process for approving biosimilar versions of insulin, by prohibiting pay-for-delay agreements, reducing the exclusivity period for brand medications, ensuring that interchangeability determinations do not present an unreasonable barrier, and counteracting abuses of the drug patent system.

We also believe it is important for Congress and the administration to take steps that will have a short-term impact on lowering the price of insulin. These could include linking the price of insulin to lower international prices, linking the price to lower prices currently negotiated through the Federal Supply Schedule, or allowing Medicare to negotiate prescription drug prices.

Next, I would like to talk about prices for generic drugs. The Trust has worked hard to increase the percentage of our members who use lower cost generic drugs. But since 2015, we have experienced significant price increases for various generic medications. For example, the price of Digoxin increased from $131 to $989. The price of Tetracycline jumped from $31 to $450.

Of particular concern, spending for high priced generics has increased enormously, even though they have safe and effective generic competitors that are much less costly. We are also concerned about the enormous price differences that have arisen between generic capsules versus tablets, particularly with extended release tablets.

We believe Congress and the administration could address these problems by cracking down on abusive actions by generic manufacturers who take advantage of short-term supply problems and moving proactively to ensure there are sufficient producers of generics.

Lastly, I would like to comment on prices for biologics and specialty drugs. Spending on these drugs represents a rapidly rising share of the Trust's total spending. In 2018, we spent $778 million on these medications, about 38 percent of our overall drug expenditures. Publications predict that spending on those drugs will increase to 50 percent of total plan costs by 2021.

To counteract this trend, we believe it is important for Congress and the administration to limit the price of biologics and specialty drugs and to encourage the introduction and availability of lower cost biosimilars. The range of steps we outlined in our earlier discussion of insulin would all be important in this regard.

We also urge Congress to pass the CREATES Act to address REMs abuse, and we urge you to consider legislation to address direct-to-consumer advertising for biologics and specialty drugs.

In our written testimony, we also comment on a number of steps Congress and the administration should take to help restrain prices for drugs under part B, as well as those under part D.

In conclusion, we appreciate the opportunity to testify on the subject of prescription drug prices. We believe the actions we have suggested would help to save money for individuals, healthcare plans, and for Medicare.

Thank you.

[The statement of Mr. Reuther follows:]

Chairman Neal. Thank you.

The chair would recognize Dr. Antos to proceed please.

STATEMENT OF JOSEPH R. ANTOS, PH.D., WILSON H. TAYLOR SCHOLAR IN HEALTH CARE AND RETIREMENT POLICY, AMERICAN ENTERPRISE INSTITUTE

Mr. Antos. Thank you, Chairman Neal, Ranking Member Brady, and distinguished members of the committee. Thank you for this opportunity to testify today.

American consumers and policymakers are increasingly concerned about the high cost of prescription drugs. Reducing prescription drug costs is an important goal for policy, but it is not the only goal. We also need to promote future innovation that can bring us our next cure. We need to find solutions to slow overall health spending while improving value for patients.

The root cause of high drug prices is the protection of intellectual property, which is a fundamental principle of a dynamic economy and crucial for the development of new and better therapies. Patents and marketing exclusivity rights for approved drugs provide strong incentives for pharmaceutical research and development, but they also create pricing power for the inventors of the new therapies.

Congress has adopted policies to temper that market power and promote competition. Recent proposals seek to expand entry to the market by discouraging anticompetitive behavior. Expanding entry to the market promotes competition and can help slow price growth.

The market for Hepatitis C drugs demonstrates the effect of vigorous competition on prices. Sovaldi, the first cure for the disease, was introduced to the market in 2014 at a

list price of $84,000 for the course of treatment. Subsequent introduction of competing products forced down prices. Mavyret was introduced in 2017. It has a list price of $26,400.

Now, that is not inexpensive, but the point is that the price dropped by two-thirds over a very short period of time as a result of competition.

PBMs play a key and controversial role in determining what consumers actually pay for their prescriptions. Manufacturers are willing to offer lower prices in the form of rebates to PBMs in exchange for favorable placement on the drug formulary. Consumers may pay a modest fixed-dollar copayment for a preferred generic. A nonpreferred brand drug could require coinsurance based on the percentage of list price without taking into account rebates or discounts. Consumers needing specialty drugs are likely to face substantial cost-sharing amounts.

The administration recently proposed to remove the Safe Harbor protection for rebates that are paid to PBMs or health plans operating in Medicare part D. Rebates would be allowed only if they are passed through at a discount to consumers.

The Medicare Actuary points out that although the intention is to relieve the cost burden on Medicare beneficiaries who use more prescription drugs, that would not be accomplished without imposing new costs on other beneficiaries and taxpayers.

Other proposals would change current incentives that drive up the cost of Medicare and put seniors at risk for unaffordable cost. Reforms for part B drugs include converting the part B add-on payment, which is now 6 percent of the average sales price, to a fixed fee. This straightforward change reduces the incentive to prescribe higher-priced drugs.

One could also permit the flexibility to use tools such as step therapy to manage part B drug costs and ultimately replace the buy-and-bill system with a system of private vendors to negotiate prices.

Part D's benefit should be restructured so that the plans receive most of their Federal payments through the prospective direct subsidy rather than reinsurance. That would reduce the incentive to negotiate higher rebates rather than lower list prices and would help promote the use of lower cost alternatives on the formulary.

Several changes include:

Reducing Medicare's individual reinsurance subsidy below 80 percent. MedPAC suggests moving it down to 20 percent. But certainly lowering that would, I think, make sense.

Excluding manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending. Capping the amount that part D enrollees spend out of pocket is a particularly important reform. This is still the only program, Medicare is still the only program that does not provide that protection to its beneficiaries.

We could also allow part D plans greater flexibility to manage protected drug classes. That can include removing certain drug classes from protected status, broader use of prior authorization and step therapy, or excluding specific drugs within protected classes.

The pricing of pharmaceutical products is a difficult subject for public officials because society has an interest in both medical progress and affordable access to beneficial treatments. There is a growing concern that current policies do not strike the right balance between innovation and competition. Clearly, there are no easy and politically safe answers, but the system can be improved with sensible reforms.

I look forward to your questions. Thank you.

[The statement of Mr. Antos follows:]

Chairman Neal. Thank you.

We will now proceed under the 5-minute rule with questions for the witnesses, and I will begin by recognizing myself.

All of our constituents are having difficulty affording drug prices, and we heard from Ms. Ojewumi today. She expressed her own personal courage about the challenges in affording drugs even with good insurance. Mr. Reuther talked about his members rationing insulin challenge that they have, a century-old drug that diabetics across the country need to survive. Oftentimes constituents will say to us they have to decide between rent, food, or needed medicines to survive.

The question is a general one for the panelists. Do you think there is a silver bullet, one policy that will fix this problem for all Americans, or do you think there need to be multiple approaches that will tackle different aspects of the challenge? And we will begin with the first witness and move along the panel.

Ms. Ojewumi. In response to your question, I think increased regulation on drug pricing would assist. More specifically, caps on price gouging of medications.

And also in legislation looking at disabled people as humans. Oftentimes we are looked at as a liability and not actual human beings that can contribute to society. There needs to be an element of compassion in viewing disabled people as contributing members of society. I work for my healthcare, essentially I have private employer healthcare, and I deserve a right to life just as much as the next person.

Chairman Neal. Thank you.

Dr. Miller.

Mr. Miller. I don't think that there is just one policy. I tried to say this in the 5 minutes. I think a comprehensive piece of legislation needs to look at patent and exclusivity abuses, things like CREATES and pay-for-delay. You need to restructure the

risk in part D and change some of the part B payments, as almost every person has mentioned.

And then, for those very expensive drugs where you don't have competition, I think you need to start thinking about some additional tools, again, like many of the panelists mentioned.

Chairman Neal. Attorney Sachs.

Ms. Sachs. I agree. Drugs have high prices for many different reasons, and the system is highly complex. Any particular reform could have the effect of causing trouble elsewhere in the system or might benefit only a small number of patients.

So a comprehensive package which gets at not only these drivers of the problem but also injects competition back into the system should be considered by this committee, one that looks at different aspects, as I have laid out in my testimony.

Chairman Neal. Thank you.

Mr. Reuther.

Mr. Reuther. I also agree. Just looking at insulin, in the long term there is a range of things that are needed to help promote greater competition, like eliminating pay-for-delay agreements, patent abuses, et cetera.

Those are necessarily going to take a long time to have an impact. We think there is a need for more immediate action to limit sharply higher prices for insulin so they don't have the harmful impact on beneficiaries and healthcare plans.

Chairman Neal. Dr. Antos.

Mr. Antos. [Inaudible.]

Chairman Neal. Well, tangentially, you are all connected, I mean, in your opening statements. I think it highlights the challenge we face.

Would you please speak into the -- turn your microphone on?

Mr. Antos. A point that I would add to these excellent comments is that we should worry about the interactions among the policies. It won't be one bill. It will be potentially dozens of bills. And it is very hard to know what the reaction will be on the part of the government because the government will implement many of these things, and we don't always know how that implementation goes, and then the response of the private sector and the response of the patients.

So I think we need to be very careful about how we proceed to make sure that we don't accidentally have an interaction with policies that lead us in the wrong direction.

Chairman Neal. Thank you.

One of the approaches that could help reduce high prices would be to require the manufacturer to pay a rebate if the price of the drug rises faster than inflation. Certainly, based on your testimony, it isn't going to be a cure-all for the problem, but it is a targeted approach to help address one particular issue.

The Department of Health and Human Services Inspector General and Medicare Payment Advisory Commission both recommended that Congress create such an inflationary rebate for Medicare part B drugs to protect Medicare from large price hikes for these medicines. President Trump has included a part B rebate proposal in the President's budget. So this truly is an idea that could have and would have bipartisan support. It seems like a commonsense protection for taxpayers and their dollars. Seniors' Social Security checks certainly aren't going up faster than inflation.

Mr. Miller, do you agree with OIG and MedPAC that Congress should establish an inflation rebate program for Medicare part B drugs to help protect Medicare from many of these increases?

Mr. Miller. This will be short: yes.

Chairman Neal. Thank you. And we have had encouraging conversations with

Mr. Azar on this as well. He certainly recognizes the challenge.

Attorney Sachs, can you answer the same question? Do you agree with MedPAC and OIG that Congress should establish an inflation rebate program for Medicare part B?

Ms. Sachs. I do. I would also note there is an OIG report looking at part D and the potential savings there as well for inflation-adjusted rebates, so it might be something to consider to support part B.

Chairman Neal. With that, let me recognize the ranking member for the purpose of inquiry.

Mr. Brady.

Mr. Brady. Mr. Chairman, thank you for bringing these excellent witnesses to the table.

In preparing for this hearing and working through our priorities, we think, as Republicans, Congress needs to work together to lower out-of-pocket healthcare costs, focusing on cracking down on overpriced drugs; secondly, just giving patients far more power to choose the most affordable medicines for them; and eliminating incentives in Medicare that reward bad actors and lead to high prices, as has been noted in the testimony.

I confess I do worry about some proposals, for example, the proposal to provide direct negotiation by the Federal Government in Medicare drugs.

What I worry is that Congressional Budget Office has studied the issue and concluded there would be negligible effect on prices and spending unless the government created one government-controlled formulary that confined seniors to a closed list of medicines, that would by nature exclude life-saving innovative medicines that they are counting on, and then restrict how they receive those medicines.

I don't think that is medically acceptable or politically acceptable, and I think the

solution for lowering out-of-pocket prices will be much more sophisticated than that.

I spent the evening reading Dr. Miller's presentation in the Senate earlier this year. Dr. Miller is an old friend of this committee from the years at MedPAC. Reading Dr. Antos' review of the legal, regulatory, and market environment for that drug pricing, is something that ought to be probably required reading for members of this committee.

So let me start with you two. Your points are that this is complicated, that there are a number of incentives we get wrong in this process. We have to be careful so that as we lower prices, we continue to encourage innovation. But all of you have identified areas that we should focus on.

So to Dr. Miller and to Dr. Antos, where should we be begin as a committee in focusing on getting the incentives right in healthcare? Specifically, we are not in the business, this committee, of the pipeline of drug creation and getting to market. But after that, the reimbursement of those medicines, as it goes to the manufacturer, to the middlemen, to the pharmacist, to that physician, the hospital, ultimately to that patient's pocket.

Where would you recommend, in a bipartisan way, we begin to focus in order to try to drive those prices down the right way?

Dr. Miller.

Mr. Miller. So I do want to say that the pipeline needs to be addressed. I understand that that is outside the jurisdiction of this committee, but that is important. So I would have you focus first on getting the incentives of the purchasers in part D, the PBMs, correct by taking up that set of requirements that changes the risk structure for them and pushes them to negotiate better prices.

There was a set of statements made throughout the panel with respect to part B. I would direct your attention to all of those. And you could, in fact, create, as Joe was

saying, if you wanted to move in that direction, more opportunity for physicians to organize and try and negotiate -- or a vendor -- to try and negotiate.

Mr. Brady. Lower prices.

Mr. Miller. You could do that. So that is D and B, and I know it is very fast given the time that we have.

Mr. Brady. You would begin there.

Mr. Miller. I would begin with those two.

The more difficult thing, and I know this creates tension within the committee, is that I still think there will be drugs where you don't have negotiating power, the program, the providers, the PBMs, no one. And so you need to think about different tools there. And maybe you can narrowly focus it on those drugs that don't have competition and not do it in a widespread way.

Mr. Brady. Thank you.

Dr. Antos.

Mr. Antos. So, yeah, I largely agree with Mark's statement. I think, to me, the question is, how do you deal with those one-off drugs that don't have any competition? And there is not a clear answer to that.

However, I think the bigger problem remains the basic structure of part D. The part D program in total is the biggest producer of drugs in the country, and so there is a lot of leverage there.

The reason why Congress went with individual private plans was precisely because individual private plans, as long as you have choices for beneficiaries, individual plans can exclude a drug from a formulary, and that gives leverage.

Mr. Brady. Negotiate.

Mr. Antos. Right, sir.

Mr. Brady. Thank you, sir.

Thank you, Mr. Chairman.

Chairman Neal. Thank you, Mr. Brady.

The chair would recognize Mr. Doggett to inquire.

Mr. Doggett. Thank you, Mr. Chairman.

Just over 15 years ago, the Medicare part D prescription drug program was forced through this House in the middle of the night after hours of threats and arm-twisting. Pharmaceutical manufacturers poured millions into lobbying the Congress to manipulate an important benefit for seniors for themselves instead.

With the opening of the largest market in America, Big Pharma ensured that it would retain monopoly power by inserting one notable line: a prohibition on Medicare negotiation of drug prices.

With prices for the most commonly prescribed drugs under Medicare soaring at about 10 times the rate of inflation, more than 2 years ago I was joined by most committee Democrats in respectfully but unsuccessfully asking for a hearing from the then chair on drug pricing. Today we finally get that hearing. I would ask unanimous consent to include the rejected request in the record.

Chairman Neal. Without objection.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Doggett. Today's witnesses have offered compelling testimony regarding the harm of the committee's previous indifference and the harm to Americans of leaving a vital part of our healthcare system in the control of pharmaceutical monopolies and oligopolies. Chairman Neal is absolutely correct that a number of different legislative proposals are necessary because, unfortunately, there is no wonder drug for price gouging.

I have been joined by 110 Members of the House in advancing House Resolution 1046, the Medicare Negotiation and Competitive Licensing Act. I would ask Professor Sachs what advantages this competitive licensing offers to achieve fair prices.

Ms. Sachs. Thank you for the question.

So once Medicare negotiation is on the table in whatever form, there is this question about what would happen if the pharmaceutical industry refused to negotiate a fair price or a mutually beneficial resolution.

And so one set of policies we have already heard a little bit about is threatening exclusion from a formulary even if the product is the only one in its class. Even though it might be unlikely that a company would abandon the U.S. market, that threat of exclusion would pose access concerns that we have heard about.

And so the licensing proposal has the benefit of dealing with that problem by providing incentives for generic or biosimilar manufacturers to fill the gap that the branded company was disinclined to fill.

Mr. Doggett. So one advantage of it is that you don't have the argument that we just heard in prior questioning, that we are going to deny life-saving drugs to some seniors on Medicare with competitive licensing. You assure access to all types of pharmaceuticals but at a more reasonable price than under the current system.

Ms. Sachs. It makes it far more likely that patients would not be denied, yes.

Mr. Doggett. Because you can't go to the negotiating table without something to

compel negotiation, can you?

Ms. Sachs. Yes. I believe that is correct.

Mr. Doggett. And don't all the other alternatives envision ultimately some type of formulary which does, in fact, deny some drugs in order to get negotiation at fair prices?

Ms. Sachs. To my knowledge, that is correct.

Mr. Doggett. One of the alternatives that you mentioned and that Dr. Miller mentions is to use compulsory arbitration as an alternative way of achieving fairer prices for some drugs. What limitations does that approach have?

Ms. Sachs. Well, as with any complicated procedure, there are a number of details to be worked out, and the procedure is often closely related to the substantive outcome that is achieved. I will mention two just in the interest of time.

One would be, how would the government's offer be set in the first instance? What instructions would be given to the arbiter in terms of enabling them to choose between the different offers that were provided?

And then what is the enforcement mechanism as we have discussed? What is the incentive to arbitrate in the first instance, or what would happen if the pharmaceutical company chose not to accept the price that the arbiter set? That puts us back into the discussion we have just had about threatened exclusion versus licensing.

Mr. Doggett. Is there also the possibility of simply shifting responsibility for Medicare or from the Secretary to an unknown arbiter for the final decision?

Ms. Sachs. The choice of the arbiter would be a topic that this committee would want to consider carefully, yes.

Mr. Doggett. Thank you so much, and to all our witnesses.

Chairman Neal. I thank the gentleman.

With that, the gentleman from California, Mr. Nunes, is recognized for inquire.

Mr. Nunes. Thank you, Mr. Chairman.

I want to pick up where Mr. Brady left off with Dr. Antos.

You were just getting into Medicare part D and some of the successes, possible challenges as it relates to maybe some of the more expensive drugs, the new drugs that are in the pipeline.

And can you walk us through how Medicare part D is successful in dealing with some of the more generic type drugs and the choice that patients have there versus some of the new drugs in the pipeline?

I think it would be good to shine a little light on how we can build on the process that is already created and maybe ways that we can make it better.

Mr. Antos. So I would argue that it is the basic structure of the part D program that has caused considerable success in spite of the fact that there are obviously some defects in the structure.

But the basic idea of having competing independent private health plans or part D plans that give consumers a choice of plans is a critical element here. You are not consigned to one formulary. You are not consigned to one set of options. And you can also choose to select the more expensive plan and pay a higher premium.

So this is, I think, very consumer friendly. It doesn't solve all of the problems.

Clearly, one of the great failings has to do with the payments made, the so-called reinsurance payments made above the catastrophic zone. A mistake was made there. We did not protect beneficiaries from potentially unlimited costs on the one hand; and on the other hand, we have the taxpayer picking up 80 percent of the costs. That doesn't make sense to me.

There needs to be some reduction there so that the drug plans and the pharmaceutical companies have a stake in lowering their list prices and negotiating bottom

line prices rather than increasing list prices and negotiating for higher rebates.

One other point that I should make, and that is that if we can fix that problem, that will have an effect across the entire health industry, across everyone that uses drugs, because, of course, when drug companies negotiate higher rebates and get higher list prices as part of that negotiation, that is not confined just to Medicare. That spreads through the entire health sector.

So I think Medicare, being the pivotal purchaser in this case, really has a responsibility to solve that problem.

Mr. Nunes. So what about the new drug that is in the pipeline that needs billions of dollars of research put into it? You know, clearly, this is one of the challenges that many Americans face all the time. They have got some rare disease, or there is a new drug that is on the market, and it costs thousands and thousands of dollars a month.

So is there a mechanism that we can learn by with Medicare part D on how to treat those new drugs?

Mr. Antos. Well, I think there is kind of a negative lesson, which is that if we were to go to a price-setting mechanism, there is always the question, what is the right price? Nobody knows the answer to that question other than it has to be lower.

And if we go to a price-setting mechanism, then we are confounded by the problem that we are going to discourage the pipeline of new products down the road. So we may not see it right away, but we will experience it. We may not recognize it. We will experience a negative effect down the road because we have discouraged innovation.

Mr. Nunes. I mean, this really is the challenge that we are faced with here, right? It is trying to have the government or some quasi-government agency negotiate these prices down so that people aren't getting gouged. I mean, there are plenty of examples that make no sense, like EpiPens and insulin.

And if we, the government, come in, or if we give power to the executive branch to go in and start to do this, I think the challenge that you are left with is, what drug company is going to be making investments here in the U.S. into putting new products in the pipeline? That is, I think, the crux of what both you and Dr. Miller discussed here today.

So with that, I want to thank you all for your testimony today.

I yield back, Mr. Chairman.

RPTR BRYANT

EDTR CRYSTAL

[11:01 a.m.]

Chairman Neal. I thank the gentleman.

And I would like to recognize the gentleman from California, Mr. Thompson, to inquire.

Mr. Thompson. Thank you, Mr. Chairman.

Thank you to all the witnesses who came today for your outstanding testimony.

Ms. Ojewumi, I want to thank you in particular. It takes a lot of courage to talk about your individual issues and the impact that it has on your life. And I think everybody on this dais has heard from someone, probably more than one person in our district, similar stories about the challenges that they face.

I know I have just received a letter this week from a constituent in Santa Rosa, Suzanne, who said she has ulcerative colitis, and the drug that she has to take for that, I think it is pronounced Dipentum, is outrageously expensive. She pays a thousand dollars a month for that drug, and there are no generic alternatives to that. So she is boxed in, that is all that she can take.

And in my home State of California, one in four Californians pay at least a thousand dollars a year out-of-pocket cost for the drugs that they have to take. And, clearly, there is something that has to be done in regard to this terrible burden that are placed on so many families in all of our districts.

We have heard a lot about different ways to bring about competition to try and lower this. The one that I guess you hear -- I hear a lot of anyway -- is to try and look at the VA model, where they use competition to lower their drugs. And I think that that is something that we clearly should look at.

But the VA does other things as well. And I get my healthcare, at least some of my healthcare, through the VA. If you get a drug through the VA, you get the generic drug unless there is a reason that you can't get that drug. So they go right to the lower cost drug.

Now, Dr. Miller talked about the high cost drugs where there are no alternative. And I am wondering, maybe Dr. Miller and Ms. Sachs, is there something that we can do to invest in development of competition amongst these high cost drugs with no alternative? Should INH be investing money in that? Are there some sort of grants that we can do specifically for those drugs without alternatives?

Mr. Miller. We are investing some money in this question right now to look at different ways to support innovation, whether it is through NIH, whether it is through different kinds of tax credits, or whether it is through prize money, or those types of things.

I think those probably you have some targeted opportunities, but I don't think you want to lose entirely the notion that a manufacturer has some incentive to develop an innovation. So I think you would have to think about it in a targeted way.

But I do want to add one other thing to this. In the discussion back and forth with high price drugs, there was the assumption that drugs had to be taken off of the formulary in order to have a negotiation position. That is true, that is generally how it works. But I think Medicare, given the fact that you have 60 million beneficiaries, you could also say to the manufacturer to sell any drug in Medicare, you could have a posture in which you negotiate and say that is how the strength is brought to the table. And Medicare's position could be: We cover it all, we just want to set a price.

And one point I want to make in that is that we do that in part B. In part B, there is no lack of innovation in cancer drugs or rheumatoid arthritis drugs, where a lot of drugs were all through part B.

Ms. Sachs. So I agree. And just to add a little bit in response, in terms of trying to encourage competition in some of these products, we have seen that in a class like insulin where there are multiple manufacturers, even that might not be enough to actually drive prices down.

So another strategy could be to say that in exchange for these government-granted monopolies, these patents, these exclusivity periods, these tax credits, these grants that we have already given to these manufacturers, after some period of patent-protected exclusive time on the market -- and we can discuss what that might be -- then companies ought to agree to reasonable pricing controls, right, where competition cannot be assured in that market. That would be another strategy to consider.

Mr. Thompson. Thank you.

California just passed a law that requires a 60-day notice if there is a 16 percent increase in drug cost or more. Does that sort of transparency help?

Chairman Neal. I will let the witness finish.

Ms. Sachs. Transparency is often helpful, but it doesn't help in terms of lowering prices in general in this case.

Chairman Neal. I thank the gentleman.

And let me recognize the gentleman from Florida to inquire, Mr. Buchanan.

Mr. Buchanan. Thank you, Chairman Neal and Ranking Member Brady. I am very excited about the possibility of working together. We need bipartisan solutions.

I can tell you, in my district people want results. They want us to work together and find a way to bring down ans bend the curve on cost. So the bipartisanship is a big thing.

I was just sitting here thinking about this, I wanted to get some of your opinions. Just looking at the demographics, for example. I am in Sarasota, Florida, and have one of

the oldest districts, and, of course, the State in general is probably one of the oldest areas.

But the observations I have seen there, when you look at the baby boomers, the demographics, for example, we have an assisted living facility the Lutherans run. They are out of Minnesota. They set this up many years ago in Venice, Florida, just south of us, and I had a chance to tour it.

The gentleman, the general manager running it had been there for 20 years. I asked him, what was the average age that were here? And these are people that are active, engaged. And he said, the average age 20 years ago was 72. I said, what is it today? He said, 88 to 90.

My mother-in-law, unfortunately, passed away last month. She was 99. Her sisters lived to 101 and 103.

So when we look at drug cost, the overall cost, how much is it being driven by the demographics, the fact that 10,000 people -- a lot of them are moving to Florida -- 10,000 people a day are turning 65? How much is that a factor, in your opinion, in terms of that, Dr. Miller? I just want your comment on that. How much of a factor is it?

Because I look at statin drugs. My cardiologist mentioned to me he thinks it is somewhat of a miracle drug. I am not trying to give anybody any credit, but he is saying that a lot of people are living longer as a result of it.

But how much of a factor is the demographics when we look at overall drug cost?

Mr. Miller. And I can't quantify precisely for you how much is demographics, how much is units that people are taking, and how much is price per unit. But that is essentially the three elements that you have to deal with when you are thinking about spending and how to solve the problem.

Decidedly, the costs in Medicare are driven, in part, by the demographic change, more people entering the program, and you definitely see that. But the high spend area of

Medicare and then in part B, the majority of the growth in the high spend area, the catastrophic area in D and in part B, is a price phenomenon or the introduction of new expensive drugs.

Mr. Buchanan. Thank you. I have just got limited time.

Mr. Antos, do you want to add to that? What is your general thought about that? Because to me, a lot of these programs were put in place in the sixties and some changes since then. But how much of a factor is it today?

Mr. Antos. Yeah, I think it is a substantial factor.

One of the issues here is that people are not dying cheaply and early. They are, in fact, not only making it to 65, they are making it to 90. And now the conditions that people have tend to be chronic conditions rather than acute conditions.

I mean, we have had a miracle in medicine. Heart disease has largely been cured or at least largely --

Mr. Buchanan. Let me ask you another question, because my time is up. But let me just say, what are the things that we could focus on, on a bipartisan basis, that could make a big difference in terms of bringing down cost?

Or let me throw out the idea of generic drugs. I see where you get more competition, it brings down the overall cost of these generic drugs. And we need more players, it seems, in that space. We would be able to move quicker to the generic status. What could we do more in that space?

Mr. Antos. Well, I think to some extent this has to do with intellectual property protections. We see instances where some drugs seem to retain patent protection or market exclusivity for a very, very long time. So I think that is an issue that needs to be looked at.

Mr. Buchanan. It seems like that is an area we can move quicker through that

process to get to the generic status so we can get the cheaper drugs, and then get more competition in that space to bring down cost in general.

Mr. Antos. I agree. And FDA has obviously been working on trying to streamline the drug approval process while maintaining safety and effectiveness standards.

Mr. Buchanan. Thank you. I yield back.

Mr. Reuther. I just wanted to say we very much agree that having more generic producers would be important and would help combat the spike that we are seeing in the price of generic drugs. So that is an important area.

Chairman Neal. Let me recognize the gentleman from Connecticut, Mr. Larson, to inquire.

Mr. Larson. Thank you, Mr. Chairman, Ranking Member Brady.

I do think, as Mr. Buchanan said, there is an awful lot of opportunity here for us to work again as a committee to come up with a solution, given the President's positions that he has taken, especially as it relates to prescription drugs, and also some of the longstanding concerns that this committee has had.

Let me ask a followup on some of the line of questioning that Mr. Thompson had before. And it seems to me that this always boils down to, well, if we just let Medicare negotiate directly prescription drugs with all the various pharmaceutical entities, then we ought to be able to lower that cost.

And I believe, Mr. Miller and Ms. Sachs, you were getting at that. Is that your general opinion, or is it more complicated than that?

Mr. Miller. I mean, I don't think it is a simple path to go down, but creating part D originally also was a fairly complex undertaking, and we managed to do that.

I think what I am trying to say is that you might focus on a narrow set of drugs where you don't have leverage and try and either move down a negotiation road or a

reference pricing road for those types of drugs. As Rachel began to lay out, there are some complications in either road, but I think they are potentially surmountable.

Mr. Larson. So given that there are those complications and I think you were saying also that we could add into that some kind of incentive, whether it be lengthening of patent or whatever, was that what you had in mind? Or how would you look at strengthening the part D process to lower prescription drug costs?

Ms. Sachs. Well, I was considering a more certain period of exclusivity. We have heard a little bit about strategies companies use to extend patent protection. I was referring to the idea that we might have a defined period beyond which pricing would be moderated for our public payers.

But I agree that this trade-off between how to guarantee exclusive rights up front and then how to lower prices for payers are important. And I agree that negotiation is complex. And yet I proposed it as part of my testimony because I do think it is a necessary element for some of these products and would be particularly effective for these ones with no competition.

We have heard a lot today already about the importance of market forces, but there are few, if any, other markets where we both provide government-granted monopolies, exclusivity periods, grants, tax credits, and then guarantee reimbursement on the back end through the public, and the combination of those factors causes some of the difficulties.

Mr. Larson. And can you change that all within part D successfully, do you think, or how would you go about that?

Ms. Sachs. I would love to see this Congress make bold steps towards both lowering prices and trying to promote innovation.

Mr. Larson. Mr. Miller.

Mr. Miller. If I could just add to that. I mean, I think she has laid this out.

Either you have to go at the front end of the pipeline and limit how long a patent and exclusivity period lasts so that competitors can enter, or you have to go after it -- in this conversation, you are saying Medicare. If you don't do that, then you have to go at it through the Medicare price options that we are talking about, or ideally some combination of the two. But that is how you are going to get at the problem.

Ms. Sachs. I agree. Government-granted monopolies are critical for the expensive, lengthy process that these companies must go through to bring products to market. But we have heard, I think, agreement about some of the games that companies can play to extend those monopoly periods. So I think that would be a particularly fruitful locus of bipartisan compromise.

Mr. Larson. I yield to my colleague who wanted to have a followup as well.

Mr. Doggett. Thank you very much.

Professor Sachs, both you and Dr. Miller have made a compelling argument that fair prices are not inconsistent with innovation and finding new cures.

And to the point you were just raising, I note from your testimony the average price for a month's supply of the best-selling drug in the world, Humira, for rheumatoid arthritis is currently -- and I want to get the numbers correct -- $2,669 in the United States, $1,362 in the United Kingdom, and $822 in Switzerland.

And you point out that while this drug was approved in the United States in 2002, that it will not face any generic competition until 2023. Is that right? Twenty-one years without competition.

Ms. Sachs. Yes, due to intellectual property settlements between the branded company and biosimilar applicants.

Mr. Doggett. Thank you.

Chairman Neal. I recognize the gentleman from Nebraska, Mr. Smith, to inquire.

Mr. Smith of Nebraska. Thank you, Mr. Chairman.

Thank you to our witnesses.

I think the topic of our hearing today is very timely. I think that as we sort through these issues, this is a tremendous opportunity to work together, realizing that we have a challenge ahead of us where we have the success in many respects of Medicare part D, and the dynamics and the overall framework of Medicare part D have proven very successful.

My question is, how can we take those dynamics and make sure that there is ample competition and choice and access for seniors, and actually not just seniors, but everyone, all demographics?

And I know that this issue is really so important to folks of all ages. I mean, the rising out-of-pocket healthcare costs in general are impacting more and more Americans. As illustrated by my constituents that tell me that $30,000 a year out-of-pocket expense for their health insurance is not what they would consider to be affordable. And I hope we listen to them.

When we look at bigger premiums, higher deductibles and fewer plan options, patients are faced with higher and higher costs for these essential medicines, such as the insulin mentioned by Mr. Reuther.

In order to bring down these costs in the long term, we need to address the problems with incentives built into our healthcare system which benefit those bad actors and hurt the long-term competition. It is necessary for both sides to come together to find consensus solutions, as I mentioned earlier, which address these incentives, bring new solutions to the market faster and increase healthy competition.

As Mr. Reuther expressed, the long-term solution for the present high cost of insulin is to foster greater competition among the manufacturers of insulin. In contrast, Medicare for all plans would increase, not decrease, government manipulation and

spending on the healthcare system while failing to address these underlying factors.

Now, take, for example, Medicare part D, as I mentioned earlier, a widely popular program which has performed actually better than its originally projected costs, because the private insurers compete against one another to offer a variety of competitive plans.

Increasing government involvement in the program by repealing Medicare part D noninterference would simply be an exercise in price setting rather than negotiation. In fact, the CBO has said in the past that allowing the Health Secretary to supposedly negotiate drug prices in Medicare would only save money to the extent that the Medicare program is willing to limit seniors' access to certain drugs. We have touched a little bit on that here this morning.

Mr. Antos, can you further elaborate and explain why the CBO would have come to this conclusion and what the broader effects a repeal of noninterference would have on the pharmaceutical market and consumer access?

Mr. Antos. Yes. I think it is a fundamental view of virtually every economist that unless you are willing to walk away from a product, you are not going to be able to get a much better price.

Medicare is not in that position. Every President that I know of since 1965 has said we are not going to touch Medicare. And the obvious fact is that it is very, very difficult to say no, especially in this kind of situation where we may be talking about a very expensive drug that could be potentially life-saving for some senior citizens. So being able to walk away is just not in the cards.

The other problem, though, is how do you know you have actually gotten a good price and will it really last? So you may actually negotiate a price that looks pretty good one year, but that doesn't necessarily mean that you are going to be able to keep that price.

After all, when you negotiate a price, oftentimes that is the floor price, not -- I

mean, that is the ceiling price -- sorry, that is the floor price, not the ceiling price. Prices go up from what you negotiated. And so that eliminates an important element of competition.

If you have competition, there might be another product that might actually drive the price down of that original product, but you won't see it if you have negotiated what is essentially a floor price.

Mr. Smith of Nebraska. Very good. Thank you very much.

I just hope that we as a committee will keep in mind, number one, consumer choices for seniors, especially with Medicare part D, but Medicare Advantage. I mean, there are more and more seniors who are very pleased with what they have access to with Medicare Advantage and certainly Medicare part D.

And the numbers are indisputable in terms of actually helping keep some of those costs down for Medicare part D. We need to look at how we can make sure that other costs are facing more competition and more consumer choice.

Thank you. I yield back.

Chairman Neal. I thank the gentleman.

Let me recognize the gentleman from Oregon, Mr. Blumenauer, to inquire.

Mr. Blumenauer. Thank you, Mr. Chairman.

Welcome. I deeply appreciate the testimony and the range of complexities that you are offering up to us.

Dr. Miller, welcome back. You over the years have dealt with a number of things.

You, Ms. Sachs, had some options.

MedPAC has been putting these before Congress for -- I have only been here 22 years, but they sound hauntingly familiar. I am hopeful that we are reaching a point now where we might actually take some steps to do something about it.

The situation that Mr. Reuther outlines, you have got two-thirds of a million people and a fixed amount of money to be able to deal with them. So, in a sense, we should be thinking about that with the Federal Government. There is not unlimited money, and what we do has an impact on plans like yours to be able to deal with the challenges.

Dr. Miller, one point you made that I think is very important is that for all the talk about potential negative consequences of some of the options that you and Ms. Sachs have offered that may restrict a little bit of choice or that they may pinch a little bit, there are costs for doing nothing. You point out that we are rationing drugs right now in this country, according to price, availability.

And there are 150 million people who get their healthcare through employer-authorized insurance. Is that unfettered access to pharmaceuticals? Are there modest controls that are imposed with those 150 million beneficiaries?

Mr. Miller. I am not sure I understand the last part of your question, but I do say very clearly in the testimony that we are engaged now in rationing through the prices that are being set, deductibles and copayments, the specific patient cases that we see here.

I strongly believe that there are steps that can be taken on prices that do not cut into the research and development stream that prices are high. Joe is right that it is hard to find the right price, but there is a lot of evidence that we are paying the wrong price right now, just indicated by the fact that other countries aren't paying for these drugs at these same prices as at least one indication.

Mr. Blumenauer. The part of my question that wasn't clear is that for the half of America who gets coverage through employer-sponsored programs, are there any restrictions on the pharmaceutical benefits for those insurance?

Mr. Miller. I am sorry, I forgot, I missed your question. Yes. I mean, like in part D, they are run through an insurance company and a PBM, and they make decisions

about what is on the formulary. So all through part D and all through the commercial market, people don't have access to each and every drug.

Mr. Blumenauer. I think that is an important point when we hear some of the concerns about some restrictions on choice with making some adjustments in the Federal program to speak to our values, to speak to other areas of access, that this is something that routinely happens for most Americans all the time.

The worst is rationing by price, where they can't afford it, but there are nonetheless responses that are being made in corporate America with those programs all the time.

Mr. Reuther, I really appreciated the example that you laid out in terms of the situation with insulin. And I am wondering if that might be an area that we really ought to hone in on, because it is such a pervasive problem. The alignment here of what we are paying for, the fact that this is not a new modern wonder drug that requires expensive investment by pharmaceutical industries. We have had it forever.

Would this be a worthy source, do you think, for us to drill down to try and understand the complexities of this problem?

Mr. Reuther. We would strongly encourage the committee to consider solutions directed specifically at insulin. Our plan is not unique. Spending on insulin has skyrocketed generally for private healthcare plans, part D and the employer community, and there is a huge number of people who are being negatively impacted by this. We have seen the horror stories in the press recently. And whatever you do more generally, we think targeted solutions at insulin would be important.

Mr. Blumenauer. Thank you.

Thank you, Mr. Chairman. I thought that this might be an area that we might be able to unwind some of this to look at potential solutions that affect so many people so dramatically.

Chairman Neal. I thank the gentleman.

And let me recognize the gentleman from Pennsylvania, Mr. Kelly, to inquire.

Mr. Kelly. Thank you, Chairman.

And, again, thank you all for being here today.

I want to make sure I say your name the right way. Ms. Ojewumi? Okay.

Well, first of all, just being here today and relaying your story is incredible. I think there are so many people across the country that face those same challenges.

I am just trying to remember, because you all have basically the same ideas and the whole panel. I mean, we all agree that the cost of staying well or trying to stay well and the pharmaceuticals that you need are really high right now.

I am just trying to understand, because everybody uses the term "complicated." I don't think it is that complicated. There is a desire in our society to stay well, no matter what the cost. And we are willing to look at any type of innovation we can to overcome whatever it is that we are challenged with, right? And so we constantly are looking for these new developments.

Now, what can we do to extend life beyond what normally would have been expected, or what can we do to extend someone who is very ill with a newly developed pharmaceutical?

Then the question becomes, well, if we have created that market or we have created that culture, then we have also created a situation where people will work to get to those answers. And some of these things are very costly.

Mr. Antos, what is the best price, and how do we understand that? I hear these things about how there will be discounts of 30, 40, 50, 60 percent. And also, it reminds me so much of the Sunday paper, looking at jewelers who say, take 40 percent off our already 50 percent off price. And I say to myself, what the hell did that cost that you can

give that kind of a discount?

So walk me through this. What is the best price and how would we know what the best price is?

Mr. Antos. Well, I don't know that we would know. But you are raising an important point, which is that the way we finance all of healthcare, not just drugs, has this effect of insulating people and concealing what the price actually is. It is true for drugs, it is true for hospital services, frankly, it is true for physician services, because the relevant price for most people is the price they pay out of pocket.

Now, I happen to know that I pay $20 when I go to the doctor, but that is about all I know. And I am supposed to be an expert about this. So imagine how everybody else is. That is the same issue. People do not have the right kind of price transparency.

So telling people what the list price is, is not relevant to most people because they have insurance. What matters to them is what is going to come out of my pocket at that moment. And that could vary, depending on whether I have satisfied my deductible or not. So it is a very, very complicated situation.

There is no best price. There is only feeling your way, I would say. And we need to change some of the institutional arrangements, especially in the Medicare program, that have fostered this acceleration of list price and rebates. I think that interaction has contributed greatly to what most people see as rising prices.

Mr. Kelly. To a degree, with the efforts that we have tried to make through legislation, have we created this incredible complicated market that is out there? I just wonder. Sometimes we think, well, government is the answer to almost every trouble we have or every problem we had. And I said, no, I think government is the problem why we have some of these things.

There was a comment made about how other countries don't pay the wrong price.

What does that mean when it comes to some of the pharmaceuticals?

Mr. Miller. There are a couple things I want to say about the right price. In a negotiation, whether you are talking about drugs or anything else, you come to an agreement between two parties. I mean, is that the right price or is that the price that those two parties agree to pay?

And so in a negotiation, you are reaching to find a right price, and that allows both parties to participate in it.

There are also other ways to think about the price. There are methodologies that look at the clinical value of the drug, how much it extends a patient's life. You could look at methodologies that say, this drug at this price does, in fact, make this a valuable investment, at a different price it wouldn't. There are ways to track to the price where it is not just a complete free for all in trying to find a reasonable price.

Mr. Kelly. I am running out of time. But, Mr. Antos, if you can get back to me later.

I have got to tell you, we are all incredibly invested in this. We have to make sure that people can afford these and we can get to some point. But it does seem like a mountain that is so high right now.

Mr. Antos. It is very difficult. I would point out that there are more than two people involved here. There is the patient. I mean, part of the problem is the nature of insurance.

Mr. Kelly. That is my point.

Mr. Antos. Right.

Mr. Kelly. Thank you so much.

Chairman, thank you so much. Thank you all for being here.

Ms. Ojewumi, we will be praying for you every day, because I think you are

incredibly brave.

Ms. Ojewumi. Thank you so much.

The Chairman. I thank the gentleman.

Let me recognize the gentlelady from California, Ms. Sanchez, to inquire.

Ms. Sanchez. Thank you, Mr. Chairman.

And I want to thank all of our witnesses for joining us for what I hope will be one of many hearings on the rising cost of prescription drugs.

It is impossible to ignore the fact that millions of Americans find that their medications are increasingly unaffordable, and many consider it a national crisis. In fact, I think it is about 80 percent of Americans think that the cost of prescription drugs is unreasonable.

And whether that is medication that they have been taking that has been on the market for decades and continues to increase or the incredibly high list entry price for new drugs, a lot of people feel like they are being priced out, and that means that a lot of people's lives are being put at risk.

People believe in the Medicare system. Medicare, like Social Security, was supposed to be there for seniors in their time of retirement. It is a system that they pay into over the lifetime of their working careers, and they believe that it will afford them with some dignity in their retirement and a little bit of security and that security of being able to access affordable healthcare.

But what the rising cost of prescription drugs shows us is that people are being priced out. And I have one example from a woman in my district in Whittier, Alice. She shared her story with us. She said that, "Last year I went into the doughnut hole in June and couldn't afford my insulin. So I had to go between my primary doctor and my diabetes doctor, basically begging for samples. I was humiliated."

Now, nobody who needs life-saving medication should have to go from place to place begging somebody for samples so that they can continue to take their medicine. That is a medication that has been on the market for nearly a century, and yet it has tripled in price just since 2002.

Alice, this woman in my district, is just one of 44 percent of Americans who worry about whether or not they are going to be able to afford their medication and then are faced with these impossible choices between buying their life-saving medicines or paying for other basic necessities such as food or rent.

I want to begin my questions by asking Ms. Sachs, why have we seen prescription drug prices increase faster than inflation? I mean, is it the cost of the materials that go into making the drugs? Is it the energy that goes into making the drugs? Why are they outpacing the cost of inflation?

Ms. Sachs. It is really the combination of these exclusivity rights and monopolies that we give companies on the front end and our choices on the back end to pay for all of these drugs that are produced by these companies. As we have already heard, you can't obtain a good deal if you are not willing to walk away from the table when these list prices are increased over time.

So there are absolutely misaligned incentives, as we have discussed, within the system for PBMs to strike these deals where a product with a very high list price but a large rebate would be placed in a preferred situation on a formulary; and yet the patient, as you were mentioning, would be exposed to a very high out-of-pocket cost, particularly in the deductible phase or in the doughnut hole phase.

So there are situations where there are other actors who are really contributing to some of these problems. But pharmaceutical companies are able to set high list prices and to raise those prices year over year, because they can far too often, because competition is

really not present in too many of these markets.

Ms. Sanchez. Thank you.

Mr. Miller, Mr. Reuther mentioned earlier, because he manages the healthcare plan for many retirees, that there need to be more generic drug producers. Why do you think there aren't more generic drug producers?

Mr. Miller. There aren't more generic -- I am sorry?

Ms. Sanchez. Generic drug producers, producers of generic brand drugs.

Mr. Miller. Oh, producers. I am sorry, I missed the point.

Okay. Well, the general way the market works is somebody gets a patent, innovates a drug. That patent is supposed to end. The generic manufacturers enter, drive the price down. And then the price gets so low that some generic manufacturers begin to drop off or they say, I am going to go to a different name brand drug and start working that particular market.

So as the price falls, you may get suppliers who leave the market, and that is where you get those opportunities where somebody then ends up with a single license for that generic and then can drive the price back up.

So you have something of an economics issue. When the market works well, the price falls and the manufacturer can't make as much money, they exit the market. And that may mean that you need some kind of supplementary support there to keep competition in that market, and there are a couple of different ways to think about that.

Ms. Sanchez. Thank you so much.

I yield back.

Chairman Neal. I thank the gentlelady.

The gentleman from Missouri, Mr. Smith, is recognized to inquire.

Mr. Smith of Missouri. Thank you, Mr. Chairman.

I have recently held several healthcare roundtables throughout our district to understand what was working and what was failing with patients in our healthcare system. I heard two consistent themes: Patient out-of-pocket costs for prescription drugs are too high, and we need more price transparency in our healthcare system.

Patients and pharmacists understand these problems. Patients in southeast Missouri keep paying more and more at the pharmacy counter and they can't figure out why.

A woman I represent, we will call her Mrs. R, wrote me to ask for help. Mrs. R is 74 years old and on a fixed income. She has Medicare, a Medicare supplement, and a part D drug plan. She took every step in her power to make sure she could afford her medicine. She did everything right, but her healthcare system is still failing her.

The same generic drug she was taking for the last 30 years suddenly rose in price by over 3,200 percent. Not by double, not by triple, this generic drug suddenly cost her more than 32 times what it cost her the month before for no apparent reason.

Pharmacists continue to remind me that they are being hammered by unpredictable fees months after filling prescriptions for their patients. None of the savings from these fees gets passed on to patients like Mrs. R when they fill their prescriptions at the counter. That is a problem.

Thankfully, President Trump has taken action to help our seniors afford their medicine. I applaud the Trump administration for working to address our Nation's high prescription drug prices head on. The administration's leadership, starting with their May 2018 drug pricing blueprint to lower drug prices and reduce out-of-pocket costs, showed us that President Trump is serious about his plans to fulfill his promise and work to finally put America's patients first.

For starters, we successfully lifted the ban on pharmacy gag clauses. Because of

President Trump's leadership, pharmacists are allowed to tell their patients if they can save money on their prescriptions by not using their insurance. That is a step in the right direction to benefit our patients, but there is a lot more to be done by simply following the administration's blueprint.

The Trump administration has been active over the past few months. They put out multiple rules to put patients in the driver's seat. They are working to address unpredictable retroactive fees pharmacists pay into the system, to untangle the complicated rebate structure, and simplify the supply chain so you don't need a Ph.D. to understand your insurance bills.

Ultimately, the administration is working to make sure our patients can afford their medicine and taxpayers are not asked to contribute more than they already do.

Dr. Miller, which one of the administration's recent rules would make the biggest difference for patients in my district like Mrs. R when they go to the pharmacy counter to buy their life-saving medicine?

Mr. Miller. If you took the IPI, which they proposed for part B, the International Price Index, and applied that to the payment benchmark in part B, it would probably have the biggest impact of things that I have seen out there.

There is the PBM rule, but that has a couple of positives and negatives in it. So I would say the IPI.

Mr. Smith of Missouri. Dr. Antos, I understand these rules won't solve everything. In your opinion, where might Congress need to step in to help make sure patients are put first and make drugs more affordable?

Mr. Antos. Well, I think one of the big challenges has to do with the incentives that PBMs have to set their formularies. Increasingly, we see that more expensive drugs are placed on more preferred tiers precisely because there is this incentive in part D to get

your customers into the catastrophic zone where the taxpayer is paying 80 percent, and that has a rebound effect throughout the entire sector.

Mr. Smith of Missouri. To follow up, how do we incentivize lower drug prices without applying socialist principles of foreign countries, such as price fixing?

Mr. Antos. Well, again, the problem is insurance. So you can choose to buy a $1,000 iPhone or you can choose to buy a $500 phone of something else, some other manufacturer. You don't have those kinds of choices generally in healthcare, because the insurance system is intervening between the negotiation that ideally you would have between the customer and the seller.

That said, I think the challenge is to promote more competition. The more competitors there are, the more likely it is that we are going to see those prices be bid down.

Chairman Neal. I thank the gentleman.

With that, let me recognize the gentleman from New York, Mr. Higgins, to inquire.

Mr. Higgins. Thank you, Mr. Chairman.

As has been said, Medicare part B spends $30 billion a year for drugs for 55 million Americans. The Veterans Administration, with 20 million Americans, pays 40 percent less for drugs than Medicare. That is a considerable savings when you consider $30 billion a year for Medicare for drugs.

In 2018, Americans' annual spending on prescription drugs reached $1,200 per person. That is 18 percent of all health spending.

I have said it before. I don't want to be redundant, but obviously, there are certain benefits by using the leverage of the numbers under your particular program to drive down the cost of healthcare generally, and particularly prescription drugs, and driving up the quality. The VA does it. I understand the nuance. I understand the complexities of it.

I understand the layers, the gradations. But there has got to be a way that the Federal Government can use its leverage of 55 million people to drive down the cost of prescription drugs.

I just want to talk a little bit about Alzheimer's. Alzheimer's disease is a disease whose origins are unknown and whose end is absolutely certain. It takes away your cognitive ability, it takes away your dignity, and then eventually it takes away your life. It exacts a price on the afflicted, but an enormous price on those who love and care for the afflicted as well.

In 1996, a drug was approved for the treatment of Alzheimer's called Aricept. That was 23 years ago. It promised to delay the onset of Alzheimer's symptoms. But in reality it may delay that for 6 months, and it really hasn't gotten any better in 23 years.

Despite that, we spend an enormous amount of money. Aricept is the most prescribed drug for people with Alzheimer's disease. There are 6 million people with Alzheimer's. That will triple. That will triple in the next 30 years.

I want to talk to you about drug companies marketing directly to consumers. The United States and New Zealand are the only two countries that allow drug companies to appeal directly to consumers. And in a free society, that is something that we celebrate and we want to preserve. But the problem when it comes to illness is that these drug companies appeal more to emotion than they do to science. If you ever watch a drug commercial you are going to be good looking, you are going to be healthy, you are going to be happy, and it is always a sunny day.

So what happens is a consumer goes to a doc and says, I have a couple of chronic diseases, I need this drug. In the doctor's office, drug representatives are there all the time offering all kinds of incentives, at least implied, to prescribe this drug. Marketing of drugs is a $7 billion industry, and it goes up by about a billion each year. It is typically

targeted to older people with several chronic diseases.

Dr. Miller, I would ask you to provide some insight relative to the impact on advertising directly to consumers as it relates to the cost of those drugs, because obviously, that $7 billion annually is being offset by the cost of the drug.

Mr. Miller. I can't speak to how much effect it has, if that is your question, but I think our view of it is, is that if companies want to engage in that they should at a minimum not get preferential tax treatment to do it. And, in fact, if they want to engage in it, it should come directly out of their pocket.

Mr. Higgins. Anybody else?

Ms. Sachs. I think I would just add briefly not only that I agree, but you suggested that sometimes the advertised benefits might not match up with the actual benefits for patients. So thinking about trying to support disclosure requirements of how effective these products might be would be another way to change the advertising model.

Mr. Reuther. We also agree that these advertisements create an incorrect impression that the brand drug is better than lower cost generics, which may not be true.

Mr. Higgins. I yield back.

Chairman Neal. The chair would recognize Mr. Rice from South Carolina to inquire.

Mr. Rice. Thank you, Mr. Chairman.

I have been reading recently about how the United States is the leading innovator in pharmaceuticals in the world. Would you all agree with that? And would you also agree that the primary reason perhaps is our patent protection, our intellectual property protection? Would you agree with that?

Ms. Sachs. I would also ascribe it to the tremendous investment through the National Institutes of Health.

Mr. Rice. So we have this tremendous benefit in that this innovation in medicines has led to cures not even dreamed of not that long ago in life expectancy increasing and all these tremendous benefits. But the flip side of that is too often people who need these medications the most are price or unavailability of insurance or whatever reason. Too often people who need these drugs are denied.

And there are absolutely huge problems. Mr. Doggett was talking about how Humira has been under intellectual property protection for far longer than the initial 12 years. Isn't that right? We normally allow 12 years. Isn't that correct?

Ms. Sachs. Patents last 20 years from the date of filing, but because some time is lost in the FDA approval process, although some of that can be made up, effective patent life is typically shorter. However, because of the complications of a product like Humira, they have been able to extend their patent life through gaining additional patents over time.

Mr. Rice. And he was referring to lower cost in other countries, England and I think he said Sweden. But isn't it true that some of the reason why these other countries get lower costs is because basically American users and American taxpayers somewhat subsidize the cost of those medicines, correct? I mean, aren't they able to charge these other places less because we pay more?

Dr. Miller?

Mr. Miller. Well, I think there are probably a couple things going on. It is correct that the innovation generally centers here. And you mentioned the patent protections, NIH I completely agree with, and what you can charge when you can get that drug out, all drive the level of innovation in this country.

Mr. Rice. But if the manufacturers say, “well, gosh, we are going to make X dollars of profit here in America, then we can charge a little bit less in Switzerland.”

Mr. Miller. I was just bringing you up to that point, which is, I am not quite sure

that is how the calculation goes. I think the manufacturer wants to maximize its charge anywhere it can. Those other countries engage in other activities to keep that price lower.

Mr. Rice. I love a lot of the suggestions that I have heard from you today about negotiation, about limiting patient out-of-pocket cost, and others, and look forward to working on this. This is such an enormous problem.

The thing that really gets the headlines that really bothers me, though, is where we hear about all these bad actors, and there are case after case after case, like the EpiPen. One case that I heard -- I represent dentists in my district -- and they called me and they said that they used to. One dentist in particular said that he used to buy an antibiotic because your teeth are closely connected to your heart, the bloodstream, and he would give his patients an antibiotic because it was so cheap. It was like $5 for a prescription. I think it was doxycycline, if I recall correctly. And that prescription within a few years went from $5 to $100.

So you are talking about, well, we don't have enough competitors in generics. One of the reasons is economics. You say we need to encourage competition in generics. How do we do that, Dr. Miller?

Mr. Miller. Well, I mean, I think you have a couple of different ways. I mean, the way that we have been talking about, one way to approach it -- and, again, it might be outside of this committee -- is much stricter enforcement on patent life and exclusivities that are granted.

Mr. Rice. Doxycycline has been out of patent forever.

Mr. Miller. So one is to bring more generics to the market.

Then when you hit the question that the other Congressman was asking about when the price falls, you may have to have other actions in order to bring generics to the market. So, for example, if the number of generic manufacturers falls below one, two, pick your

number, you allow importation for those drugs in that particular instance. There are methods like that where you bring more competition to the --

Mr. Rice. Okay, I have one more question for you, Dr. Miller. Why has the cost of insulin tripled?

Mr. Miller. Go ahead.

Mr. Reuther. The basic answer is there are only three producers and they are using their market power to increase.

Mr. Miller. I agree. And what is really concerning about that situation is there are three producers, and so you would think there would at least be some kind of competition between the brands there, but that has not occurred. And some of the behavior that has been engaged in -- and Rachel has referred to some of this in her testimony -- is patent thickets and keeping competitors and paying competitors to stay out of their market.

Mr. Rice. So insulin is still protected by patent?

Chairman Neal. I will let the witness finish.

Ms. Sachs. The delivery device around insulin is often still protected by patents. This is also true in the EpiPen context. The drug itself is old, but the device is constantly being updated and evergreened, if you will.

Mr. Miller. That is the patent.

Mr. Rice. Why can't they get the old insulin without the delivery device? Wouldn't that be a whole lot cheaper?

Ms. Sachs. Because of the incentives that we have discussed for companies to set high list prices with large rebates and get preferred formulary placements for that, there are often barriers to that. It is also just the case that patients sometimes may be locked in clinically to a newer version. It may also be that some of these older products have

stopped being produced for different reasons.

Chairman Neal. I thank the gentlelady.

And I thank the gentleman for his inquiry.

With that, the chair is going to declare a 15-minute recess so that the witnesses might stretch.

[Recess.]

Chairman Neal. The hearing is called back to order. And, with that, I would like to recognize the gentlelady from Alabama, Ms. Sewell, to inquire.

Ms. Sewell. Thank you, Mr. Chairman. I would like to thank you for today's hearing on rising prescription drug costs.

You know, no American should die because they can't afford the best medicines and treatment available on the market. I also believe that no American should be subject to poor outcomes or less mobility because the drugs they need are financially out of their reach.

Millions of Americans will visit pharmacy counters this week to get medicine that will allow them to lead a productive life. For some, the medicine will prevent a medical emergency and keep them out of the hospital, and for others that prescription can be critical to their very survival.

The unfortunate reality for too many Americans is that they will leave the pharmacy without the medicine they need; or, if they can scrape together the money, it might be so expensive that they will have to neglect financial obligations elsewhere.

Without insulin, a type 1 diabetic cannot survive more than a few days. For psychiatric patients, a change of medication or a missed dosage can be fatal. Thanks to the advancement in HIV/AIDS research, the disease has gone from being a death sentence to one that is treatable and cannot be transmitted if the patient takes his or her medication

every day.

So it is an imperative, I believe, both economically and morally, that we make sure that the costs never come between a patient and the medications that they need to survive.

One of our witnesses, Ms. Ojewumi, in fact, had such a profound statement that I would like to re-read her statement or testimony so that all of us can remember how powerful it is. She said: Though you may not see us in me, you do see us in me. We are one in the same. I may use a wheelchair, but this is your future. We all will experience disability at some point in our lives.

We do see you, and we thank you for being a witness.

This reminds me of my father, who was a high school basketball coach at Selma High School -- go Saints -- for 30 years. And he was a larger-than-life figure. In some ways, people said he was a living legend. He was definitely that in his own mind.

But my dad suffered a series of strokes, nine to be exact, towards the end of his life, which left him fully dependent on a wheelchair and disabled. He was unable to take care of himself, and our world as a family was turned upside-down.

We couldn't have predicted that he would have gotten so sick so quickly. My dad had comprehensive quality healthcare coverage, though, and it was a blessing. He had been a high school teacher and had public school system healthcare, which, according to my grandmother, was good insurance. But so many of the people that I represent don't have good insurance.

When many of my elderly constituents get to the pharmacy counters, they often have to pay a neighbor to bring them. I have many, many constituents who live in rural communities, and transportation is a serious issue. Or their child or relative is using their lunch break or taking time off work just to get them to the doctor.

If their medication isn't available or their insurance no longer covers it, the copay is

often too high and their medicine requires new prior authorization.

This is especially true when the doctor is an hour or 2 away. Like in my dad's case, we lived in Selma, Alabama. Everybody knows Selma because of the civil rights movement. But Selma is a town of 19,000, and the best medical care is in Birmingham, Alabama, which is 2 hours away.

Can you talk to us a little bit about your experience and how getting prescription medication, being disabled, a disability that you profoundly said all of us will experience sometime in our lifetime?

RPTR MERTENS

EDTR CRYSTAL

[12:09 p.m.]

Ms. Ojewumi. Thank you so much. And I do want you to understand that I really feel for your father, because that is usually how medical tragedies happen. That is exactly how my medical tragedy happened. It came all at once. Less than 2 years, a year and a half, boom, I went from being a normal 9-year-old kid to 11 years old, you know, on a breathing machine.

And I want to show the members here this. These are just my morning medications. I get my medications delivered to my house, and these aren't -- this is just from one of the three pharmacies that I use. This is the reality.

Ms. Sewell. It is a blessing that you can get them delivered to your home.

Ms. Ojewumi. It truly is a blessing.

Essentially I have had to -- I have gone to CVS pharmacy multiple times. I have been in the hospital last year four times alone. And oftentimes it is because of my transplants and because I have a weak immune system, and as a result, I get infections.

There have been plenty of times where I have been at the counter, and they have told me this antibiotic is $200 and I say, "No, I can't purchase it." We go ahead and look in our medical cabinet at home to see if we have something similar.

One of the members mentioned Doxycycline. That is a $200 copay under my good health insurance.

In addition, I had a surgery about 2-1/2 months ago, and there were two options. I could have surgery and a specific treatment, and the treatment costs $1,500 out of pocket because the insurance refused to cover the treatment, but they allowed me to have the surgery for $200 to remove diseased tissue, and the disease has returned to my body. I

have had two surgeries for this.

The reality is I take good care of myself, but I am millions of Americans living with something that is completely out of my control. And oftentimes we are told that it is a result -- I would say oftentimes it is pervasive misconception that disability is a result of something you did wrong or how you are living your life, how you are eating, and in reality, a lot of the stuff is genetic.

And you can do all of the right things and end up in the same position that I am. Because I had good health insurance throughout my entire life, I was able to start a nonprofit at 19, work in the Obama White House at 20, and graduate college at 21.

Ms. Sewell. Thank you so much for sharing your story and being brave enough to really reflect your story being representative of many, many, many Americans. I wish you good health.

Ms. Ojewumi. Thank you so much.

Ms. Sewell. I yield back.

Chairman Neal. Thank you. We thank the gentlelady.

And with that, the gentleman from Arizona, Mr. Schweikert, is recognized to inquire.

Mr. Schweikert. Thank you, Mr. Chairman. And you have powerful stories like that I think we all need to get our heads around because I believe there is a revolution. We are actually in it. It is on the cusp. It is starting to roll out in genomic biologicals, some revolutionary pharmaceuticals that are here, but their cost because they are so customized.

There has been already a lot of discussion of alignment of incentives. When you hit the 80/20 split, should there be risk sharing or some other model there that incentivizes?

And I spoke with Mr. Miller just a bit as we were passing there. I wanted to do

one or two things to sort of broaden this conversation, because my fear is if we do some things to deal with pharmaceutical pricings right now, we need to future-proof ourselves, because what is on the cusp coming at us?

Dr. Miller, in your writings, for part D claims, you tell us that 1 percent of pharmaceuticals in 2017 now have become a quarter of the spending. And I am going with that. Do you see that as part of the trend of some of these new biologics, some of these new revolutionary pharmaceuticals starting to move into the pipeline?

Mr. Miller. Yeah. I mean you have two things in Medicare. You have more people hitting the catastrophic cap and that spend escalating, and then you have more and more high cost drugs, which are often biologics or specialty drugs, and that trend is also accelerating. What I have been trying to say to the committee is you need to look out over the next years because the acceleration of these drugs is going to drive the part D spending.

Mr. Schweikert. That is really important, what he just said. We need to future-proof ourselves.

Here is a paper. I am very excited about this. Hemophilia A. There are only about 8,000 of our brothers and sisters in the country that have this. Really good chance by the end of this year a single-shot cure, that the efficacy is off the charts. What is the value of that drug?

But also, if it rolled out at a million and a half per injection but it cures it, it is over, and that population, no one is going to build a second biologic in that because you have cured the disease.

We also need to have this discussion in these hearings. We have been working on things like our healthcare bonds, these ideas of how do you finance disruptive pharmaceuticals that may move in. But we need to come up with the reality. This is our future.

Dr. Miller, one other thing. I just want to make sure I am reading some of your I think it was testimony in the Senate, for part B, on some of the movement we have seen there in pricing. There is a discussion in the MedPAC on possibly moving to something that is closer to a PBM model in dealing with some of that pricing and incentives. Do you see that as an appropriate methodology to deal with some of the escalations we are seeing in part B?

Mr. Miller. I think you can think of part B a couple of ways, and I will come right to your question. But before I do, is you can go after the buy and bill payment system that you have now and look at things like an inflation cap or setting the benchmark at a different place; or, and potentially and, there is the idea that you are referring to where you allow the physicians to organize, construct a formulary, and try and negotiate under the government's set price.

Mr. Schweikert. Mr. Chairman, Dr. Miller, within there would you also try to incentivize that we build a value-based model because that value-based model could cross platforms more than B and D but even some other places?

Mr. Miller. I mean, the idea is that if the physicians can negotiate down from what the government would have paid, they keep some portion of that savings, and the idea is that they are motivated to seek the highest quality drug at the lowest price.

Mr. Schweikert. And where I may have a slightly different vision is how do you -- back to our Hemophilia A cure -- how do you price it? It is a value. Once it is distributed, it has functionally put itself out of business. But if the mean cost for maintaining someone quarter million dollars a year, it is almost like your baseball analogy.

And in our last couple seconds here, in the tyranny of a 5-minute clock, I want to socialize a concept of a biofoundry, a way in the future that we can almost have a production line of these revolutionary pharmaceuticals.

I also want to argue we actually have this piece of legislation already out there. It is a HIPAA-compliant data capture model to radically reduce the time to bring pharmaceuticals to market, because much of the population data we actually need for drug trials is sitting on hospital servers all over the country. We just haven't been able to get to it.

And I also want to turn to a number of you and have the discussion of a financing mechanism, we call them the disruptive healthcare bonds, to be able to bring in these disruptive pharmaceuticals and be able to not have the crisis we had in the early days of Hep C.

And with that, Mr. Chairman, I yield back.

Chairman Neal. I thank the gentleman. I am particularly pleased that he referred to the clock as embracing tyranny and not the chairman of the committee.

We are going to move now to a 2 to 1 until we see members start to sort themselves again. So with that, I would like to recognize the gentlelady from Washington State, Ms. DelBene.

Ms. DelBene. Thank you, Mr. Chairman, and thank you for holding this very important hearing. One of the issues that I hear the most about from my constituents is about drug pricing, and I am glad that we are finally having that discussion here today.

I want to share one story from a constituent of mine, Linda from Arlington, Washington. She said: "I was diagnosed with common viral immune deficiency, which impairs the immune system, in 2016. I need intravenous immunoglobulin infusion therapy every month for the rest of my life.

"I am 67. I live on a fixed income and rely on Medicare. The medication I need costs over $5,000 a month, and my out-of-pocket expense is over $1,000 a month, which I can't afford. I am now in the process of applying for assistance programs, but I don't

know if I will qualify.

"The stress of this disease is bad enough, but the stress of not knowing if I will ever be able to afford the treatment is killing me. What the drug companies are putting me through is cruel, and I know there are so many people out there much worse off than me."

So this story is not unfamiliar, and it is sad that in a country with so much wealth that so many people are in too similar of a situation. And so I wanted to focus on some of the issues that might have put us in this place and have been driving up higher costs.

Medicare has a number of perverse payment incentives which could be leading to higher cost drugs and greater out-of-pocket costs for seniors. Medicare part B covers outpatient doctor visits and physician-administered drugs, like the situation described by my constituent, Linda.

She needs to go to the doctor each time for her treatments, but in part B, when a doctor is reimbursed for a physician-administered drug, like intravenous immunoglobulin infusion therapy, physicians are paid the average sales price of the drug plus 6 percent to cover costs. But the more expensive the drug is, the greater the add-on payment.

Mr. Miller, you talked about this a bit. I believe most doctors do the right thing and give their patients the drug that best meets the needs of their patient. But doesn't this create an incentive for physicians to pick a more expensive drug? And doesn't this provide little to no incentive for the manufacturers to lower the price?

Mr. Miller. It does provide an incentive for the physician to provide a higher cost drug. I think there is a flat fee approach that you could take that would help with that situation.

Ms. DelBene. Any other alternatives for reimbursement there, or you think a flat fee is the best way to approach that?

Mr. Miller. I personally think that you should consider the inflation rebate

approach, and I also think that the actual level, the ASP level, can be brought down either by taking down the add-on amount or thinking about different reference prices to use in that setting.

Ms. DelBene. And in the situation of my constituent, Linda, there is no out-of-pocket cap to protect her, is there?

Mr. Miller. In part B, no. No, there isn't, unless she is in a managed care plan which often have catastrophic caps. But if she is in straight ahead fee-for-service, the answer is no.

Ms. DelBene. So continuing on that, let's talk about Medicare part D. In 2016, the Medicare Payment Advisory Committee recommended changing how Medicare subsidizes part D plans whose beneficiaries fall into catastrophic coverage. Mr. Miller, can you explain how the current reinsurance program in Medicare part D incentivizes high drug prices?

Mr. Miller. So fundamentally you have an insurance -- to try to and do this quickly, okay -- you have an incentive that if you use a higher cost drug, if you provide the patient a higher cost drug, they hit the catastrophic cap faster. And that means that the government takes over 80 percent of the risk. And depending on the drug, the PBM can get a rebate in addition to that by driving the patient to that drug.

So in a simple way -- there are a couple other steps along the way -- but in a simple way, those two factors create the incentive to provide the higher cost drug if a lower cost drug would have been a good substitute.

Ms. DelBene. And do Medicare beneficiaries have out-of-pocket caps even when they enter catastrophic coverage?

Mr. Miller. They are more limited in what they have to pay when they hit the catastrophic cap, but they have to pay indefinitely.

Ms. DelBene. Thank you.

And I yield back, Mr. Chairman.

Chairman Neal. I thank the gentlelady.

With that, the chair will recognize the gentlelady from California, Ms. Chu, to inquire.

Ms. Chu. Mr. Reuther, I want to get your take on what we can do to bring down the high cost of prescription drugs. I think about Judith, my constituent from Arcadia, California, who says, "I am on insulin for my diabetes. Last year when I went into the doughnut hole, I couldn't afford my insulin. I now rely on assistance programs, but I never know when those might disappear."

Now, I wish Judith's story was unique, but, unfortunately, it is all too common, and it is unacceptable. While the witnesses and my colleagues have done an exemplary job of demonstrating how the system we have in place incentivizes higher prices, I want to focus on the role that the pharmaceutical companies play.

For example, the company AbbVie has increased the price of their top-selling drug anti-inflammatory drug, Humira, that treats arthritis, three times over, from over $1,000 to $4,441 for one pen injector.

Insulin was first used to treat diabetes nearly a century ago, but since 2002, the price has increased by more than 200 percent.

The company that manufactures Evzio, a drug that reverses opioid overdose, has increased the price from $690 to $4,500.

And according to a study done by AARP, the average annual cost for one brand name medication used on a chronic basis was almost $6,800 in 2017, almost $1,000 higher than the average cost in 2015.

So it is clear, drug companies are continuously setting their list prices higher and

higher. We can debate various payment methods. But at the end it is either the patient, the plan, or the government who ends up picking up the tab.

So, Mr. Reuther, are rebates alone enough to combat the impact of rising list prices on both plans and patients? And what policies should we then pursue to bring down high list prices?

Mr. Reuther. No, we don't think changing the rebate system is the answer. We think a combination is needed of long-term steps to increase the producers of various drugs. That involves reducing exclusivity period, ending pay-for-delay, various actions like that, that creates that.

But we think in the case of drugs like insulin, where there has clearly been manipulation of the price, we think there is an urgent need for short-term actions to bring down that price. We think there is a variety of options that this committee could consider: referencing international prices which are much lower, referencing the prices that the VA has which are much lower, or negotiation directly by Medicare.

Ms. Chu. Okay. Thank you.

I would like to ask Dr. Miller to expand further on what Mr. Higgins was asking further on the commercial advertising of these drugs, particularly the tax credits given to drug companies to inundate us with the many fancy commercials that they do on television.

Dr. Miller, is it true that the United States is one of the only nations that permits direct-to-consumer advertising for prescription drugs?

Mr. Miller. That is my understanding, yes.

Ms. Chu. And is it true that the five largest pharmaceutical companies currently spend 70 percent more on marketing to consumers than on research and development?

Mr. Miller. If you look at different companies, these ratios change from company

to company and change over time, but at any given point in time you can find over a series of years companies putting much more of their revenues into marketing than they put into R&D.

Ms. Chu. And do you happen to know how much money top pharmaceutical companies happened to get from the GOP tax bill?

Mr. Miller. From the?

Ms. Chu. The GOP tax bill.

Well, that is okay. I actually have an article here. It is the Journal of Law, Medicine and Ethics, and it is titled "The Tax Cuts and Jobs Act of 2017 and the Pharmaceutical Industry." It shows that the law provided a median tax savings of $2.5 billion per company.

And I would like to enter this article into the record.

Chairman Neal. Without objection.

[The information follows:]

******** COMMITTEE INSERT ********

Ms. Chu. So, Dr. Miller, we are all concerned about innovation, but would eliminating the tax credit for advertising for these drugs stifle innovation?

Mr. Miller. In my opinion, no, it would not.

Ms. Chu. Thank you for that.

And if I may ask also, I am very concerned about the numerous lawsuits ongoing that allege collusion between brand name and generic manufacturers intended to raise prices on existing drugs.

Dr. Miller, what could be done to address these anticompetitive practices within the pharmaceutical companies?

Mr. Miller. At least two things that I think a number of people have mentioned here today, the CREATES Act to go after the REMs abuses and the pay-for-delay legislation. Drafts of both of those legislation are floating around and to my understanding have been fully scored and could be acted on by the Congress.

There are other steps as well. I think they are included in everybody's testimony. But those are at least two that are right there.

Ms. Chu. Thank you. I yield back.

Chairman Neal. I thank the gentlelady.

With that, let me recognize the gentlelady from Indiana, Mrs. Walorski, to inquire.

Mrs. Walorski. Thank you, Mr. Chairman.

I just wanted to add, I am excited, and I think this has been an incredible panel today. I thank all of you for coming, for what you have shared. And I am excited in looking for a bipartisan solution, that we can actually come to the American people and solve this with working together, and I think that is very possible.

And, Dr. Miller, I just wanted to thank you for bringing up the issue of the patent thickets. I was going to bring this up, and you did right before the break, the issue where

a company claims any kind of number of patents on a drug to use it to stop competition from coming into the market. I was going to bring that up.

I just wanted to say thanks for doing that because there is a drug that I have been familiar with in our district, and it is called Revlimid. I don't know if you ever heard of it. You are all shaking your heads that you have.

And just to add, I guess, how devastating -- and to your story, ma'am -- how devastating when you are in need, and you find yourself in need, then you find yourself not being able to afford what is out there because of these patent thickets that are walls behind walls behind walls that never bring these drug costs down but only increase them.

And in this case of Revlimid, it was in the market in 2016 at $6,195 per month. Now it costs over $16,000 per month. Not that either were tolerable, but just as an example of what happens when things increase behind all these walls of patents.

But, Dr. Antos, I just wanted to ask you very quickly, we all remember when the ACA took the benefit away of being able to pay for over-the-counter medications through the different kinds of health insurance plans, flexible plans, health reimbursement plans, medical savings accounts, and it actually put in a barrier now. So if you are trying to shop around for drugs you want to buy over the counter, the restrictions on HSAs are causing families to spend more money out of their own pockets and on their overall health.

According to the Consumer Healthcare Products Association, every dollar spent by consumers on over-the-counter medicine saves the U.S. healthcare system $6 to $7, contributing to $102 billion in savings each year.

Last Congress the House passed H.R. 6199, the Restoring Access to Medication and Modernizing Health Savings Accounts Act. This bipartisan bill would have allowed nonprescription drugs and female hygiene products to be considered qualified medical expenses for all of those HSAs, MSAs, FSAs.

Can you give some other commonsense ideas, ways we can incentivize patients to use lower drug costs, such as those over-the-counter products, instead of having to take brand name prescriptions all the time? Are there any changes you could see that we could make to H.R. 6199 or ideas you have to just continue to incentivize lowering the cost?

Mr. Antos. Certainly you are correct that if you were to buy aspirin at the CVS, it would be much cheaper than if you were to buy it as a prescription drug, and there are plenty of examples like that.

The HSAs are generally limited in any event. I would raise a border question that goes beyond drugs. The issue that I see is that we are tied to having to come up with the receipt. So this ties us to the fee-for-service system if you have an has, and there is a whole fundamental mental inefficiency there.

But you are certainly correct that the impediment, to the extent that people are aware of this, I am not sure that they are, but the impediment to using your has money for appropriate over-the-counter medications does add to cost.

Mrs. Walorski. Thank you.

Mr. Chairman, I yield back.

Chairman Neal. I thank the gentlelady.

The gentleman from a Pennsylvania, Mr. Boyle, is recognized to inquire.

Mr. Boyle. Thank you, Mr. Chairman.

Recognize that my senior colleague from Michigan just got back, I am happy to yield to him.

Mr. Kildee. I am later because I wasn't here.

Mr. Boyle. Okay. All right. I just didn't want to --

Chairman Neal. Not bad for modesty.

Mr. Boyle. I didn't want my colleague to be grumpy at me.

Well, thank you, Mr. Chairman, and thank you especially for holding this important hearing, one of the most significant issues facing the country.

And forgive me if I mispronounce your name. You are probably accustomed that. But, Ms. Ojewumi, I was really touched particularly by your story. The fact that someone who is so young and looks so healthy has had such extensive health issues is really striking and a reminder to any one of us that, as you pointed out, we might not be in your shoes now as being part of the disabilities community, but at some point each and every one of us will end up with our own health issues.

Obviously we are about a decade and a half after the addition of prescription drugs as part of the Medicare program, a program started in the 1960s primarily to deal with hospitalization costs. Based on the statistics I have looked at, prescription drugs now take up approximately 30 percent of the overall Medicare costs.

So I was wondering, specific to the Medicare program, how could we make it more affordable for seniors beyond just the obvious issue of bulk purchasing and the ability to negotiate? Are there other strategies out there that you are aware of and can speak to that we should be aware of? And I am happy to direct that to any one of you to tackle.

Mr. Miller. Well, first of all, I just want to say this. I think that the drug spending stream in Medicare is about 19 percent, okay.

I think just quickly -- and other people have said this, and I will hand this off -- there are a number of mechanics that we have talked about here. The part D risk structure changes should be considered. The part B changes to the buy and bill system on the flat fee, the rebate, you could look at bringing more PBM-like tools into part B. Those are some actions you could immediately take on Medicare that are different than the reference pricing or the negotiation.

Ms. Sachs. So I agree and would just say that it is a complex problem with many

layers that requires a comprehensive solution, and so the three areas I laid out in my testimony, lowering patients' out-of-pocket costs is a core part of it, as well as fixing misaligned incentives and lowering overall spending.

So on the lowering overall spending point, one important thing to consider might be using value-based pricing, benchmarking price to the clinical value of the drug to make sure we are getting the most help for our Federal dollars. That is an important thing to consider as the committee moves forward.

Mr. Boyle. Thank you.

And just quickly to follow up on the discrepancy on the percent, I was citing a statistic from the Kaiser Family Foundation in their report in January that estimated 30 percent of Medicare spending is prescription drugs.

Moving on from Medicare specifically and just more globally, we have had a couple instances in the last few years that have gotten a great deal of press attention. One was Martin Shkreli, the so-called Pharma Bro. The other had to deal with EpiPen. And these were instances in which companies were able to take advantage of their monopoly power over a drug that actually existed for quite some time, in the case of Martin Shkreli, a patent that I believe was a century old.

What would be some strategies to address that specific problem when one company has a monopoly and is able to spike the price 700, 800, 900 percent?

Ms. Sachs. Congressman, I am so glad you brought up those two examples because the price of the EpiPen and the price of Daraprim were so high for very different reasons.

So Martin Shkreli was able to increase the price of this, as you said, almost a century-old drug because he was the only manufacturer on the market. But there weren't generic competitors because he had a small market. It is only, I believe, around 10,000

patients a year. That is a situation where something like government procurement or government manufacturing or contracting for the production of drugs would be a very good idea. That is a sort of natural monopoly situation.

That is very different from the situation around the EpiPen where there are patents on the delivery device, there are regulatory complications that discouraged generic approval. So a comprehensive solution would be essential here.

Mr. Boyle. Well, my time has expired, but I would love offline to be able to follow up with you on that.

Thank you. I yield back.

Chairman Neal. I thank the gentleman.

Let me recognize the gentleman from Virginia, Mr. Beyer, to inquire.

Mr. Beyer. Mr. Chairman, thank you very much, and thank you for convening this fascinating hearing.

And thank you to all of our panel of experts. I suspect expect any American watching this hearing today has learned more about drug pricing than they ever suspected.

And I want to thank you for your specific recommendations. I have a whole page full that you have made for us today for us to consider. So I have 2 hours' worth of questions about only 4-1/2 minutes.

Dr. Sachs, you quote Donald Trump's HHS Secretary, Dr. Alex Azar, who pushed back strongly against the idea that reining in drug prices would mean lower innovation, calling them, quote, "mathematically unbelievable." Can you expand? Do we need to worry about a significant decline in research and innovation if we get our arms around drug pricing?

Ms. Sachs. So just to say I do not have a Ph.D. or an M.D. I am not a doctor. I am merely a law professor. So thank you very much, but I appreciate it.

So in my view as a scholar of patent law and health law, I think it is important to keep innovation at the front of these discussions, but I think it is also important to think about what we are paying for as a society and how much value we are getting from that. So we need to care about not only the amount of innovation but also the kind.

So if Medicare is paying more for things that work amazingly well, like some of the terrific new therapies we are seeing come out, that would be one thing, but if we are paying the same amount for drugs that are not cost-effective or not effective at all, that is a problem.

So Secretary Azar, as you mentioned, has said that there is a lot of head room in the system right now in the proposals that the administration has put forward. Even those that would threaten the pharmaceutical companies' bottom lines would make only a small dent in any potential R&D that could be affected. So I believe that is what he is referring to, and as a former pharmaceutical company executive, he would know that.

Mr. Beyer. Thank you very much.

And, Dr. Miller, you wrote that prohibiting citizen petitions filed by competitors are usually found to be frivolous. Are these actually citizen petitions? And is the usual strategy to suppress competition?

Mr. Miller. They are often filed by competitors. And so I think what I was trying to say in the testimony is you could think of changes in regulation where you would say competitors can't file the citizens petitions; or if you think there is a particular competitor who was filing citizens petitions that turn out to have no value, you could begin to fine them for that behavior.

Mr. Beyer. Dr. Miller, you also talked a lot about patent thickets. I was impressed when you said 75 percent of drugs associated with new patents were drugs already on the market, and of the roughly 100 bestselling drugs, nearly 80 percent obtained

an additional patent in order to suppress competition. How do we work our way out of this patent thicket?

Mr. Miller. I think that is complicated, and I would like to recruit Rachel into this answer pretty quickly. I mean, I think it is some of the things that we have been saying, that you either have to begin to enforce the end of the patent life, and that requires reforms both at the Patent and Trade Office, FDA could be a place because exclusivities are granted through FDA.

But you could look at things like CREATES, pay for delay. There are probably enforcements in patent and exclusivities. And then there are things like the orphan drug abuses and areas there where you could make changes to try and clear some of that out.

Mr. Beyer. Professor.

Ms. Sachs. I completely agree. In my testimony, I lay out six different ways scholars have identified that companies have attempted to game their patent protections to extend them over time, in addition to the problems with the Orphan Drug Act or evergreening. And I would be very happy to discuss any of those solutions in more detail.

But it does require both changes to the intellectual property system and then potentially also to the way in which FDA exclusivity periods are administered. So we have seen some companies bring older drugs to market in an effort to obtain the benefit of new exclusivity periods, and that is something that could be curtailed as one example.

Mr. Beyer. And, Professor Sachs, we only have 30 seconds left, but you mentioned that Pharma is not incentivized to look for treatments for early stage cancers and diseases prevalent in low income Americans. Is this just because there is no profit there?

Ms. Sachs. It is not so much necessarily because there is no profit. It is because the system we have set up gets us certain kinds of things and not others.

So your example, perfect, of early stage cancers. There has been research showing that because you have to file for patents early on in the development process, if the clinical trials you would need to run to prevent early stage cancers are so lengthy that you would lose much or all of the patent in that clinical trial process, you are going to be discouraged from doing so relative to looking for late-stage cancers.

So there are certain kinds of incentives we might consider increasing for those companies who are willing to invest in those kinds of drugs.

Mr. Beyer. Thank you very much.

Mr. Chairman, I yield back.

Chairman Neal. I thank the gentleman.

The gentleman from Ohio, Dr. Wenstrup, is recognized to inquire.

Mr. Wenstrup. Thank you, Mr. Chairman.

And, Ms. Ojewumi, I thank you for being here today, and I appreciate your courage and strength through your battles and your fight for your life.

I also would like to point out, too, the goodness of humankind, and that comes from your donors. Let's not forget the part that they played. And it is a wonderful thing that you are able to be here with us today.

I also want to talk about the potential benefits of innovation as far as long-term costs. We look at a drug as being expensive, and we also need to always look at what we save in the long run.

I look at the cure for Hepatitis C, what we save in palliative care. I look at biologics for rheumatoid arthritis, which may be expensive.

But at the same time, rheumatoid arthritis, there are 360 joints in the body, and it can hit every one of them. As a surgeon, as a foot surgeon, I did massive undertakings of reconstruction of feet because of the damage done from rheumatoid arthritis, and I used to

lecture on it.

That went away. That is gone. And not only is the surgery gone, but so are many injections people had to get and oral medications. And the formation of things like rheumatoid nodules, I quit seeing it. I mean, on one patient one time I removed 16 nodules. And the deformities that come, that often lead to ulcers and infections, all that is gone.

So we should always also when we are taking a look at things look on the other end of what we are actually saving in the long run. And I think we do that.

But I do want to talk about part B. Ms. DelBene brought up some good points. And, Dr. Miller, I want to address you.

You know, the average sales price plus 6 percent, I would like to believe the doctor is going to recommend what is best for the patient at all times. But I think what we are hearing is that that creates an incentive for the provider then to use the most expensive medication amongst their choices because they will get reimbursed more. So it is kind of a perverse incentive there.

And for the pharmaceutical company, I believe what is being said is they sometimes feel empowered to raise their price because it will make it the drug of choice if it is more expensive because of the reimbursement. And therefore, as a result, the patient pays more as well.

Is that what we are talking about in this scenario?

Mr. Miller. That is precisely what we are talking about. And I also don't think that the physician's decision has to be not in the interest of the patient. You could have two drugs that are equally effective and one is more expensive. You go with the expensive one.

Mr. Wenstrup. But that is what I want to get to, is to go toward the less expensive

one, if all things are being equal here. How do we get to that? So I want your thoughts on my suggestion that the provider gets paid the cost of the medication that they pay for in a flat fee, as you have recommended. Then there is really no incentive. They are going to get paid back what the drug cost. They get a flat fee.

Now what I think that might drive and should drive is a conversation with the patient where I often did this with patients. I will give you a good example of treating neuropathy. There is a medication, Gabapentin, it is very inexpensive, and it works for a lot of people. If it didn't work, then I might go to an alternative, like Lyrica or something like that. That is more expensive. And I have that conversation with my patients.

And I think that should be the same with all these part B drugs as well, where you are in a situation where you sit with the patient and say, you know what? I have got these four options. Transparently, I can tell you what it is going to cost you out of pocket or give you some idea, and I think either one can be substituted. So what do you want to do? And you make that decision with your patient.

Mr. Miller. I mean, I think I agree with you. In a flat free environment, you have removed the incentive for the provider to go for the more expensive one.

Mr. Wenstrup. Do we really have to mandate the conversation to take place between the doctor and the patient, or do you think that would happen naturally? Because to me it happened naturally.

Mr. Miller. I mean, my inclination is that it happens naturally, that you don't need to mandate it, but I think the most important thing is to remove the financial incentive.

Mr. Wenstrup. So anybody who wants to weigh in, what do you think of that idea of reimbursing the provider the cost of the medication plus a flat fee?

Mr. Antos. I clearly support that idea.

I wanted to address the question of the conversation between the doctor and the

patient. You may be the exceptional physician.

There is pressure, as you know, to run your practice, but patients often need help, at least especially the case we see with people with diabetes. One of the reasons that they aren't willing to change is that they are used to precisely the packaging, the way it is injected, and so on.

And they need help. They need help by someone that they trust who has a medical background, doesn't have to be a physician, who can guide them through that choice. And that may take more time, and it might take a little more hand holding than a physician would have.

Mr. Wenstrup. Well, there are certainly a lot of things the government has done that have taken away the time for the hand holding, and that is why you see so many doctors running for Congress, but that is another story for another day.

And I yield back.

Chairman Neal. We thank the gentleman.

The gentleman from Pennsylvania, Mr. Evans, is recognized to inquire.

Mr. Evans. Thank you, Mr. Chairman. Like others, I would like to thank you for your leadership on having this discussion today. It is very appropriate.

Ms. Sachs and Mr. Reuther, the cost of rising prescriptions, obviously, is the title of this discussion. And I want to go back to something that I heard around the issue about insulin. And I heard some potential suggestions around that. In terms of the question of health disparities, that is an issue that I constantly hear about from my constituents.

So can we take a little time and drill down on what I think I heard some solutions? I heard Mr. Reuther talk about targeted solutions, right, specifically in this area. Do you want to speak a little bit to that?

Mr. Reuther. In the short term directly impact the price of insulin. We think

there are a number of alternatives referencing lower international prices similar to what Secretary Azar has proposed for part B prices, or you could link it to the lower prices under the Federal Supply Schedule, or you could have some type of direct negotiation by Medicare.

All of those actions would provide immediate relief for patients with insulin and for healthcare plans that provide it, and it would give time for the longer-term solutions on getting more producers to take effect.

Mr. Evans. Ms. Sachs, I noticed when I said health disparities, you noted that is obviously a huge challenge.

Ms. Sachs. Yes, absolutely. So there are these short-term solutions, and there are also long-term solutions to the problem of insulin in terms of changing the regulations, which I know the FDA has recently begun to work on. There might be anticompetitive behavior, which I know a number of State attorneys general have looked into.

But there are, of course, these key questions about social determinants of health around patients being able to travel, as we have heard from other Representatives as well, to obtain these medications and the like.

So there are so many increased patient burdens that might be particularly acute in the insulin context that should be dealt with.

Mr. Evans. Dr. Miller, in the last 5 years, between 2011 and 2016, we have seen drug spending increase by 27 percent, which is more than 2.5 times the rate of growth.

I am vice chair of the Small Business Committee, and the question I wanted to ask is, Dr. Miller or Ms. Sachs, does this have lasting impact on patient prescription drug prices in general, in general in terms of the economy, kinds of things, you can speak to that specifically?

Mr. Miller. Well, just to make sure I understand the question you are asking, if the

increase in drug prices has implications for the economy --

Mr. Evans. Right.

Mr. Miller. -- in general.

So if I understand your question and redirect is I would say, yes, I think the issue that we have talked a lot about in this committee is that we are financing a public program. We are collecting taxes to do that. It is currently deficit financed. To the extent that we are driving that deficit up, that is a drag on the economy because we have to service the debt, and that is money that could have been invested in growing the economy.

For an individual business, which is what I think you are getting at --

Mr. Evans. Correct.

Mr. Miller. -- is that consumes more of their cost of production, because if you are going to pay knows benefits to your employees, that becomes a cost of doing business and once again detracts from the ability of bringing an efficient product to market, if I followed you.

Mr. Evans. Yes.

Ms. Sachs.

Ms. Sachs. And I agree. And I would just say that for some of our public payers, including Medicaid, it is much harder to finance that over time if States have to balance their budgets every year. Too often they have to make tougher financial choices on shorter timeframes even than the Federal Government on occasion.

So for particular kinds of products that have such a particularly high burden on the Medicaid program, some of the reforms that we have suggested could be fruitfully applied to that program as well as part of a comprehensive package. I understand that is not our focus today.

Mr. Evans. Thank you, Mr. Chairman. I yield back the balance of my time.

Chairman Neal. I thank the gentleman.

And the chair would recognize Mr. Suozzi to inquire.

Mr. Suozzi. Thank you, Mr. Chairman. And I want to thank you again for your commitment to holding detailed hearings on these different topics that we investigate. They are so complicated. This is such a complicated topic and so hard to follow.

I want to quote one person who tried to simplify this when discussing the pharmaceutical industry. President Trump, in January of 2017 before he took office, said: These guys are getting away with murder.

This is a very simplistic way of looking at it, but I mean, this is so complicated. There is something going on in this country that people are really suffering from what pharmaceutical companies are doing in the cost of prescription drugs.

So I have a lot of stories of different constituents, but I don't think any constituent could tell the story better than you did, Ms. Ojewumi. That was really very, very moving, and thank you so much for being here.

Eighty percent of Americans believe that prescription drug prices are too high, so I don't think we have to convince anybody that that is a real problem in the country. And we all hear these crazy stories from people that we meet, but none are more elucidating than what Mr. Reuther talked about related to the insulin prices that we have.

I was shocked when someone from the staff pointed out to me that the insulin patent -- the three researchers who first injected insulin into a patient with diabetes was in 1922, and they licensed their patent for isolating insulin to their university for $1 as a gift to humanity.

I mean, it is really kind of ironic that we see these crazy prices that Mr. Reuther talked about, but they licensed this as a gift to humanity for $1, the patent, back in 1922. And the fact that there are only three producers of insulin today is obviously a big cause of

the problem, as was just pointed out.

We all agree that prices in foreign countries are cheaper than they are in America. Now, Dr. Antos, do you think that the foreign pharmacy companies are making money in these foreign countries?

Mr. Antos. I think the way I would look at this is that these are separate markets. And as I think Mark may have said earlier, the companies are seeking to get the best price they can in every market.

Mr. Suozzi. Right. They are always seeking the best price they can. That is the nature of business, is they want to seek the best price they can wherever they can. My question is, do you think they are making a profit in these foreign countries?

Mr. Antos. I suspect that is the case.

Mr. Suozzi. They wouldn't be in business if they weren't making a profit in the foreign countries.

So the big question we hear about is any regulation that we do, any efforts that we do to try and correct this may have an impact on innovation.

And, Dr. Miller, is it correct to say, as some of my colleagues have pointed out before, but I just want to highlight this, that pharmaceutical companies spend more money on marketing than they do on innovation, on R&D? Would you say that is generally accurate? I know you said it fluctuates from time to time. But is it accurate to say that pharmaceutical companies spend more money on marketing than they do on R&D.

Mr. Miller. I do want to emphasize that it fluctuates from company to company and over time. But, yes, at any given point in time you can find large companies, over long periods of time, spending more on their marketing than on R&D.

The other fact that I would point you to, and this is Peter Bach's work, he pointed out that the amount of revenue coming from the United States far exceeded the worldwide

investment in R&D, something like 70 percent. So I would point to that number as well.

Mr. Suozzi. And I just want to point to another 70 percent number that was told to me from our staff, is that pharmaceutical companies, the top five pharmaceutical companies spend 70 percent more on marketing than they do on R&D. I understand that it fluctuates from time to time.

Ms. Sachs, does it surprise you to know that America is the only country in the world other than New Zealand that permits pharmaceutical companies to advertise on television?

Ms. Sachs. As a lawyer, it does not surprise me.

Mr. Suozzi. So only two countries in the world, America and New Zealand, advertise on television. They spend billions of dollars, and it increases every single year. The only two countries in the world.

And then what do they say in all these advertisements? I think it was Brian Higgins was talking earlier, everything is sunny and everybody is happy and your life is going to be better if you take these drugs. But every single time at the end of the commercial they say: Ask your doctor. After seeing the commercial, go ask your doctor. Which sounds like a reasonable thing. And if every doctor was as reasonable as Brad Wenstrup and would take the time to explain things carefully to people and not have any conflict of interest, that would be great.

But pharmaceutical companies spend even more on marketing directly to doctors, taking them to lunch, buying lunch for the office, having conferences, going on cruises, and having sales reps go to these doctors and giving them incentives to use specific drugs. They spend even more on that than they do on advertising on television. Do you think that could result in a conflict of interest for a doctor, Ms. Sachs?

Ms. Sachs. Well, I am not a physician, but I would say that any system that gives

tax preferences to both advertising and R&D might want to reconsider the balance of those priorities.

Mr. Suozzi. Okay. Thank you. I will yield back my time.

Chairman Neal. I thank the gentleman.

The chair would recognize the gentleman from Kansas, Mr. Estes, to inquire.

Mr. Estes. Thank you, Mr. Chairman.

And I want to thank all the witnesses for being here today to help with this very difficult process that we are working through.

You know, throughout this hearing we have talked a lot about some of the systemic problems that are raising the price of prescription drugs, and we have also highlighted some of the goals of being able to work together to help lower those prices. As we have talked about, there is not any one single problem that is out there, and there is probably not going to be one single solution that solves that.

Just talking through that, as we talk about the major innovations that have driven a lot of new drug pricing, we have also seen that on existing drugs, some recent years in particular, we have seen some spiraling increases in some of those costs. And as healthcare and health insurance costs have gone up, particularly over the more recent years, we are seeing more of those costs being shifted to the consumer as patients.

And then also we have talked a lot about Medicare part B and part D and that they don't in general seem to have the right regulations and the right incentives to help make sure that we keep the bad actors out and keep the prices down.

So what do we do? Well, let's recognize that consumers as patients need to have a lot of transparency in order to pick the optimal drug at the optimal price to address their specific health needs.

We also need to keep an eye out on open and competitive free markets to make sure

that we can keep those costs down and address that competitive environment within the free market instead of making sure that there is a one-size-fits-all government-mandated, whether it is a Medicare for all or whether it is other single-payer schemes that won't necessarily lead to better results for the patient but won't necessarily help with costs and drive innovation out of the country.

So while we do everything we can to lower drug costs, we need to look at the use of some of these new drugs, this new technology, this new capability that is out there.

You know, as we look at some of the incentives for Medicare to help make sure that we keep drug prices down, I mean, I don't want to unduly criticize Medicare, but how can we look at some of these different incentives to help make sure that the bad actors work together to lower prices?

Mr. Antos, you had mentioned something about a rebate system that would help. Can you talk a little bit about what effect that would have on a pricing system and how that would affect the total costs?

Mr. Antos. So I am not sure what you are referring to on rebates, but what I think I was trying to get at was that the structure of the part D benefit drives list prices up, drives rebates up, drives patients to more expensive drugs, and drives costs to taxpayers. So we need to look carefully at that issue. This is the job of this committee.

One can go beyond that, though. There are some other things that we can do. Certainly, the idea that we are counting, in the so-called true out-of-pocket calculation, we are counting money that actually doesn't come truly out of a patient's pocket doesn't make any sense to me, and I have often wondered why we have the word "true" in front of that.

So I think there is a lot that can be done in part D. There is a lot that can be done in part B. I mean, I would argue that moving away from the buy-and-bill system is probably the fundamental reform. If we can't get there, at least deal with the add-on

payment to part B.

Mr. Estes. Thank you.

I mean, we talked a little bit about some of those incentives in terms of how do we make Medicare more effective. And obviously, as we work to lower out-of-pocket drug prices, there are so many things that we need to do differently.

You know, we live in a time when there are a whole bunch of therapies, particularly from biologics, that are helpful. So as we look at these different incentives, particularly in Medicare, trying to figure out how we come up with some bipartisan solutions to help with that regard.

So I want to make sure that we are looking together, whether it is helping individuals that maybe have private insurance or going through Medicare and using those incentives, and how do we make sure we maintain those incentives and lower their prices.

Unfortunately, I am out of time, but I will yield back the balance of my time, Mr. Chairman.

Chairman Neal. I thank the gentleman.

With that, the gentleman from Illinois, Mr. Schneider, is recognized to inquire.

Mr. Schneider. Thank you, Mr. Chairman.

And I want to thank the witnesses for your patience and the fact that you are spending time here today sharing with us your perspectives and your experiences.

And in the case of Ms. Ojewumi, I want to thank you for sharing your personal experience. It is an act of real courage to share with us your story and your medical history, and I think you demonstrated courage as you talked about your story and what you have been through.

So I want to wish you a long lifetime of good health, and may we always continue to find the innovations that will give you the ability to reach all of your potential.

I think we all agree that we live in an amazing time when there are drugs coming to the market and in the development pipeline that are truly life-changing. Many of the diseases that we have looked in the past as death sentences no longer are such, and some are even now curable. We have the drug that can cure Hepatitis C, as we have talked about. CAR T can cure cancer with a single treatment.

And there are new gene therapies that are increasingly sounding more like science fiction than science, but looking on the horizon of curing blindness and other things.

But these extraordinary treatments often come at an extraordinary price, and others have touched on it. But innovation, as wonderful as it may be, is of no value to any of us as an individual if it is inaccessible because it is too expensive.

Half of all Americans are worried that they won't be able to afford the cost of their needed prescriptions. A quarter say that they or a family member have not filled a prescription, cut pills in half, or skipped doses. Too many consumers are going too long without the medicines they need.

Ms. Ojewumi, you shared in your opening remarks that you went without medication, if I get it correct, for 4 years. And if you are willing, I would be curious to understand the thought process as you were thinking about it, the choices you were making, the trade-offs you had to consider as you looked at the cost of your medications.

Ms. Ojewumi. Often when I speak I compare 1 month of my medication can pay for one semester of my college tuition at the University of Maryland, College Park. So the trade-offs are easy.

I have also spoken about how being in college, it was often the choice between a textbook or medication. And, obviously, maybe a textbook took priority, because I knew if I needed to get to where I wanted to be, get a great job, and get good health insurance, I needed to be in school.

And to be frank with you, it is just a matter of choosing which condition impacts me more. My mitochondrial disease and missing the medication for that may not kill me as fast as missing medication for my organ transplants.

And I will say this. When medications are inaffordable and inaccessible to young people with disabilities, it literally clips their wings. It allows them to drop out of school. It allows them to look for other ways and means of paying for their pills.

I don't want to take too much your time, but some of the greatest minds in this world have been disabled, and the investment in youth with disabilities begins with affordable medication.

For example, we had a disabled President, FDR. I love using him as an example. Without him, we wouldn't have a lot of the things we have or we wouldn't have exited the Great Depression. But when you invest in us, when you make medications affordable, we, in turn, change the world.

Mr. Schneider. Thank you. The way I say it is, you may have challenges in one capability, but you may have gifts in another.

And one of the things, as you talked about it, is thinking when people are making their choices between medications, as you said, whether or not to take a class or get a textbook, those choices are hard. And if I expand that to our entire economy, when people are making choices to give up the opportunities for advancement or further education, that is hurting all of us, and we need to move forward on that.

Shifting gears a little bit, the Trump administration's recent rules on step therapy in six protected classes also worry me, and the testimony indicates more flexibility in the plans are warranted.

Mr. Reuther, I will turn to you. You talked about interchangeability determinations in your statement. I was hoping you in the last few seconds could have a

chance to elaborate on that a little bit and the impact it is having on your retirees.

Mr. Reuther. Well, we just think it is important that these not prevent an unreasonable barrier to lower cost biosimilars coming to market, and that would be the key.

Mr. Schneider. And I think in my last second, again, one of the challenges as people are going and they have to go through various steps to get to the treatment that will actually give them the ability to live their full life and reach their full potential, as, Ms. Ojewumi, you are doing, and we are proud of what you are accomplishing, we need to make sure that medications and the cost of the medications aren't a barrier to people to living a healthy life and full adulthood.

I yield back.

RPTR BRYANT

EDTR CRYSTAL

[1:10 p.m.]

Chairman Neal. I thank the gentleman.

With that, let me recognize the gentleman from California, Mr. Panetta, to inquire.

Mr. Panetta. Mr. Chairman, I appreciate this opportunity, Ranking Member Brady.

And all of the witnesses, thank you for being here, as well as your preparation to be here.

Mr. Reuther, I just wanted to ask about your plan there at UAW and the use of generics. And if you could kind of elaborate a little bit more of how that actually brings down cost, if it does.

Mr. Reuther. We have moved aggressively to increase the percentage of our members who are using generics. It is now up to 89 percent. But, to our surprise, we have now in recent years seen a spike in generic prices. And sometimes it is because there are not sufficient producers of generics.

Sometimes the reasons are not explainable. We have been seeing differences between generic capsules versus tablets, and it goes both ways. And even though both do the exact same thing, there are hugely different prices.

So we think that is a need for the FDA to step in and regulate some of these abuses, and also to educate physicians that simply prescribing a generic, there may be wildly different prices in two generic price products for the same thing.

Mr. Panetta. Do any of the witnesses have any explanation as to why there is this swing in prices between these types of products?

Ms. Sachs. Well, I just want to agree with Mr. Reuther that this is a growing

problem that needs to be considered by the committee, but also that the drivers of this problem are different from those we have seen in the branded context. So here patents, FDA exclusivity periods are much less of a concern, if a concern at all.

So some of the factors are, as we have heard from Dr. Miller, a declining number of generic producers. Others are I am aware that there are antitrust lawsuits against some manufacturers for potentially price fixing. There are other reasons why the way in which the FDA not just approves drugs but then the PBM structure would discourage companies from listing or producing generics. So it is the combination of those.

Mr. Panetta. Got it. Great.

And then, Mr. Miller, you mentioned earlier in your testimony in regards to getting generics to the market, you mentioned some of the things that Ms. Sachs said. But you also briefly said importation, and you said that there are certain limits on that. Can you elaborate on that, please?

Mr. Miller. Well, the only thing I was mentioning there, and there are a number of different mechanisms that we have touched on here, but the specific idea -- and I think this came out of Aaron Kesselheim in Harvard -- is the notion that if the number of manufacturers declines in a generic market and you get down to, let's say, one manufacturer, and then they have that ability to spike the price, you say in that instance the FDA has a reciprocity agreement and you begin to import that generic from a foreign source, so that you have more than one producer, and you can try and drive the price back down.

Mr. Panetta. Got it.

Now, obviously, there are limitations on what we can import when it comes to generics, and I think that has sort of been set out, I guess, in NAFTA and the USMCA. Are you familiar with some of the proposals in USMCA that may provide those limits, like

the 10-year exclusion rule on certain --

Mr. Miller. Now, that affects the biologics.

Mr. Panetta. Exactly.

Mr. Miller. And is granting longer patent periods. And it is very frustrating that some of the effects that we live with end up getting negotiated as a small part of the trade agreement, yet they affect the country more broadly. And it is something that we need to pay attention to.

I don't feel particularly expert in it, so I hope you are not going to drive me much deeper on this one,

Mr. Panetta. Understood.

Well, thank you very much. I appreciate it.

I yield back my time.

Chairman Neal. I thank the gentleman.

The chair would recognize the gentleman from New York, Mr. Reed, to inquire.

Mr. Reed. Well, thank you, Mr. Chairman. And truly, this has been a great panel of witnesses and input here, and I appreciate the focus on this.

And I would be remiss if I didn't thank my colleague from Colorado, Diana DeGette, who she and I teamed up as co-chairs of the Diabetes Caucus with both type 1 diabetic children, did really take a deep dive into insulin pricing. And so I am really glad to hear a lot of discussion today about insulin prices and what has happened there.

I would also like to take a moment and thank you, Dr. Miller, and the foundation you represent. John and Laura Arnold are people I have met, I have talked with, saw their NBC News segment where they are committed to taking on this issue and getting it resolved. So you are a testament to them.

Mr. Miller. I appreciate that.

Mr. Reed. And, Ms. Ojewumi, I so appreciate your story. And I hope today demonstrates to you that Republicans and Democrats want to come together to solve this problem that you so correctly and greatly represent and articulate with your life story. And I am going to take a gamble here, and I am going to try to see if I can crystallize a lot of the testimony that we heard today. And if you would bear with me, Ms. Ojewumi.

We are talking about marketplaces here. And I think there is a great disparity between the understanding of the marketplaces from you as a patient and the doctors, and then what a lot of the testimony has been focused upon is other actors in this area.

So as an American citizen who has lived this story, to you, what is the marketplace? Who is the buyer and who is the seller in your pharmaceutical transaction?

Ms. Ojewumi. In my thought, I have always thought of the doctors and the Big Pharma companies as the sellers and the patient as the consumer.

And I got my degree in government and politics, so I am aware that price is created out of demand. But I am also aware of the fact that medicine shouldn't be looked at as an industry. When doctors take the Hippocratic Oath, their oath is to help heal patients.

Mr. Reed. See, this is I think the issue here, Ms. Ojewumi. Because you are absolutely right, most Americans believe the buyer and seller are you, the doctors and the pharmaceutical company that are there.

But I will turn to Dr. Miller and Dr. Antos. To you, in the Medicare world in particular, who is the buyer and seller? Who is the buyer, Dr. Miller?

Mr. Miller. Well, I think in the Medicare program, it really reduces down to the taxpayer and then the patient who pays a premium.

Mr. Reed. But who is paying the transaction? Who is negotiating the transaction?

Mr. Miller. I think in D, it is the insurance plan and the PBM. In B, it is the

physician.

Mr. Reed. Okay. So it is really, it is people between. So that marketplace is much different than what the American people understand the marketplace to be, correct? I mean, the patient wasn't indicated in your testimony to us.

And so the issue that I am trying to get to is, when they are negotiating that transaction in part D, and we talked about list prices today, why would the patient be calculating their deductible, their co-insurance, off of that list price when that list price has nothing to do with the fundamental transaction of Medicare part D? That is not what the transaction results in, in Medicare part D.

The list price is an artificial number, as I look at it. And you are charging the patient their deductible and their co-insurance off that list price. I have never heard anybody give me a rational explanation as to why that would occur. Is there a policy reason why we should be charging the patients based on the list price that has nothing to do with the marketplace that we have intentionally or unintentionally created under Medicare part D?

Mr. Miller. And I think the issue they have to resolve in order to answer that question is, is the way D is set up, the ultimate net price happens long after the transaction at the counter.

Mr. Reed. Correct.

Mr. Miller. So, you know, it is made up through the rebate that comes at the end. So you would have to solve that transaction in order to bring the discount --

Mr. Reed. Nobody did this by design. Nobody set this system up and said, we want to charge patients based on a list price that has an incentive under part D, in my opinion, to just keep going up and up and up. And what they are eating, what the patients are eating is nothing that we put into motion. This is an unintended consequence of this

marketplace, is it not?

Mr. Miller. Yeah. And you and I are not disagreeing that the patient is paying too much here.

Mr. Reed. So how do we fix that? I got 8 seconds left.

Mr. Miller. A couple of things. A couple of things. We have talked about the notion of putting more pressure on the PBMs in order to negotiate the prices through the change in the risk structure that everybody on the panel has spoken to.

If you wanted to be more aggressive, you could change the underlying structure and move away from the rebate model. We don't have the seconds to talk through that. That is a bigger change. But that would bring your discount to the patient at the counter. But there are definitely some issues that would have to be worked through.

Mr. Reed. And that is definitely what we want to do. We want the patients to get the benefit of this transaction.

The Chairman. I thank the gentleman.

The gentlelady from Florida, Mrs. Murphy, is recognized to inquire.

Mrs. Murphy. Thank you, Mr. Chairman.

And thanks to the witnesses for your testimony and your endurance.

I think there are few issues that come up more in conversation with my constituents in central Florida than the high and unpredictable price of prescription drugs. The conversations tend to be really moving and the feelings are really raw. You know, understandably, my constituents are confused, anxious, and sometimes really angry. And that is because when they look at the system, they don't understand it. It is opaque. It seems arbitrary. And from their perspective, it doesn't even seem like the system was designed to be with their best interest in mind.

I want to tell you a little bit about Sandra. She is a 66-year-old retiree living in

Orlando. She is on Medicare, having worked her entire life and paying into that system. Her only income is Social Security, $1,200 a month.

Like many Americans, Sandra has diabetes, and her medications used to cost $100 a month. But not long ago, for reasons she cannot explain and can't be explained to her, the cost tripled to $300 a month.

And as you can imagine, she is on a fixed income. And so tripling the price of her drugs basically puts her in a situation where she can't afford her medicine and her bills for food and housing. So she has basically stopped taking her medicine altogether.

And here she is at 66 in her retirement considering going back to work so that she can simply afford her medicine. But, unfortunately, she is so sick because she is not taking her medicine she can't work. And recently she has even been hospitalized a number of times.

So this experience has been really harrowing for Sandra, but it is an experience of many Americans. My heart just breaks for her.

But I think these Americans want more than just sympathy from their Members of Congress. They want to see solutions. And that is why I am really glad we are having this hearing today.

I put a chart up on the board. It is a little bit of an eye chart for you all. But basically, this is a chart of the supply chain for prescription drugs. And it has got all these arrows pointing in every different direction, showing the different stakeholders and the flow of drugs, services, and payments between them. It reminds me a little bit of my days at the Defense Department where there would be a slide mapping out the complexities of conflict, and the general would note: When we understand the slide, we will have won the war. And perhaps that is the case here.

You know, it is hard enough for health policy experts to understand all of this.

Imagine how hard it is to explain to Sandra. And she is just trying to understand how she gets her drugs so that she can live a healthy life.

First, I just wanted to ask each panelist, if you had the power to redesign the prescription drug system in this country from scratch, would any of you choose to design it this way? No takers?

Well, I want to preface my next question with an observation. You know, when you talk to all of the players in the drug supply chain, my sense is that they genuinely want the system to work better for patients. I know they care about their bottom line, but I don't think any of them are in this business to hurt people. However, when you ask them who is to blame for our current flawed system, they tend to point the finger at others, not themselves, and that is understandable, but it makes it harder for us to legislate in a comprehensive way.

Ideally, Congress would require every player in the system, not just one or some, to make improvements within their own spheres. I think everyone needs to be a part of the solution for it to be effective and enduring.

So I would like to ask Dr. Miller, if you had to name one change we would require of each player in the system, think about it as the first best step for each actor, what would that one change be?

Mr. Miller. With respect to Medicare, I would ask that the risk structure for the PBMs be changed.

With respect to a set of high-priced, low-competition drugs -- and this would come from the manufacturer -- I think those prices would have to be set differently than inside the PBM system, either through reference pricing or through a negotiation process.

I would probably still look for patent reforms as well, which would also come from the manufacturer.

Those would be at least two places that I would go to on that chart.

Mrs. Murphy. Thank you.

My next question is for Ms. Sachs. We have spent a lot of this hearing talking about people who do have some sort of coverage, but there are a number of people who are uninsured in my community. Florida has some of the highest number of uninsured. How do those people get access to the drugs they need and who ends up paying for it?

Ms. Sachs. Well, often they don't, unfortunately. And the answer is we all often end up paying for it if the patient gets sick enough to go to the hospital, where we do end up covering their care through other sorts of programs. So it is absolutely the case that making sure that patients having access to the drugs they need is a benefit, not only for those patients but also for the system as a whole.

Now, there are, of course, patient assistance programs that can be helpful in some cases for some of these patients, but as we have heard a little bit, we don't know exactly who is being helped, under what circumstances, how far. So it is very important to consider expanding access to healthcare and health insurance so that these patients can afford these medications.

Mrs. Murphy. Great.

Thank you, and I yield back.

Chairman Neal. I thank the gentlelady.

The gentleman from California, Mr. Gomez, is recognized to inquire.

Mr. Gomez. Thank you, Mr. Chairman.

I am glad you put up the chart, because I have seen that chart before and it is definitely hard to follow.

And then on Sandra, Sandra is a senior citizen on fixed income, just like people that are senior citizens on fixed income in my congressional district, but now those seniors are

starting to file their taxes. So they are on fixed income and starting to realize they owe taxes for the first time in 20 years.

So we can't look at all this in a silo, because people don't live that way, right? They live with housing costs, transportation costs, fuel costs, health costs. So, unfortunately, Sandra is probably going to take a big hit when it comes to her taxes this year after that tax reform that was passed.

But I want to just kind of go on and ask a few questions. One of them, a colleague on this committee at the beginning said we should allow the market to lower costs like the cell phone in your pocket. I am not sure if anybody had followed up on that comment, but, Mr. Miller, can we lower drug costs like a cell phone in a pocket through competition, or a flat screen television?

Mr. Miller. I think the fundamental difference is, is what is granted to the manufacturer at the beginning of the process, the patent and market exclusivities that they get, and their ability to continue to build and extend them that differentiates the drugs from the cell phone. That is at least one way that they are different.

Mr. Gomez. So they are different?

Mr. Miller. I think so, yeah.

Mr. Gomez. If it was that simple, we would have a lot cheaper drugs.

Dr. Antos, you are more of a free market guy. Do you believe the market alone can solve or lower drug costs of prescription drugs?

Mr. Antos. Well, clearly, part of our problem is insurance. I mean, your example of the cell phone is illuminating in the sense that if I buy a cell phone, I am buying it. You are not paying for it for me. I wish you would, but you are not.

And so, therefore, I am much more aware of the cost. I may not be that knowledgeable about the technical aspects of it, but other people are. That is how product

markets that do not have third-party payment generally operate.

So we have a general problem, this is not just a prescription drug problem, we have a general problem in healthcare that third-party payment gets between the patient and the provider in a way that conceals the cost and leads to inefficiencies.

Mr. Gomez. Yeah, but there is also a difference, right? A person who doesn't have, like you don't have a cell phone, you are not going to die because you don't have that cell phone. Yeah, you may not be able to play whatever, Candy Crunch or anything like that, but you are not going to die. And you are not going to end up in the hospital, which you are going to cost people more out of their tax pockets, because we have an obligation to take care of those people when they get to the emergency room, right? That is kind of like this whole concept.

So I just want to kind of move away from this idea that the market itself is going to solve the problems. Yeah, I think that there might be a place where revealing the true price of different things could help, but that is also what do we consider, what should we take into account when we decide the price of a particular service or product?

One question that I often come back to, people say drug companies use marketing dollars to advertise a particular drug. Does anybody believe that limiting the marketing dollars of pharmaceutical drug companies would have a positive impact on lowering drug costs? Any of you?

Mr. Reuther. Yes.

Mr. Gomez. Okay.

How about Ms. Sachs?

Ms. Sachs. Well, it won't lower drug prices directly. There are indirect patterns for it to do so. So we have heard about patients who are told to ask their doctor for a drug, but it may not be very effective and it may be very expensive. So it would be through

lowering spending on those drugs, which don't provide much value to patients.

Mr. Gomez. I appreciate the comment.

One of the things that I wanted to also understand is that I understand that this is complex. And we have a system, I think, that is kind of broken across the board with all these different actors that are within the supply chain, and really kind of getting under control we have to take a comprehensive approach. I would love to see what kind of package we can actually pass that does that.

I am out of time, so I am going to yield my time back to the chairman.

Chairman Neal. I thank the gentleman.

With that, the gentleman from Texas, Mr. Arrington, is recognized to inquire.

Mr. Arrington. Thank you, Mr. Chairman.

And thank you, panelists.

We at the end of the chain here get to have the benefit of the discussion and the questions and answers. And so my comments will be more observations. I may have a question or two. And I appreciate the dialogue just preceding my time about markets.

We talk a lot about the problems of our current system, and there, in fact, I think, is a problem, and that is, how do we get best value? Not just highest innovation, but lowest cost, that combination.

And I agree with what you said, Dr. Antos. How do we strike that balance between innovation and competition? And that is really what is at question. How do we get there?

But I was former vice chancellor for research and commercialization of technology at Texas Tech University System and got a front row seat and hands-on experience to early stage technology innovation and commercialization. We are on the front end of early stage discovery at a university. And I will tell you that this system has incentivized the

very best platform for new technologies and innovation, the likes of which are unmatched in the world.

And so I recognize there is a double-edged sword to this, because it is costly, and we need to look for ways to recalibrate. But I would say that these new ventures and these new technologies, it is very risky to take a life science technology to market. It is extremely costly to do that. And, in fact, universities are best to just license them to people that know how to do that and have the ability to raise the capital.

But I would have faculty say: You know, I don't know about the capitalists, greedy capitalist pharmaceutical companies, the corporations, but they loved their new discovery and they believed it would change the world. And I said: You got a choice, you can publish that or you can partner with somebody that has a for-profit motive and change the world and actually have an impact on the quality of lives of millions of people. And so there was a lot of that sort of discussion.

I do believe markets are the most efficient way to solve these problems where we can. And I do think that I am very suspect of sort of big government, government-controlled, central planning solutions to this. And I worry about the slippery slope. Their history, I think, is littered with well-intended government-controlled solutions.

The Affordable Care Act would be case in point. I mean, the CBO said that the premiums and deductibles would go down for the first time since the creation of the, quote, Affordable Care Act. But it was market-based solutions that were allowing for that in our American Health Care Reform Act.

And so I would like to try to find ways to maximize. Where do we need to activate market forces that don't exist now that could in this system? And where do we need to amplify those that exist that just need the dial turned up?

And I do appreciate, Dr. Miller, what you are saying. There are places where there is market failure and we need evidence-based -- I can't remember exactly the words you used, but it was evidence-based intervention when markets can't solve it. I agree with that.

But where can we amplify? Where can we activate in transparency and competition and aligning the incentives, Ms. Sachs, as you have talked about? I think there is a lot of room to improve there before we leap to some big government solution.

I think government has a role, but for every government action there is a sometimes equal and opposite reaction of inefficiency, fewer consumer choices, less access to quality. So I want to be really careful that we don't lurch too far on that side.

So give me your thoughts, Dr. Antos, on your top one or two ways to amplify or activate the market, just quickly.

Mr. Antos. Well, I think maybe the biggest thing is we get the consumer involved, have patients become consumers rather than inputs into a medical process. And that certainly involves knowing about prices and about therapeutic alternatives, but it especially depends on their physician.

Patients do not go to the physician and then tell a physician what to do. It goes the other way around. The physician has to be more involved and understand more what the trade-offs are beyond the therapeutic trade-offs, has to have more awareness of the cost for the patient, and needs to have better information. Basically, all parties need better information, and that revolves around the insurance company. We need to bring all that economic information together along with that clinical information.

Mr. Arrington. My time has expired, Mr. Chairman. Thank you, and a great panel.

Chairman Neal. Thank you. I thank the gentleman.

With that, let me recognize the gentleman from Nevada, Mr. Horsford, to inquire.

Mr. Horsford. Thank you so much, Mr. Chairman. The fact that just in 1 week you have scheduled two critical hearings on healthcare speaks to your commitment to these issues, and the leadership that you are providing to this committee is much appreciated. So thank you.

I have a short amount of time and I want to cover so much, based on the rich panel that we have in front of us.

First, I want to thank Ms. Ojewumi for sharing your personal story. Like you, I have heard from so many constituents who are facing health challenges and are having to choose between having the resources and the money to buy life-saving medications or whether to pay rent, buy food, invest in their education.

And we have to keep that at the forefront of what we are doing here today. I know there are many people who have focused on innovation, and I respect the role of the private sector in healthcare, but what does it matter to have innovation if patients who need the life-saving products that they are producing can't afford it? And so I would like to focus on that part of the debate today.

There are two constituents of mine who have shared their story, like you. Joy from Las Vegas, whose husband is a diabetic and has MS. And when their insurance changed, his prescription for insulin changed and their cost went from nothing to $110 a month. They can't afford to refill it, and his MS medications are also very expensive. Joy herself went on to share that her own prescriptions for asthma and health complications cost an additional $190. She tells me this is all too much for a retired person to afford.

Then there is Pamela from Pahrump who has COPD and can no longer afford even the three inhalers that she depends on. She says that she cannot afford the oxygen tank. Needless to say, the quality of her life has deteriorated. She says that it is hard to do

anything useful when you can't breathe.

Ladies and gentlemen of this committee, she cannot breathe. A constituent, an American citizen, cannot afford to breathe because of policies affecting them that we in Congress have an ability to affect and change.

So I want to get to the crux of my question, and first it is around insulin. The cost of insulin since 2002 has increased 197 percent. Some of this is due to increased diagnosis and prevalence and some is due, in part, to high-priced insulin.

Dr. Miller, aside from these factors, what are the drivers contributing to the increased price tag of insulin?

Mr. Miller. So you have a couple, three manufacturers who are able to maintain their monopolistic positions by adding patents, often through the delivery devices, and they also engage in activities to keep competitors off the market.

Mr. Horsford. And is there a generic available for insulin?

Mr. Miller. I don't think that there is a readily available generic.

Mr. Horsford. So over 100 years of the insulin being available, with modest changes over that time, we have three manufacturers that have contributed to the cost of insulin increasing 197 percent and we don't have the ability to offer a generic alternative.

Ms. Sachs, most of my colleagues have talked about the fact that five of the largest drug manufacturing companies spent 70 percent more on marketing and admin costs than on research and development, which we have heard over and over. Are the details of those costs disclosed to the public on marketing and admin costs?

Ms. Sachs. Typically, no, they are not.

Mr. Horsford. So how are we supposed to know whether these are legitimate costs or not? And where is the proprietary argument as to why that information cannot be disclosed?

Ms. Sachs. We have already seen this very complex chart that Congresswoman Murphy helpfully put up. Much of that information is kept secret, and it is very difficult for us all to know exactly which factors go into the costs that they do report, and then how the money is distributed within the system. And learning more information about that would help us propose more evidence-based ideas to you all.

Mr. Horsford. Thank you.

Mr. Chairman, I know I am out of time. I have 20 more questions. I will submit them for the record and hope to have your response.

Chairman Neal. I thank the gentleman.

With that, the gentleman from North Carolina, Mr. Holding, is recognized to inquire.

Mr. Holding. Thank you, Mr. Chairman.

Dr. Antos, we have got a lot of good drug pricing ideas floating around the committee room today, and one of them is to use the drug pricing policies that are used in Medicaid today in the Medicare program. And one idea that is gaining traction is an inflation cap on price increases for certain drugs in Medicare part B.

So my question is how do the current pricing policies used in Medicaid and the VA limit access or drive higher prices in the rest of the market? Specifically, what impact do you think an inflation cap in Medicare would be likely to have on the price of drugs in the private market? And would it create an incentive for drug companies to increase or decrease their prices?

Mr. Antos. So on the inflation cap, I believe that the major effect would be through the launch prices of new drugs. There would be an incentive to, in essence, get ahead of that cap first time out. Once you are on the market, you are subject to the cap. So getting that high price up front I think would be issue number one.

Now, that is not most drugs. That is just the drugs that are introduced. But eventually, that is a system that will erode. It won't work forever.

Mr. Holding. Good.

Another thing we have been talking about is transparency, and that is something that my constituents certainly understand, I certainly understand, because we have absolutely no idea how much a drug costs as a patient. And, obviously, if you have transparency, then the patient consumer is involved in understanding the price, and that would lead to competition, I believe.

So how can we achieve that transparency? I mean, what can we do to empower consumers with that transparency, drug pricing, so that they can negotiate and be a factor in hopefully driving the price of drugs down? I mean, how do you achieve the transparency?

Mr. Antos. Well, the first thing that I think is absolutely necessary is for access to information to the consumer about what his net price will be, his or her net price. In other words, not the list price. Don't tell me about the discounts you got. Just tell me, what is it going to be before I get to the pharmacy, what is the price going to be for me?

I mean, we do hear plenty of stories of people who are at the pharmacy and they leave the bag behind because it is a price they didn't expect and they don't have the money. That is totally unnecessary.

But let's not wait at the pharmacy. This is a discussion that I believe that the patient needs to have with a physician. If there are alternatives, then they need to have an honest discussion about both the therapeutic aspects and the cost to the patient.

Mr. Holding. Very good. Very good.

Mr. Chairman, I think this has been a very informative panel. I appreciate you convening them. And I yield back.

Chairman Neal. I appreciate the gentleman's comments.

And with that, I would recognize the gentleman from Illinois to inquire, Mr. Davis.

Mr. Davis. Thank you very much, Mr. Chairman.

You know, as I listened, I represent a congressional district that has 24 hospitals, 4 outstanding medical schools, 2 schools of public health, a number of research institutions, great health institutes.

I have been involved in health now for 40 years. I have been a member of the American Public Health Association, World Health Organization, National Association of Community Health Centers, American Psychological Association. I have attended thousands of meetings about health. I have been in hours of discussions and lectures.

Mr. Chairman, I have never been to a more informative discussion than what we have had here today, and so I want to thank you for holding this hearing in particular.

Ms. Ojewumi, you are an inspiration, absolutely, unequivocally, and without a doubt. You remind me of two people that I have had the good fortune to work with. One, a gentleman, Mr. David Benz (ph), who started out as the chairman of our disabilities committee. But David always said he didn't have a disability, he just had some challenges. And like David, you have accepted and worked with your challenges as an advocate that obviously inspires people all over the world.

The other is a fellow, Reverend Steve Richardson, who co-chairs my ministers advisory group. Reverend Richardson has had two heart transplants and a kidney transplant, has two jobs, works every day, and still serves as an advocate, works with a group called the Gift of Hope that provides help for individuals seeking transplantation.

And so everything that I have heard today is relevant and really reminds me of my parents. My father was of the opinion that there were no simple solutions for very complex problems. And my mother would counter with: Yeah, that is true, but wherever

there is a will there is a way.

But if you want to go south, the first thing you have got to do is turn and face that direction. And every time you take a step, you get a little bit closer to Mississippi. But if you are heading up towards New York, chances are pretty good that you are not going to get to South Bend.

I have always been appreciative, Mr. Reuther, of the United Auto Workers' quest for improving the quality of life, not just wages and fringe benefits but quality of life. And so this idea of looking at greater utilization of generics didn't just fall from the sky. How did you all arrive at that as an approach?

Mr. Reuther. I think many people were involved in the push to make generics more available, but we now face the challenge with getting biosimilars to market with all these new very high-priced biologics and specialty drugs, and also with insulin, which has only recently been named by the FDA to be a biologic.

So that is sort of the new frontier. But we have to do the same thing that we did back with the original Hatch-Waxman legislation, to make sure that there is a pathway to get these less expensive products to market more quickly.

Mr. Davis. Thank you.

Mr. Chairman, I believe firmly in a national health plan. I make no bones about it. I believe in Medicare for all. And I think, Mr. Chairman, today we have taken a step and we are on our way. I yield back.

Chairman Neal. I thank the gentleman.

With that, the chair would recognize the gentleman from Georgia, Mr. Ferguson, to inquire.

Mr. Ferguson. Thank you, Mr. Chairman. And I am going to be you all's favorite member today, because I think I am dead last.

Oh, you are going to be the favorite member today.

So as we go through this, I want to thank you all for your time today. There have been some great conversations here, really good questions from both sides of the dais here, whether it is a question about the high cost of and the wrong incentives on part B medications, whether it is the question the lady, my colleague from Washington State, asked about some of the perverse incentives in part D, or the really good conversation about patent reforms that have taken place here today.

And I would even push even further to say, should we look further at our Tax Code to maybe be more innovative with that so that we incentivize more on the front end and more research and development, because right now it seems like we have to recover that cost on the back end. Maybe it is weighted differently, and just something to consider.

But in that model I want to take just a minute and see if I have got part of our system right. What seems like what we do in all of this is we incentivize this kind of weird deal where you have to raise the price to give a bigger discount that ultimately doesn't show up in your bill at the pharmacy counter, okay? Not clearly. So it seems pretty opaque the way that this happens, all right?

Can anybody in a very short period of time, in a way that you would talk to a constituent -- please don't read them the phonebook, please don't make it overly complicated -- but can you explain how we incentivize a higher drug cost to actually fund this very complex supply chain in the middle and tell me where the discount actually winds up?

Dr. Miller, if I could start with you. And you get to do what I do and answer this in 30 seconds. You got 30 seconds.

Mr. Miller. Yeah, okay.

The way it is generally supposed to work is the PBM and the manufacturer

negotiate the price. There is a discount. The discount comes at the end of the process, and that is supposed to be reflected in the premiums that people pay in a subsequent year, and then they have coverage as a result of that.

In Medicare, the incentive structure in particular encourages using high-cost drugs and that is what is helping inflate the Medicare cost. And you need to change the risk structure in Medicare to get --

Mr. Ferguson. Got it. Okay. Thank you. I don't mean to cut you off.

Mr. Miller. No, that is fine.

Mr. Ferguson. Dr. Antos, can you touch on that as well?

Mr. Antos. I would just add that I agree with Mark and the --

Chairman Neal. Put your microphone on, please.

Mr. Antos. I agree with Mark. And the premiums are, in fact, held down for Medicare beneficiaries. The person holding the bag is the taxpayer.

Mr. Ferguson. So it sounds like, and at the risk of overgeneralizing this and making men and women of the cloth angry, it seems like we have created something called a preacher's discount. It is what some folks back home refer to. Someone comes in, you raise the price. If something costs $100, you charge them $200 and then give them a 50 percent discount to make everybody feel better. Okay?

And I don't mean to make light of it, but when you try to explain this to a patient -- and I was in practice for 25 years -- or you try to explain that to a customer at the pharmacy, it is the most opaque process that I have seen. And it is really not fair.

I am not trying to say that the drug companies are wrong or the PBMs are wrong or the insurance company is wrong or the hospitals or the doctors. I just know that the patient is having to pay more out of pocket year in and year out.

The second thing is, is that with this lack of transparency, people can't make good

choices. They can't make good decisions.

Dr. Antos, do you think transparency in this entire process helps us?

Mr. Antos. I am sorry?

Mr. Ferguson. Does transparency in this process help drive down cost, ultimately?

Mr. Antos. The right kind of transparency, yes. It has to be the price that is relevant to the decisionmaker. In the case of the patient, it is generally the out-of-pocket cost. In the case of the hospital administrator, it is a larger cost. In the case of the PBM, it is a different cost. Every actor in the system is properly focused on different prices. But for the consumer it is clear what the number, what the price is. It should be.

Mr. Ferguson. Thank you.

I yield back, Mr. Chairman.

Chairman Neal. I thank the gentleman.

With that, let me recognize the gentleman from Michigan, Mr. Kildee, to inquire.

Mr. Kildee. Thank you, Mr. Chairman.

And I thank the panel. I will try not to be redundant. I know a lot of the questions have been covered. I just want to make three historic observations, observations on recent history.

The reason I was late is that I was attempting to get to Detroit to attend the services for the late Congressman John Dingell, who for every 1 of the 59 years that he served in this place, dating back to 1955, tried to find ways to bring healthcare to more Americans.

And I see Mr. Reuther sitting here. Yesterday, I was in Flint, on February 11, which is the 82nd anniversary of the first UAW contract resulting from the sit-down strike that your father Roy was very much a part of and your uncles obviously were a part of.

But even before Mr. Dingell was here and even before the UAW was able to get that first contract which led to healthcare for hundreds and hundreds of thousands if not

millions of people, insulin was introduced in the early 1920s. Almost 100 years later -- and this is a bit redundant but I have to say it -- after almost 100 years, with all this notion and discussion about how competition in the market is going to be the way to drive down prices, why do we only have three insulin producers in this country?

Dr. Miller?

Mr. Miller. I mean, I think it is because manufacturers can take advantage of the patent extensions and exclusivity, market exclusivity rules, that they can maintain their monopolistic position, keep competitors off the market. I think that is a huge piece. And then I think sometimes they directly go at competitors and either force them off the market or pay them to stay off the market.

Mr. Kildee. I am glad you said that, because the implication of some of the comments that we hear in this debate is that we need to keep government out of it, and I think we have to ask ourselves in what way. Perhaps there is a way that we can get government to allow for more competition and create some more price pressure that would allow these prices to come down.

The idea that people are rationing insulin and dying as a result in the 21st century in America after 100 years of that drug being available to save lives is just absolutely outrageous.

Mr. Miller. It is crazy. And I think you either have to go upstream to the patent and exclusivities and force competition back into the process, or at the back end say, if you are going to allow that to happen, the government grants the monopoly, then the government should reassert its right when this happens and competition isn't occurring and control the price, or some mix of the two. But you are going to have to deal with one of those two processes.

Mr. Kildee. Or at the very least, if we want to have competition, even if we only

have three producers, we ought to be able to have them compete for us, not just so much as a government regulator, but as the biggest customer. They ought to have to compete.

Mr. Reuther, I wonder if you would comment a bit on what steps that you have been able to take or are initiating, trying to take in order to bring down insulin prices for the customers, the members that you represent.

Mr. Reuther. We have not been able to do that. Insulin has been our single largest drug spend.

Mr. Kildee. So utilization is down, as I understand it.

Mr. Reuther. Yes.

Mr. Kildee. And your costs have gone up over 50 percent.

Mr. Reuther. Exactly.

Mr. Kildee. In a 4-year period.

Mr. Reuther. Agree very much with what Mr. Miller has said in terms of the solutions, getting at the patent abuses, but we also think there is a need for immediate action to get at the high prices.

And there has been talk about rebates before, but the companies give rebates to try and get a preferred position in your formulary. And we have not been willing to do that for insulin, because that is going to disrupt the therapies that many of our members are getting, and we don't want to come between them and what their doctor has recommended. So the rebates aren't the answer there either.

Mr. Kildee. Thank you. I will yield back my time.

I just want to thank you for this hearing, Mr. Chairman. It is an important hearing. And it is a source of a lot of frustration for many of us, especially those of us who have family members who depend upon insulin.

My daughter, who is 26 years old, was diagnosed as a type 1 diabetic when she was

7 years old. We are one of those families that pay real close attention to this issue. And I encourage you to continue to speak out in the way that you have.

So thank you. I yield back.

Chairman Neal. I thank the gentleman.

I think we would all agree that the members' questions were really well-targeted and the responses from the witnesses were superb.

I want to thank the members and the witnesses for your participation today. It has been an opportunity to begin our examination of the current drug pricing challenge. And I expect it will be the first of multiple committee meetings focused on the topic. I look forward to working with colleagues on both sides of the aisle to identify solutions.

Please be advised that members have 2 weeks to submit written questions to be answered by the witnesses later in writing. Those questions and answers will be part of the formal hearing record.

With that, the committee stands adjourned.

[Whereupon, at 2:00 p.m., the subcommittee was adjourned.]

Submissions for the Record follow:

Kaiser Family Foundation

Michael G. Bindner Center for Fiscal Equity

American Speech-Language-Hearing Association

Association for Community Affiliated Plans