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HIF124140

NEGOTIATING A BETTER DEAL: LEGISLATION TO LOWER THE COST OF PRESCRIPTION DRUGS

TUESDAY, MAY 4, 2021

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to notice, at 11:30 a.m., virtually, via Webex, Hon. Anna G. Eshoo [chairwoman of the subcommittee] presiding.

Present: Representatives Butterfield, Matsui, Castor, Sarbanes, Welch, Schrader, Cardenas, Ruiz, Dingell, Kuster, Kelly, Barragan, Blunt Rochester, Craig, Schrier, Trahan, Fletcher, Pallone [ex officio]; Guthrie, Upton, Burgess, Griffith, Bilirakis, Long, Bucshon, Mullin, Hudson, Carter, Dunn, Curtis, Crenshaw, Joyce, and Rodgers [ex officio].

Also Present: Rush, DeGette, Schakowsky, Soto, McKinley, and Pence.

Staff Present: Jacquelyn Bolen, Health Counsel; Jeff

Carroll, Staff Director; Waverly Gordon, General Counsel; Tiffany Guarascio, Deputy Staff Director; Fabrizio Herrera, Staff Assistant; Stephen Holland, Health Counsel; MacKenzie Kuhl, Press Assistant; Una Lee, Chief Health Counsel; Aisling McDonough, Policy Coordinator Meghan; Mullon, Policy Analyst; Kaitlyn Peel, Digital Director; Tim Robinson, Chief Counsel; Chloe Rodriguez, Deputy Chief Clerk; Rebecca Tomilchik, Policy Analyst; Kimberlee Trzeciak, Chief Health Advisor; C.J. Young, Deputy Communications Director; Alec Aramanda, Minority Professional Staff Member, Health; Sarah Burke, Minority Deputy Staff Director; Grace Graham, Minority Chief Counsel, Health; Caleb Graff, Minority Deputy Chief Counsel, Health; Brittany Havens, Minority Professional Staff Member, O&I; Jack Heretik, Minority Press Secretary; Nate Hodson, Minority Staff Director; Peter Kielty, Minority General Counsel; Emily King, Minority Member Services Director; Bijan Koohmaraie, Minority Chief Counsel, O&I Chief Counsel; Clare Paoletta, Minority Policy Analyst, Health; Kristin Seum, Minority Counsel, Health; Kristen Shatynski, Minority Professional Staff Member, Health; Olivia Shields, Minority Communications Director; and Michael Taggart, Minority Policy Director.

*Ms. Eshoo. The Subcommittee on Health will now come to order. Due to COVID-19, today's hearing is being held remotely, and all members and witnesses will be participating via videoconferencing. As part of our hearing, microphones will be set on mute to eliminate background noise, and members and witnesses will need to unmute their microphone each time you wish to speak.

Documents for the record should be sent to Meghan Mullon at the email address we provided to your staff. All documents will be entered into the record at the conclusion of the hearing. The chair now recognizes herself for five minutes for opening statement.

A U.S. law prohibits Medicare from negotiating directly with drug companies. We are the only developed country in the world with such a law, and because of that, Americans are paying three to four times more for prescription drugs than other countries. We can change that, and if we do, we will not only save lives, we will prevent bankruptcies across the country.

In the absence of direct negotiation, American prescription drug prices have gone up year after year while large drug companies saw huge profit margins of about 20 percent on average. These price hikes have caused Americans to choose between buying their prescriptions and paying rent and buying food.

For example, one in four diabetes patients report rationing their insulin. Thirty percent of Americans have skipped a medication dose due to cost. The Council on Informed Drug Spending Analysis has estimated that by 2030, 1.1 million Americans will die prematurely due to high out-of-pocket drug costs.

Every member of this committee has heard from their constituents about high prescription drug costs. Today our subcommittee can help them by moving H.R. 3 forward, the Elijah E. Cummings Lower Drug Costs Now Act, obviously named after our beloved colleague.

H.R. 3 will finally give Medicare the power to negotiate lower drug prices for drugs that have no market competition, and extend those lower prices to all Americans. The legislation caps out-of-pocket spending on drugs at $2,000 for Medicare beneficiaries. Today, seniors can pay more than $50,000 a year for a single prescription drug. During our markup of H.R. 3 in 2019, I added a provision to the bill to cap how much seniors with high out-of-pocket costs pay per month to $250.

H.R. 3 will also stop drug price hikes like the ones we saw from EpiPen and Martin Shkreli. If a manufacturer raises the price of a drug, including generics, above the rate of inflation, then the manufacturer must pay the entire price above inflation back to the Treasury.

Nonpartisan analyses found H.R. 3 will reduce U.S. drug prices for negotiated drugs by 40 to 55 percent, on average; save the Federal Government and taxpayers $500 billion over ten years; save patients $158 billion in lower insurance premiums and out-of-pocket costs, and save private businesses $46 billion.

With these savings, we can make a major investment to kickstart drug research and development at the NIH, FDA, and the Advanced Research Projects Agency for Health, ARPA-H, which the President described in his address to Congress last week. These investments will support the development of innovate cures that will be available and affordable to all Americans.

This bill is popular, and it is bipartisan across the country. In an April poll, 93 percent of Americans support giving Medicare the power to negotiate with drug companies to lower prices. AARP, the American Hospital Association, the American Medical Association, the Purchaser Business Group, and the AFL-CIO all support H.R. 3.

A recent poll of executives from 300 large private employers found that 72 percent agree that a stronger Government role is needed to negotiate prices for high-cost drugs. This bill could be bipartisan. In Congress, there has been bipartisan support for the VA's direct negotiation authority for 30 years. Several provisions in H.R. 3 are

similar to the Senate's bipartisan bill from the last Congress. The last Republican President also supported negotiating drug prices, but didn't deliver on it.

I think it is time to live up to our promises to lower the cost of prescription drugs for all our constituents.

The chair now recognizes Mr. Guthrie, our wonderful ranking member of the subcommittee, for five minutes for his opening statement.

*Mr. Guthrie. Thank you, Madam Chair. Thank you for holding this important hearing.

I am very concerned about the consequences of Speaker Pelosi's partisan drug bill, H.R. 3, that is before us today. There is no doubt that Congress must do something to lower prescription drug prices. We know the American people want lower prices. But they do not want to sacrifice access to life-changing treatment. H.R. 19, the Lower Costs, More Cures Act, that I helped introduce, would lower prescription drug costs while protecting innovation for new cures.

We also know the American people do not want the Medicare taxes and premiums they pay diverted to liberal PET programs, which I am afraid is the direction H.R. 3 is headed. Speaker Pelosi's bill brings us one step closer to single payer health care systems. Supporters of single payer often cite health systems around the world as examples that the U.S. should follow. However, I believe single payer

systems are a very dangerous idea.

In the United States, we have access to cutting edge, innovative drugs and the brilliant scientists and companies who develop them. The key word here is "access.'' Under H.R. 3, we would be forced to sacrifice this access for bureaucracy and fewer cures. A partial estimate from the CBO said H.R. 3 will result in 15 fewer new drugs developed, and the White House Council of Economic Advisors under the previous administration estimated up to 100 fewer drugs.

Two years ago, when we first examined H.R. 3, one of our colleagues said in a hearing that he was willing to forfeit the CBO-estimated cures that would not be developed due to Government price setting. I challenge my colleagues: Would you still agree with this statement, knowing that one of those forfeitures could have been the COVID-19 vaccine?

Last week the White House announced that 100 million Americans, almost 40 percent of U.S. adults, have now been fully vaccinated against COVID-19, and 55 percent of U.S. adults have received at least their first shot. America is in a very different spot than our allies in Europe, who due to their single payer systems prioritized price over vaccine research and development and innovation.

Thanks to President Trump, America took a very different approach than our European allies. Through Operation Warp Speed, we partnered with private industry and invested in

research and development. We have the results to our approach to prove it: three safe, effective vaccines rolled out in record time.

These vaccines have allowed our country open and move forward. H.R. 3 disincentives research and development, and had it been in place last year, could have led to a worse outcome for all Americans in the fight against COVID and the race to a viable vaccine.

There are bipartisan solutions to lower drug prices, including H.R. 19, the Lower Costs, More Cures Act that will level the playing field for American consumers while still allowing for vital innovation that Americans depend on. Just last week, President Biden said in his joint address, and I quote, "Now, if Congress won't pass my plan, let's at last pass something we agree on.''

I think that is exactly what the American people want us to do. There is room for bipartisan action to lower costs. H.R. 19 is all bipartisan policies. And I am particularly interested in value-based agreements and Medicare Part D reform. These two areas have strong bipartisan support and would positively impact the lives of millions of Americans.

I would like to yield my remaining time to Dr. Burgess.

*Mr. Burgess. I thank the gentleman for yielding. Of course, we did have this debate in October of 2019. But so many of us know we serve in the people's House. In many

ways, this is the people's committee. And in this committee, we do have a history of working both sides of the dais together for things that are important to the American people.

So I certainly appreciate, Chairwoman Eshoo, that H.R. 19 has been included in the list of policies that we are discussing today because it does include bipartisan drug pricing policy solutions that, in fact, could be signed into law tomorrow. In fact, 17 policies from H.R. 19 from the last Congress have already been signed into law. And of course, there were several Democrats who voted for H.R. 19 on the House floor when it was proposed as an alternative to H.R. 3 in October of 2019.

H.R. 3 did not become law. It did not become law because it is a partisan exercise and will limit patient access to treatments and cures. Parts of H.R. 19 did become law because they were bipartisan and they do improve patient access.

Let's do what the President has suggested and pass what we can. And Representative Guthrie is exactly right in making that request. And I yield back to the gentleman.

*Ms. Eshoo. The gentleman yields back.

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

*The Chairman. Thank you, Chairwoman Eshoo, and thank you for this very important hearing. I really think that healthcare is still the number one priority for the American people, and within that context, lowering the costs of prescription drugs is the biggest priority.

So today we are considering H.R. 3, the Elijah Cummings Lower Drugs Costs Now Act and other legislation that will provide much-needed relief to Americans, who are fed up with the outrageously high prices of their prescription drugs. And I am pleased we are holding this hearing to highlight once again why we must act and why H.R. 3 is the comprehensive solution this country needs to fix our broken market for prescription drugs.

For too long, Americans have been forced to ration their medications, go without, or exhaust their life savings in order to afford the drugs they need, all while large pharmaceutical companies continue to make record profits. Americans pay three, four, or ten times the amount that people pay in other countries for the exact same drug. And how is that fair? It is not. In fact, it is outrageous, and it is long past time that we negotiate a better deal for Americans.

Now, H.R. 3 gives the Secretary of Health and Human Services the ability to negotiate lower drug prices directly with due diligence manufacturers on high cost prescription

drugs that don't have any competition. The Secretary negotiates lower prices will be available to all Americans with private insurance.

H.R. 3 also stops unfair and unjustified price increases by requiring drug manufacturers to pay a rebate if they increase prices faster than inflation. The bill also caps Part D out-of-pocket costs for Medicare beneficiaries they Hoch pay no more than $2,000 out of their own pockets a year for their prescription drugs.

H.R. 3 provides the reforms we need to lower the cost of prescription drugs and uses some of those savings to reinvest in efforts to find the next scientific breakthroughs at the National Institutes of Health, and improved drug review at the FDA.

And H.R. 3 will save consumers and taxpayers billions of dollars, and it will lower healthcare costs and premiums while also improving health outcomes. In fact, the Congressional Budget Office estimates that because H.R. 3 will reduce drug prices, the estimated cost of health insurance will also be reduced, leading to more take-home pay for workers. CBO also determined that the Medicare program will save $42 billion in other healthcare expenditures because beneficiaries will be healthier since they will be able to afford the medicines and take then as prescribed.

And H.R. 3 will have a tremendous impact on the lives of

everyday Americans, people like Therese Ball, who is going to testify before the committee today. Her experience, while unfortunately not unique, encapsulates so clearly why H.R. 3 must become law. The medication Therese relied on to treat her multiple sclerosis, as she will tell you, wiped out her savings. Eventually she was forced to stop taking this medication because of the cost, even though she knew she would face health repercussions as a result.

I just don't believe that any American should have to choose between paying for the prescription drugs they need to stay healthy and other basic necessities like food and rent. As President Biden noted last week during his joint address, it is long past time that Americans are no longer saddled with higher drug costs than people in other countries. It is long past time to negotiate lower prescription drug prices for the American people, and I look forward to moving H.R. 3 through the committee once again and for it to become law this year, as the President suggested.

In addition to negotiation and stopping the inflation of drug prices, we also know that competition is key to bringing down costs for Americans. In 2019 alone, patients and the healthcare system saved more than $300 billion due to generic and biosimilar competition. So today, we are also discussing several other bills that will increase competition.

And then we will hear from our witnesses today about

finding comprehensive solutions to high drug prices, and why that can no longer wait. So I am pleased that we are considering all these legislative proposals today. And I would like to yield now a minute to the gentleman from Oregon, Kurt Schrader.

*Mr. Schrader. Thank you very much, Chairman Pallone, for the time to speak today in favor of a couple of bills I have here before the committee. The BIOSIM Act is a common-sense approach to increase the utilization of biosimilars in this country. As we will hear today, biologic injectable drugs are very expensive. Increasing the use of generic biosimilar forms will decrease patient costs.

The BLOCKING Act is also a market-based reform to ensure generic competition in the drug marketplace to decrease costs to patients. In the current system, some generic manufacturers delay bringing their drugs to market by "parking'' their applications once being awarded exclusivity. Doing so blocks other generic drugs that are actually ready from coming to the market, and delays these less-expensive drugs from reaching our patients.

The rising cost of drug prices is deeply impacting all Americans. It is time to move forward with policies that have broad support. And I yield back.

*Ms. Eshoo. The gentleman yields back. I thank him for his work.

I would just add a source of pride to me is that I was the author of the biosimilars legislation. So thank you.

The chair now recognizes the ranking member of the full committee, Representative Kathy McMorris Rodgers, for your five minutes for an opening statement.

*Mrs. Rodgers. Thank you, Madam Chair, and to our witnesses for joining us today.

The story of American innovation is one that should be celebrated, bringing hope and early access to the most lifesaving, life-changing treatments in the world. In the case of Khrystal Davis, who will share her story today, it saved her son's life after doctors diagnosed him with spinal muscular atrophy with no chance of survival.

Khrystal and parents like her who have a child with a rare disease, they are fighting for the promise, for the next life-changing cure and treatment. I am certain that we have all heard stories before from caregivers and patient advocates like Khrystal. We have listened to people who want a fighting chance at life.

That fighting chance came with the American way, freedom and opportunity. Take Alzheimer's, for example. We need major breakthroughs to transform how we treat this disease and slow its progression. It would life one of today's biggest costs and care burdens on both families and our healthcare system. It is more than just hope. Whether it is

a rare disease like SMA, cancer, or Alzheimer's or another dementia, new cures and treatments are a very real possibility if we can protect and spur the private investment for more discoveries.

That brings me to Speaker Pelosi's Government price control scheme before us today. It is a false choice, forcing us to jeopardize cures and breakthroughs in the name of saving money. According to CBO experts and others of the Speaker's own colleagues, it would result in dozens of fewer cures.

Last Congress the White House Council of Economic Advisors said it would lead to as many as a hundred fewer drugs over the next decade. What could one of these cures or treatments mean? We don't know. But we know that if this becomes law, we would lose hope to cure cancer or treat generic conditions. We would become more reliant on China.

And then, if those discoveries are even made at all, we would be reliant on a federal bureaucrat, someone in Washington, D.C., to let us have it, like in Canada, the U.K., or other countries. The power would rest with the Federal Government to crudely measure lives and dollars and cents.

I just heard about a family in Canada. They have two boys, both with cystic fibrosis. Their 10-year-old has his medications. For their younger son, they are forced to

painfully beg the government for his treatment. At first the government just said no. Now they are being told their 8-year-old son must drop 20 percent of his long function within a six-month period.

The mom said he has to become really sick to qualify. She said, "I compare it to waiting for a person to go on a ventilator before you give them the COVID vaccine, or waiting for a person to reach stage 4 cancer before you treat them with chemo.'' There is nothing just about a system like this. It discriminates against people with disabilities and chronic illnesses.

The preexisting conditions -- those with preexisting conditions, the National Council on Disabilities has warned us about the approach that is laid out by Speaker Pelosi that is harmful. It is discriminatory. And it will be harmful on the most vulnerable.

Unfortunately, this is the socialist healthcare system and the future that Speaker Pelosi is imposing upon us. Instead of price controls, we should focus on areas for bipartisan worker. We agree seniors and patients are paying too much out of pocket. Let's address that.

We have seen the benefit of innovation in the fight against COVID-19. Now more than ever we should be working together on American solutions, uniquely American solutions that save lives, lower costs, and uphold the dignity and the

right of every person to live a full life. Energy and Commerce can lead the way. We have plowed the hard ground with the bipartisan proposals in the Lower Costs, More Cures Act to build unity, deliver result.

President Biden signed three of these provisions already into law this year. President Trump signed 16 into law last Congress. Let's not let Speaker Pelosi's Government price control scheme jeopardize the work to lower seniors' out-of-pocket costs. Let's do what is right for moms like Khrystal, representing millions of moms, not just for hope but for real lifesaving solutions, too.

And with that, I yield back.

*Ms. Eshoo. The gentlewoman yields back.

The chair reminds members that pursuant to committee rules, all members' written opening statements will be made part of the record.

I now would like to introduce our witnesses.

First, Ms. Therese Ball is a registered -- is a retired registered nurse from Ogden Dunes, Indiana. She is a multiple sclerosis patient and a Medicare beneficiary. Welcome, and thank you for testifying today.

Mr. Michael Carrier is a distinguished professor of law from Rutgers Law School. And we welcome you back to the subcommittee, Mr. Carrier. Thank you.

Dr. Gaurav Gupta is the founder of Ascendant BioCapital.

Welcome to the committee, and thank you for being with us.

Ms. Khrystal Davis is a rare disease caregiver, a patient advocate, and the founding President of the Texas Rare Alliance. Welcome and thank you to you.

And last but not least, Ms. Rachel Sachs. She is an associate professor of law at Washington University in St. Louis. And that is the school of law. Welcome to you, and thank you for being with us.

So Ms. Ball, you are recognized for five minutes. Please remember to unmute. And thank you again for being willing to testify before a subcommittee today.

STATEMENT OF THERESE BALL, PATIENT

*Ms. Ball. Chairwoman Eshoo, Ranking Member Guthrie, and members of the committee, thank you for the opportunity to share my story. My name is Therese Ball, and I am a proud grandmother and retired registered nurse from Ogden Dunes, Indiana. I am here as a person living with multiple sclerosis, a Medicare beneficiary, and a patient advocate.

I have dedicated my life to taking care of patients. Because of my nursing training, I have provided medical care and alleviated suffering for thousands of patients. But nursing school did not prepare me for the suffering I saw when my patients could not afford needed treatment.

I had a front row seat to the horrifying reality of our drug pricing system. Drugs don't work if people can't afford them. I never thought I would be one of those struggling patients until 2003, when I was diagnosed with MS and prescribed a medication called Copaxone. Let me tell you about Copaxone.

The drug came to market in 1997 at a price of $769 a month. Today that same monthly supply costs $7,114, almost ten times higher. The drug company that makes it, Teva, accomplished this by hiking the price 27 times over two decades. This pattern was not mirrored in other countries; by 2015, the price of Copaxone was, on average, five times

higher in the United States than in other comparable nations.

I faced these prices firsthand when I began taking Copaxone. It cost me $1800 a month. And within a year, it completely wiped out my savings. It was devastating. Fortunately, I was able to find a grant from an independent charity, but I lived in fear that might lose access.

That day came in 2017 when the foundation did not renew my grant. At that point, Copaxone had increased in price to $6,000 a month. I was completely overwhelmed by this price tag, and no matter how many times I crunched the numbers, I couldn't make it work. So I made the terrifying decision to go without the drug.

The health consequences were immediate and severe. I lost my memory, and my quality of life suffered tremendously. My family began making preparations for when I no longer would be able to walk or live independently. Eventually my doctor switched me to an infusion that I am fortunate to be able to afford through Medicare.

But MS is a progressive disease, and I know I will continue to need different and likely very expensive medications. And one day I hope there will be a cure for MS, which is why I understand the importance of innovation. Drug companies have taken this idea of innovation, this hope, and turned it into an ultimatum for patients.

They say we must let them charge whatever prices they

want or we can say farewell to future cures. But that is a false choice. Expert research has demonstrated that brand-name drug companies could lose $1 trillion in sales over ten years and still be the most profitable industry in the United States.

Drug companies spend billions each year on TV ads and lobbying. They can more than afford to cut prices while maintaining their investment in research and development. We do not have to settle for a false choice. We can have more affordable drugs and meaningful innovation at the same time.

Affordable drugs are more important now than ever. The COVID-19 pandemic has not just devastated the financial well-being of millions of people; it also continues to increase the number of people with chronic disease who will now rely on expensive medications. I know this because last year I had COVID-19. The infection was so destructive to my lung tissues that now I have to take an expensive inhaler called Breo, adding to my already steep monthly drug cost.

Members of the committee, today you are considering a bill called H.R. 3. This bill would end the ban on Medicare negotiation and help beneficiaries like me by instituting a cap on what we pay out of pocket. In addition, the lower prices achieved through negotiation would be extended to everyone, regardless of what insurance they have.

Today you have an opportunity to bring relief to me and

millions of other Americans struggling to afford our needed medications. As you consider this legislation, please remember our stories. I can't control my disease or change that I have MS. But telling you my story and advocating for lower drug prices is something I can control. Thank you, and I urge you to vote in support of H.R. 3. Patients have waited long enough.

[The prepared statement of Ms. Ball follows:]

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

*Ms. Eshoo. Thank you, Ms. Ball, for being with us to tell your story.

Mr. Carrier, thank you again for being with us. You are now recognized for your five minutes of testimony.

STATEMENT OF MICHAEL A. CARRIER, DISTINGUISHED PROFESSOR OF LAW, RUTGERS LAW SCHOOL

*Mr. Carrier. Great. Thank you so much, Chairwoman Eshoo, Ranking Member Guthrie, members of this subcommittee.

Drug prices are too high, and one main reason why is that brand companies play all sorts of games to delay generic entry. Today I am going to focus my comments on two: pay-for-delay statements, and citizen petitions. This conduct makes no sense at all other than harming the generic, and if there were legislation that would pass, it would not affect innovation at all, but it would make consumers' lives better.

My name is Michael Carrier. I am a distinguished professor at Rutgers Law School, where I focus on the intersection of antitrust and intellectual property. Co-author of the leading treatise in the field on antitrust and IP. I have written 130 articles on this, and I have frequently filed briefs with courts.

So the first type of conduct that this subcommittee can address is pay-for-delay settlements. Sometimes a brand company pays a generic to stay off the market. Now, in 2013 the Supreme Court, in a case called FTC v. Actavis, said that these settlements could have anticompetitive effects and could violate the antitrust laws.

So after that decision, we saw that the number of pay-

for-delay settlements went down. But there still are pay-for-delay settlements, and the parties still have every interest to muddy the waters, to raise arguments that were rejected in Actavis, and to try to continue to engage in these settlements.

And so the legislation at issue here, H.R. 153 and H.R. 19, would address these real problems. First, it would allow the FTC to bring these cases in court. It is very hard, when the brand companies pay the generic not in cash but in these increasingly complicated deals, for the FTC to figure that all out. So this takes years and years and costs millions of dollars in litigation. And so first, in order to give the FTC a chance to win this stuff in court before a decade or two goes by, the legislation would be incredibly helpful.

And second, the legislation would fix some of these judicial mistakes. Sometimes courts don't apply Actavis the way that they were supposed to. Sometimes they fail to recognize payment. And sometimes they say that entry before the end of the patent term is automatically okay, even though the Supreme Court explicitly rejected that argument in Actavis. And so the second reason why settlement legislation is so important is to fix some of these mistakes in the court.

So at the end of the day, I am a big supporter

of H.R. 153 and H.R. 19, which would make patients' lives better without touching innovation.

Second, I would like to talk about citizen petitions. Citizen petitions are designed to raise legitimate safety concerns with the FDA, but in reviewing every petition filed between 2001 and 2015, I found that most of these petitions actually are filed just to delay the generic. And the FDA actually denies most of these, 92 percent of them, 98 percent at the last minute. These petitions are filed just to delay generic competition.

So what can this committee do? H.R. 2387, the STOP GAMES Act of 2019, would provide at least four benefits in stopping these frivolous citizen petitions:

First, it would make sure that the FDA has a summary disposition power to get rid of these frivolous petitions without spending so much time on them. Technically they have the power right now, but it is so difficult to satisfy that the FDA has never used the power at all. And so opening that up, as this legislation does, would be an excellent start.

Second, it sheds light on what a primary purpose of delay is. When you look at all these petitions and you see the recurring themes of delay petitions and repetitive petitions and ones filed at the last minute, you see a bunch of themes. And so if you take all of those facts and weave them into the primary purpose of delay, then that helps all

parties in stopping this conduct.

Third there is a time limit. You can't find out about this petition and then wait for five years, as Mylan did with an EpiPen citizen petition. You have to file it within a finite period of time.

And fourth, there is more information that the FDA needs to provide to Congress. So when you think about the fact that we don't know, the petitions that are filed, how much delay actually happens from these petitions. More information into this flat box will be incredibly helpful.

So at the end of the day, the legislation on pay-for-delay settlements and citizen petitions would not touch innovation in the slightest, but it would make consumers' lives better. Thank you very much.

[The prepared statement of Mr. Carrier follows:]

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

*Ms. Eshoo. Thank you, Mr. Carrier.

The chair is now pleased to recognize Dr. Gupta. Thank you for being with us. You are now recognized for your five minutes for your testimony.

STATEMENT OF DR. GAURAV GUPTA, FOUNDER, ASCENDENT BIOCAPITAL

*Dr. Gupta. Chairwoman Eshoo, Ranking Member Guthrie, and members of the committee, thank you for the opportunity to testify today on H.R. 3 and the deleterious effect it would have on biopharma innovation and on patients.

Let there be no doubt that we are living at the dawn of a golden age of therapeutic innovation. The first FDA approvals of oligonucleotide, bi-specific, oncolytic virus, CAR-T and AAV and lentiviral gene therapy, all took place within the last decade.

Novel small molecule drugs have cured thousands of Americans of hepatitis C, added decades to the lifespan of patients with cystic fibrosis, and positively impacted the lives of patients with sickle cell disease, while immunotherapies have transformed the lives of patients with cancer. Promising technology such as targeted protein degradation and gene editing are perhaps not far behind. Future rewards will be greater still if we preserve our current system of incentivizing innovation.

America is the global epicenter of accelerated drug development. Fifty-seven percent of all new medicines are invented by U.S. companies. The bulk of the remainder are developed by foreign companies in and for the U.S. market. An indirect benefit of this is that most novel therapeutics

undergo clinical development and early commercial launch here in the U.S. The rest of the world understands that the American patient has earlier and broader access to groundbreaking third parties via these mechanisms.

The scientific literature is unequivocal about the improved health outcomes generated from pharmaceutical purchasing. The 1.4 percent of GDP we currently spend on branded medications incentivizes future research and development and ensures that the global center of gravity, where our citizens can enjoy the fruits of early access. On top of that, the biopharma industry's economic output in 2017 was estimated at $1.1 trillion, and the sector employed over 800,000 workers, one-third in key STEM occupations.

It is undeniable that tour healthcare system does not equally distribute innovations, with high out-of-pocket costs presenting barriers to medication access for many Americans. Insurance companies, pharmacies, and pharmacy benefit managers, PBMS, all sit between the medication and the patient who needs it. An incredibly confusing system of discounts and rebates obscures how much money goes to manufacturers and how much goes to middlemen.

Actions to improve access to medications and reduce out-of-pocket costs for patients are long-overdue. We can achieve these goals while preserving America's unique capacity for innovation.

I would like to contextualize pharmaceutical spending to other cost drivers in the healthcare system. The growth in overall national health expenditure is predominately attributed to hospital spending. Branded drugs account for only 8 percent of the total. Our expenditure on prescription drugs encompasses not only what is paid to pharma companies but also what is paid out of the system to middlemen.

I would submit to the committee that a good-faith effort to meaningfully curb healthcare spending demands addressing both the largest drivers, hospitals, and hidden costs, the prescription drug middlemen.

In the context of prescription drugs, the very existence of out-of-pocket costs doesn't make sense. No patient gets a medication without a doctor prescribing it, and often insurance pans require that the doctor seek explicit prior authorization. It doesn't follow that insurance companies haven't agreed that a patient needs a particular medicine based on FDA labeling for that product, then ask a patient to put skin in the game by paying a portion of the cost. They have skin in the game, their disease.

Insurance reforms that tap or even eliminate out-of-pocket costs, not just in Medicare Part D but also for Americans who receive coverage from their employers, through healthcare exchanges, and other types of health plans, would be a high impact step toward ensuring broad access.

The critical flaw of H.R. 3 is that it conflates drug prices and patient out-of-pocket costs. Importing foreign pricing would only marginally reduce what patients with high deductible plans, including Medicare, are forced to pay. It wouldn't solve their problem; what it would do is dramatically underline the ability of American biotech companies to develop innovative medicines that could treat and cure innumerable diseases in the future.

I would like to conclude with a point about American competitiveness. The ability for parts of today's hearing to take place in person was made possible by the whirlwind development of vaccines and monoclonal antibodies for COVID-19, and this innovation capacity out to be a source of national pride.

My perception as a biotechnology professional is that other countries are eager to siphon our pharmaceutical prowess, particularly China, which has made biotech a strategic pillar. In 2016, the market capitalization of all Chinese biopharma companies was $1 billion. Only five years later, the combined market capital of Chinese biopharma companies is north of $20 billion. In 2019, for the first time ever, a drug developed in China was approved by the U.S. FDA.

When I speak to Chinese biotechnology executives and Chinese physicians, they boast that they can run clinical

trials faster than their U.S. counterparts. The danger of H.R. 3 is that it will effectively drive biotech innovation to China. If we close up the market in the U.S. while China is opening their market to innovative new products, we will see companies launching impactful, novel medicines in China based on critical trials conducted in China.

In order for patients to be able to buy American, we have to protect America's capacity to be a home for innovation. Let's continue to nurture this important work on our soil. Thank you.

[The prepared statement of Dr. Gupta follows:]

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

*Ms. Eshoo. The gentleman yields back, and we thank you for your testimony.

The chair now recognizes Ms. Davis for your five minutes of testimony, and we thank you again for being with us.

STATEMENT OF KHRYSTAL K. DAVIS, RARE DISEASE CAREGIVER AND PATIENT ADVOCATE, TEXAS RARE ALLIANCE FOUNDING PRESIDENT

*Ms. Davis. Chairwoman Eshoo, Ranking Member Guthrie, and distinguished members, I am privileged to be here today as a rare disease parent, caregiver, and patient advocate to share my perspective and represent the 1 in 10 Americans affected by more than 7,000 rare diseases.

I founded Texas Rare Alliance to improve access and health outcomes for nearly 3 million Texas rare disease patients. That is a large number, and it is correct. More Americans have a rare disease than HIV, heart disease, or stroke, combined, and 95 percent of rare diseases lack an approved treatment. We know what happens to patients in other countries referenced by H.R. 3. They get worse access to treatments because the lives of people with rare diseases and disabled people are undervalued.

In 2011, our newborn son lost nearly all movement at two weeks of age. At one point, my husband asked if I had shaken Hunter. I could never hurt out baby, but he was hurting. When doctors diagnosed our newborn with SMA, our world changed forever.

SMA is like ALS in babies. It robs the ability to move, swallow, and ultimately, breathe, and is the number one genetic cause of death for infants. Doctors told us there

was no treatment and no hope, but we couldn't afford to listen. The stakes were too high.

With the help of a researcher, we manufactured a compound in the U.S. and took it to Mexico for a trial. Eight weeks after his diagnosis, Hunter was the first SMA patient to receive a lifesaving treatment. Nearly five years later, Hunter and his friend Ben started the Spinraza expanded access program together. Soon after, the FDA approved Spinraza, the first SMA treatment.

Upon FDA approval, insurers developed policies for Spinraza. Both Hunter and Ben were insured by United. Hunter met the Spinraza inclusion criteria. However, Ben failed to meet it because he depends on a machine to breathe for him. Ben's mom, Melissa, and I cried. She asked why Ben wasn't worth saving, too. Ben was worth saving, but I couldn't change the policy.

Biogen covered Ben in a patient assistance program until he secured a Medicaid waiver, providing Spinraza. ICER evaluated Spinraza, scoring SMA patients a .2, determining its cost was not effective. We are already advocating against the use of ICER's QALYs. Adopting reference pricing that incorporates discriminatory qualities undermines our advocacy efforts.

We know CBO scored H.R. 3 assuming the use of QALYs to set prices relied on by foreign countries. The NCD shared

their concerns with the committee on H.R. 3 and its implications for discrimination. At one point during the pandemic, we moved back to our St. Louis home after learning of QALY-based medical rational in Austin. We knew St. Louis Children's Hospital valued Hunter and worked to save his life many times.

This should provide some context for why I oppose H.R. 3. The burden studied by the EveryLife Foundation found indirect and non-medical costs accounted for nearly 60 percent of overall costs to rare disease families, with prescription medications accounting for only ten percent. We can expect to address affordability if we are focusing on such a small percentage of the problem.

Rare disease parents work hard to keep our children alive. We become medical experts, providing standard of care at home exceeding care at hospitals. That is not a smug statement. When our children are in the hospital, we don't leave their side. We know the standard of care for their rare disease, and we know if the hospital follows the protocol for a child with typical health, our children would be harmed and might not survive.

We manage machines that feed, breathe for, or monitor our babies and children. We give them medicine and do their treatments. We don't get time off because the rare diseases our children fight against never take time off. Doctors tell

us there is no hope, but we have more than hope. We have unconditional love for our children, and we refuse to give up on them. We value every breath they take and we dare not take a single breath for granted.

H.R. 3 would also greatly reduce research and development of rare disease treatments. We don't see approvals coming from those countries. They are innovation deserts, a cruel place when you need innovative treatments to survive.

Research and development are the stuff dreams are made of. We hold bake sales, runs, parties, and pretty much anything we can think of to fund research. The thing is, our funds only get researchers so far. Without follow-on funding from the NIH, biotech companies, or biopharmaceutical companies, the research stalls.

At the current pace, it will take thousands of years to secure treatments for all rare diseases. Meanwhile, a third of children with rare disease will not survive to their fifth birthday. Research for rare diseases can move with the same relentless urgency as COVID-19 research. We must respect and value the lives of medically fragile, disabled, and elderly individuals.

We cannot afford to stop opposing H.R. 3. We refuse to save our children, only to have a system adopt qualities that give up on them. Thank you.

[The prepared statement of Ms. Davis follows:]

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

*Ms. Eshoo. Thank you very much, Ms. Davis.

The chair now recognizes Ms. Sachs for your five minutes for testimony. And thank you again for being with us.

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

*Ms. Sachs. Thank you. Chairwoman Eshoo, Ranking Member Guthrie, and other distinguished members of the Health Subcommittee of the House Committee on Energy and Commerce, 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 to testify before you today about the high prices of prescription drugs, and how this committee might help solve these problems. My testimony will explain why comprehensive prescription drug pricing reform should include three types of policy solutions.

First, reform should lower patients' out-of-pocket costs. Second, reform so fix misaligned incentives and our existing pharmaceutical pricing system. And third, reform should address the underlying problem of high drug prices.

There is no single way to accomplish each of these three goals, and different countries have chosen different answers to each of them. But H.R. 3 pulls all three of these policy levers to lower drug prices. Other congressional proposals do not.

Today, prescription drug prices in the United States are high and rising. Individual drug prices are rising. Between

2018 and 2019, pharmaceutical companies raised their list prices on half of all Part D drugs faster than inflation. System-wide spending is also rising. Between 2007 and 2017, Part D spending rose from 46.2- to $79.9 billion. Part B spending rose from $15.4 billion in 2009 to $35 billion in 2018.

These dynamics create challenges for patients. About one in four people report difficulty affording their medication, and they may respond by rationing their medication or by delaying filling prescriptions. Patients have died as a result of these impossible choices. A large bipartisan majority of Americans believe that prescription drug costs are unreasonable.

This committee has an important role to play in responding to the problem of high prescription drug prices in three key areas. First, limiting patients' out-of-pocket costs is necessary to relieve the financial pressures facing many patients. Today there is no cap on Medicare Part D beneficiaries' out-of-pocket costs, and 1.1 million Part D beneficiaries have out-of-pocket spending above the catastrophic threshold. H.R. 3 addresses this problem by imposing a cap on Part D out-of-pocket costs.

This committee might also consider additional policy reforms to accomplish this goal. For instance, as the National Academy has recommended, Congress might authorize

CMS to limited patients cost-sharing for classes of drugs or treatment adherence to reduce total case costs.

Proposals in this category would help millions of patients who have difficulty affording their medication. But lower patients out-of-pocket costs in isolation could even increase financial burdens on other patients and on Medicare. So these reforms ought to be paired with others which would directly address prescription drug prices.

Second, our existing system for paying for prescription drugs waives incentives for actors to drive prices up rather than down over time. H.R. 3 identifies includes two key elements to fix these misaligned incentives. It requires drug manufacturers who raise the prices of their drugs more rapidly than inflation to pay rebates back to Medicare, as Medicaid already requires. And its Part D benefit redesign gives both manufacturers and Part D plans greater incentives to manage price and formulary designs. There are many other examples of incentives this committee should consider addressing, including some of the often criticized business practices of pharmacy benefit managers.

These attempts to address misaligned incentives are important, but they would not fundamentally address the underlying high prices of these drugs, either. So third and finally, this committee should consider reforms that would strengthen Medicare's negotiating authority and increase the

likelihood that our because payers can obtain fair prices for these products.

H.R. 3 addresses this issue by providing the Secretary of HHS the authority to negotiate with the manufacturers of select high-priced charges. To facilitate this negotiation, H.R. 3 uses international reference pricing, creating an average international market price across six countries as the basis for targeted fair price negotiations.

There are many different ways of constructing an effective drug price negotiation system, and H.R. 3 offers just one potential example. Several of the countries included in H.R. 3's market basket provide examples of this and other approaches.

This committee has the ability to help solve the problem of high drug prices not only for patients but also for our public payers. Chairwoman Eshoo, Ranking Member Guthrie, members of the committee, I am appreciative of your focus on this important issue, and I look forward to answering your questions.

[The prepared statement of Ms. Sachs follows:]

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

*Ms. Eshoo. Thank you very much for your testimony. And now we are going to move to member questions, and I will recognize myself for five minutes for mine.

First, to Ms. Ball, thank you for being willing to share your story. It is a very powerful one, as well as your work as a registered nurse. In your testimony you said that the MS drug, Copaxone, went from costing you $1800 a month to $6,000 a month.

*Ms. Ball. Yes.

*Ms. Eshoo. Was there any innovation that changed that drug between 2003 and 2017 to account for the price change?

*Ms. Ball. No. Actually, there was no innovation. What had happened was they raised the price 27 times. But what they did was they had a new one brought out in 2014. So usually with Copaxone you do seven injections, right, one a day. They brought a new one out was the 40 milligram, and what it did was it made it easier. You only did it three times a day [sic].

*Ms. Eshoo. I see.

*Ms. Ball. So it became the positions and to the evidence.

*Ms. Eshoo. Right. Excuse me. Were there other countries that saw comparable price hikes to that drug during that time? Do you know?

*Ms. Ball. Yes. But they pay less than we do, even

with that, because they negotiate o their drugs.

*Ms. Eshoo. I see. Is Copaxone your only option? Does it have any market competition?

*Ms. Ball. It really doesn't. The only thing it had was is that when it came up to do the 40 milligrams, they were starting to lose their abilities to patent it and everything. So that is why they redid it. It did not change anything.

*Ms. Eshoo. I see.

*Ms. Ball. There is no evidence that it improved. And it also --

*Ms. Eshoo. Okay. Thank you.

Dr. Gupta, thank you again for being with us today. I would look to ask you the following question. You have heard Ms. Ball's story. It is a powerful one. It covers a range of issues relative to pricing, a drug that has no competition, the price hikes over X number of years and how that has impacted her life. It is a story of many people in our country.

Specifically, what can you say to her? I mean, you hold your view, which I respect. But what would you say to Ms. Ball? What do you have to offer to her?

*Dr. Gupta. Thank you, Congresswoman. And Ms. Ball, I was moved by your story, of course. I would -- I am a physician as well as a biotechnology investor, and I can

assure you that having moved over to the biotechnology industry, I am impressed every day with the passion and tenacity of the folks in our industry, and their commitment to patients first and foremost.

And at the core or everything we do, we know patients are waiting. And that is why it is frustrating when patients don't have access to drugs. And Ms. Ball, from my understanding, the out-of-pocket costs were particularly a barrier for you, and I think that from our perspective, we agree there.

I mean, we -- the data is unequivocal. Just a $10 increase in out-of-pocket costs by insurers has been shown to increase mortality by 33 percent for some points. And these are easy fixes. And I would say that we can find common ground and make it easier to access medications for all patients.

*Ms. Eshoo. Okay. We all have limited time, and I appreciate your directing some of your comments to her.

To Ms. Sachs, as a lawyer, are there any provisions in H.R. 3 that would keep Medicare from continuing to cover all the drugs that it does today? And are there any provisions, in your view, in H.R. 3 that would limit patient choices?

*Ms. Sachs. Thank you for the question. This is such an important one. And as you know, access is at the heart of H.R. 3. By making it easier for patients to afford their

medications, it would increase access to them. And nothing in H.R. 3 disrupts any of Medicare's requirements to cover drugs, including any of its protected classes.

I also want to make a very brief clarification about what we mean when we talk about access. What we mean is that a pharmaceutical company would rather pull their drug from the American market than charge us the same prices, or even a premium, that they are already charging in other countries, and at which we know they make a profit.

So when we talk about access, we are talking about choices that the pharmaceutical company is making, not Medicare.

*Ms. Eshoo. Thank you. I think my time has just about expired. And a reminder to all of the witnesses, that members will have the opportunity to submit questions to each one of you, written questions, and we ask that you respond and answer them in a reasonable time frame.

So the chair will now recognize -- let's see. I think that I am going to recognize, per our agreement, Mr. Guthrie, to recognize Mr. McKinley. And welcome to the subcommittee, Mr. McKinley, and you have five minutes to ask your questions. And we hope and pray that your wife's surgery -- that is my understanding -- goes well.

*Mr. McKinley. Thank you. Thank you, and thank you for this chance for you give me the chance to get back to the

hospital to be with her.

*Ms. Eshoo. Certainly.

*Mr. McKinley. And for Ranking Guthrie, I appreciate it.

Look. We all know there is a need for drug pricing reform. I don't think there is any one of us who would be arguing against that. But pursuing this highly partisan H.R. 3 is just an example of overreach, unfortunate overreach, that occurs too often in Washington, and it gets in the way.

All the observers that I have read about in Washington in the press are saying that H.R. 3 is not going to pass the Senate. So I have got to say, fundamentally, why are we doing this? Why aren't we working together to try to pass something that can be signed into law?

So there are bipartisan solutions that were included in H.R. 19. So unless we change the course of this projection of this legislation, we know how the story is going to pan out. We have seen it before in immigration. We are about to see it in the infrastructure bill again, overreach on that, and we are seeing it now in this drug pricing.

These are all bipartisan issues that we would all work together on if we focus on what we need to get done, focus on those. But that is not what is happening with this. Look. We were here to get solutions to it, and I really want to get

to it.

H.R. 3, unfortunately, is an overreach, and unfortunately, it gives me the impression, for those in the package, that Congress is seemingly willing to let American patients suffer. This is a high stakes political game we are in here right now, and if the Senate doesn't pass it and it doesn't get to the President's desk for signature, the American public is going to suffer.

I think they deserve better. H.R. 19 includes caps for insulin deductibles. It passes on rebates directly to State Medicaid programs, ensuring that PBMs do not profit off Government programs. And it makes it unlawful for pay-for-delay practices whereby drug companies enter agreements with generics and biosimilar manufacturers to delay a competing drug coming to market.

These are all obvious. These are just a sampling of the 40 bipartisan bills that we already passed out of our committee. So we know the loser here is going to be the American public if we don't get a bill to the President's desk for signature.

So I would add, with -- my question is now: We know that utilizing generic medications is one of the best ways to lower drug pricing. But PBMs and Part D plans are not covering generics. And this practice costs seniors $4 billion, insurance costs, $4 billion annually.

So Ms. Sachs, in your testimony you discuss some of these issues about the formulary designed in Part D. The current system incentivizes -- places an entire cost, drug brand prices, over generics. And in the bill that I am working with Kuster about, 2846, addresses this issue by ensuring it would lower the price.

Can you speak more to this issue of formulary design and how the current trend is leading to increased cost for patients rather than lowering?

*Ms. Sachs. Yes, absolutely. So without going too far into the details of the Part D benefit design, as this committee is well aware, the current incentives unfortunately may lead both manufacturers and PBMs and plans to increase or drive up prices over time rather than to reduce them.

And so the Part D redesign elements in H.R. 3 and also in H.R. 19 are important for minimizing some of those incentivize. However, they only work where there are generic or biosimilar opportunities available for patients. And in many of these cases, there are not.

So in my testimony, I also give the example of a drug like Humira, which was first approved in 2002, and has lively biosimilar competition in Europe but where we still have no competition today, and won't for another two years. Yet it is one of the top ten-selling drugs in Part D . The idea that we would negotiate the price of a drug like Humira and

be able to obtain better prices for partners and our payers is at the heart of H.R. 3, but it is not part of H.R. 19.

*Mr. McKinley. If I could, I want to ask a last question to Dr. Gupta because the United States, we are still -- across the country still experiencing a wave of drug overdoses at a higher rate than we have ever seen before. So my question, Dr. Gupta: How would H.R. 3 affect the price and discovery or new non-addictive pain medication and treatment, medically assisted treatments? How would H.R. 3 affect that? Can you share some of your thoughts?

*Dr. Gupta. Thank you, Congressman. Yes. So I think the need for developing non-opiate, non-addicting pain medications is one that the entire biopharma industry is working hard to tackle. We are aware of both the need for treating pain but also the need of creating alternatives to opiates.

It is early stages still. There are several things in development that we don't know if they are going to work yet. And I would caution that price controls -- which, by the way, don't ensure that we will be passing savings directly on to patients -- would really put a lot of that work on risk.

*Mr. McKinley. Okay. Thank you. My time is expired. And I just want to say Anna and Brett, thank you. I want to be with my wife. So God bless.

*Ms. Eshoo. And we want you to, Mr. McKinley. I will

keep her in my prayers. Thank you. Godspeed.

*Mr. McKinley. Thank you.

*Ms. Eshoo. The chair now recognizes the chairman of the full committee, Mr. Pallone, for your five minutes of questions.

*The Chairman. Thank you, Chairwoman Eshoo.

I am going to get right to a question to Ms. Ball, and then I am going to try to get a few in to Professor Sachs. I am trying to ask you if you can limit your remarks.

Ms. Ball, can you tell this committee, in your words, why Congress must take action to give Medicare the power to negotiate drug prices, and why this task is so urgent, and how it will make an impact on the lives of individuals like yourselves who are struggling with the high cost of prescription drugs?

*Ms. Ball. Yes. Thank you for asking. The question you have asked is how it would help me. It would help me because when you lower the price of the drugs, then it is more affordable to people and they will be able to get the drugs with the H.R. 3 that not only takes care of lowering the drug prices -- it is most important because even though the cap is at $2,000, right now our Part D drug is $15,000.

So if we can do both, reduce the medication prices and also maintain the cap, it is going to help us 100 percent. There are too many people going without because of the fact

that it is so expensive.

*The Chairman. Thank you. Now, I think we all recognize that we must act, and we have to acknowledge it all. But we should also acknowledge that not all drug pricing legislation is the same, and not all policies are equally effective. There are a number of proposals we are considering today that do not include the goal of negotiating prices or the inflation rebate that is in H.R. 3. And I strongly believe that we need to act immediately on H.R. 3 because it offers a comprehensive approach.

So let me go to Professor Sachs. Three questions. As you briefly mention in your testimony, can you discuss why reforming the Part D benefit and capping out-of-pocket costs in Part D, while critical in other policies, on its own is not sufficient to actually reduce prices?

*Ms. Sachs. Yes. So although capping out-of-pocket costs is important to help patients, it doesn't actually lower prices or spending. It just moves money around in the system. MedPAC projected that lowering patients' out-of-pocket costs could even increase overall premiums a little bit and increase Medicare spending as a subsidy for those premiums.

So although it is important to reduce out-of-pocket costs, that needs to be coupled with other reforms, which would directly address those high prices.

*The Chairman. And can you explain how the different titles of H.R. 3 work in tandem, and why, in order to effectively lower prices, we have to use more than one approach to deliver real savings?

*Ms. Sachs. Yes. The restructuring of the Part D benefit is critical. It helps seniors afford the costs of their prescription drugs. And because it just moves money around in the system, the other titles are also important.

So the inhalation area rebate provisions as a floor of H.R. 3 extend to Medicare a strategy that has worked well in Medicaid to control price increases in that program, and should discourage companies from raising the prices of their drugs as we have heard ago what Copaxone.

But even that won't fundamentally address the underlying high prices of these drugs or the Government's lack of negotiating leverage. And that is where the negotiation element of H.R. 3 comes in. So particularly for specialty drugs with little or no competition, H.R. 3 strengthens Medicare's negotiating authority and enables our public payers to obtain more fair prices for these products.

*The Chairman. And then lastly, my understanding is that H.R. 19 -- this is the Republican alternative that we are considering today -- does not establish a negotiation framework, nor does it contain the inflation rebate provisions that are included in H.R. 3.

Given that, is H.R. 19 effective at reducing drug prices? And if not, why not

*Ms. Sachs. That is a correct description of H.R. 19 precisely because H.R. 19 is censored around only the restructuring of the Part D benefit. It is unlikely to save our system very much money. So it would certainly help seniors with their out-of-pocket costs, but it has no answer for the company who raises the prices of Copaxone, I believe we heard, 27 times in a decade, from 700 to 7,000.

That would not be addressed in something like H.R. 19, and it might even increase premiums for seniors and Government spending overall.

*The Chairman. All right. Thank you very much.

Thank you, Madam Chair.

*Ms. Eshoo. The gentleman yields back.

It is a pleasure to recognize the ranking member of our subcommittee, Mr. Guthrie, for your five minutes of questions.

*Mr. Guthrie. Thank you, Madam Chair. I really appreciate it. And this is a very valuable hearing. I think we are seeing this a lot, and we agree on -- I agree with a lot of what Professor -- almost all of what Professor Carrier said, a lot of what Professor Sachs has said.

We want to put together real answers, and it maybe an answer to the President's call. Let's pass what we can agree

on. And I will agree with what Ms. Ball said. I think Chair DeGette and I, we were in the -- when I was in O&I, we looked at it when we have long-existing therapeutics that increase faster than inflation. And that is something I think we need to look at, why that is moving forward.

And I think the number one is to get competitors into the marketplace. And as a matter of fact, last week, I think, Representative Schrader was in the Oval Office. I was in Kentucky getting a bill signed about dealing with patents and the way that people gain patents.

So there are ways to move forward with this. We know we are talking about negotiation, and the way this bill is structured is more price-setting. That is our concern, not just negotiating. It is a way the price-setting mechanism looks forward. And I think it was quoted that 93 percent of the people support negotiating, or essentially lower drug prices.

But I have seen similar polling just saying, if you ask at the expense of access to lifesaving therapeutics, that drops. And I can't imagine what it would be if savings in Medicare would be used as a pay-for for some other type of issues.

But the assumption in H.R. 3 to me is that you can change -- this is -- I want to get to Dr. Gupta -- you can change how you pay for a product without changing what you

receive and what you get. And that is the concern in all -- President Biden in the joint session kept talking about foreign payments and the way foreign payment drugs are moving forward.

I think COVID-19 is a good example for Dr. Gupta. The COVID -- Europe decided they want to negotiate for a COVID vaccine up front, before -- and we went the opposite. We said, we are going to invest in pharmaceutical companies working together to bring a vaccine forward. And we know the results. Europe is currently -- unfortunately, very unfortunately for our allies, in a lockdown, where we are -- in Kentucky you do get one today if you wanted a vaccine.

So Mr. Gupta, would you talk about what Europe did and how that is an example of what H.R. 3 -- if we are going to import European-style drug pricing, how that could change the results we get?

*Dr. Gupta. Absolutely. Thank you, Congressman. So we see on our side is that other countries seem to be willing to deny [audio drop] particularly acute in the setting of -- as illustrated by COVID vaccines, but also as we see routinely with cancer medications, where there are significant delays that sometimes border on years to deliver groundbreaking cancer medications to patients, in an even more extreme example.

And I think those are also examples we so look at as the

kind of risk that would be entailed here if we were to have price controls as per H.R. 3.

*Mr. Guthrie. Priced the way they price, in my opinion, without having the results that they receive. Dr. Deeks, in our long-haul COVID hearing -- and I will quote him -- he talked about how we are going to have innovative therapies for long COVID. And he said, "Developing therapies will not happen unless we somehow find a way to incentivize our partners in the pharmaceutical industry.''

And so what -- we are looking for innovative therapies. And we need to deal with situations like Ms. Ball, absolutely. But we don't need to affect the young children with SMA. And that is what we -- we want to move forward.

Also, Dr. Gupta, I want to touch on value-based agreements. These are Deems things that a new reimbursement method, where manufacturers are paid if their drug works, and if it doesn't work as intended, they will return payments via refunds or rebates. Representative Schrader and Representative Mullin and I are working on the bill for these two arrangements.

Could you talk about value-based agreements and how that could affect drug pricing?

*Dr. Gupta. Yes. Thank you. I think that is a promising avenue [audio drop] and medicine basis, which is to say sort of a voluntary basis. I think it makes sense for

companies to put together those kinds of credit-price proposals. And I think we should explore the better understanding of the potential impact, and how this could improve access.

*Mr. Guthrie. I am a big believer in the Medicare Part D, that we do need get smoothing so people don't have to pay everything up front in January when their new deductible moves forward, and also out-of-pocket expenses. If you are just subsidizing a rising drug price marketplace, it does change -- moves money around, as Dr. Sachs said.

So I think we need to do work to do patent reform, as Representative Schrader and I have worked on already to make sure that we get competition into the marketplace as soon as -- protect patents for innovation, but bring competition as soon as possible.

And Madam Chair, my time is expired. Thank you for having this hearing.

*Ms. Eshoo. The gentleman yields back.

The chair is pleased to recognize at the gentleman from North Carolina, Mr. Butterfield, for your five minutes of questions.

*Mr. Butterfield. Thank you, Madam Chair, and good morning to you. It is still morning here on the East Coast no, it is not. No, it is not. It is after 12:00 noon. But thank you. It is still morning on the West Coast.

*Ms. Eshoo. Right.

*Mr. Butterfield. But we have passed that noon mark here in Washington. But thank you for convening this most important hearing today.

You know, Madam Chair, we have talked about drug pricing on this committee now for years, and it is time for action. I could guarantee passage if my Republican friends would just work with us, not just throw one-liners at us but just work with us. We can get this done. We can get it done in this session of Congress. So thank you for the hearing today, and thank you to our witnesses.

Let me begin with Professor Sachs. Thank you for your testimony. During my time in Congress, I have heard from countless constituents who say they cannot afford their prescription medications. We all hear it when we go home. It isn't right that someone in our country should have to choose between food and medicine. It is just not right. It is not right that one in three U.S. adult patients forgo desperately needed medications because of cost.

In my home State of North Carolina, including right there in my district, we are the home to many biotech and pharmaceutical manufacturers. And I believe that innovation by these companies should be encouraged. But clearly, the American people are suffering, and we all know that.

The status quo is not acceptable. Congress must act to

ensure that the American people have access to and can afford the treatments that they need. And so all of that is to say, Professor Sachs, H.R. 3 creates a new $2,000 out-of-pocket cap on Part D spending. I think you would agree that this new limit would be welcome news to millions of beneficiaries.

You explained a few minutes ago, if I heard it correctly, to Chairman Pallone that an out-of-pocket cap cannot lower drug costs on its own. I think you said that. How will the other pieces of H.R. 3 lower costs for savings?

*Ms. Sachs. Thank you, Congressman. This is an important distinction. H.R. 3 recognizes that reducing patient out-of-pocket cost is critical, but on its own that is not the same thing as reducing drug prices. It covers those up. It actually makes it harder to see that a company is raising its prices 27 times, as we have heard from Ms. Ball.

So it is makes important to lower patients' out-of-pocket costs, and that $2,000 cap would be a huge help to many Medicare beneficiaries. But it is important to also use the other elements of H.R. 3 to discourage companies from increasing their prices as fast as we have heard them do already in this hearing, and I am sure we will hear more about it as well. And it is important to use the negotiating elements of H.R. 3 to really make sure that the Government has a strong hand in bargaining for the prices of these

products when we are paying many times more than comparable countries for the very same drugs.

*Mr. Butterfield. Precisely, and thank you so much for that. Let's talk for a minute or two about rare diseases. You may know that I am the co-chair of the Rare Disease Caucus here in the House. Over 95 percent of rare diseases -- people don't realize this -- over 95 percent of rare diseases do not have any treatment at all.

Many, like sickle cell, which predominately affects African Americans, are chronically overlooked and underfunded. We must foster the creation of cures for these conditions. Ms. Sachs, you discuss in your testimony various ways that H.R. 3 could impact future drug development. Do you anticipate a large impact on first-in-class products for rare diseases, like sickle cell?

*Ms. Sachs. I do not, and here is the reason why. Most rare disease drugs won't qualify for negotiations under H.R. 3 because only the top 125 drugs under Medicare Part D and the top 125 drugs more generally are even eligible for negotiation.

And so for top-selling drugs in Medicare, we are often talking about drugs that hundreds of thousands of Medicare Part D patients are taking, to say nothing of patients outside of Medicare, that by definition orphan drugs are treating very small populations of patients. And it is very

difficult for them to become top spend drugs of the type that would even qualify for negotiation.

I also do know that there has been bipartisan interest in Congress in the last few years of looking at when companies might be abusing the Orphan Drug Act, such as to extend their monopolies by stacking orphan drug exclusivity periods. So it is possible that there might need to be some attention to those concerns.

But it is very unlikely that rare disease drugs would be under the negotiating scope of H.R. 3 -- not never, but unlikely.

*Mr. Butterfield. Thank you so very much. I will end with the last statement that -- the first statement that I made during my remarks: 95 percent of rare diseases will not have a treatment. Colleagues, let's redouble our efforts.

Thank you, Madam Chair. I yield back.

*Ms. Eshoo. The gentleman yields back, and we thank him.

The chair is pleased to recognize the ranking member of the full committee, Ms. Kathy McMorris Rogers.

*Mrs. Rodgers. Thank you, Madam Chair. And just let me say, we are anxious to go to work to focus on cures for those with rare diseases and beyond. I am committed -- Republicans are committed -- to addressing how we bring down the cost of prescription drugs. It is a priority issue.

Anxious to work with Republicans and documents on solutions, build on right to try. We can continue to expand the generics. Transparency, accountability for problems is a priority. I am very concerned, though, about the current approach and the impact that it is going to have on innovations and curing diseases from a very big picture.

So I wanted to start with Dr. Gupta, and just thank you again for joining us, bringing your expertise and experience. You spoke about us living at the dawn of a golden age of innovation, and it is one of those times that we should just be focusing on how we continue to lead in ways that are going to result in lifesaving, life-changing therapies and treatments.

I would like to ask you: What are you most excited about? And put in layman's terms, what it means for patients and families across the country, and if you have any concerns about the proposal before this committee this morning.

*Dr. Gupta. Thank you, Congresswoman. What I am most excited about is several years ago we used to have a concept in our industry of targets that were called "undruggable,'' which meant that with the toolkit that we had to develop medicines, we simply couldn't hit them. We knew where the disease was coming from, but we couldn't do anything about it.

Increasingly, that word is leaving our vocabulary. And

I think that is the most exciting development. I hope, when I say we are at the dawn of a golden age, I really believe that. And as you said, Congresswoman, I think we should pour gasoline on the fire rather than trying to snuff it out.

*Mrs. Rodgers. Yes. Thank you for that.

Ms. Davis, I wanted to thank you for joining us today and sharing your story. Now, as a mom, I am always amazed and inspired by others, and especially all that you have done for your son Hunter and fighting for him. You basically took a never say no attitude, and that determination is one that we all admire.

I appreciated you highlighting the miracle drug that has now been made available to those with SMA. And as we just heard from Dr. Gupta, the concern is that proposals like H.R. 3 are going to disrupt the path to those breakthroughs for the next generation of children like Hunter.

As you know, the SMA treatment became more widely available in the U.S. in February of 2017. But sadly, it wasn't made available in Australia until 11 months later, or six months later in Canada, four months later in France, five months later in Germany, six months later in Japan, six months later in the U.K. The bill we are discussing today would import into the U.S. the pricing schemes from those countries who didn't have the kind of drug that Hunter needed available until much later.

So what would you tell the members of this committee about what the extra four, five, six, or 11 months without this treatment would have meant for you and Hunter?

*Ms. Davis. So for SMA, every day matters. Sometimes every minute matters. Once motor neurons are lost, we can't get them back. And so what it would mean is more babies and children would be permanently disabled, and more lives would be lost. This is something we cannot afford. In fact, we really need to be working for pre-symptomatic diagnosis and treatment, not only for SMA but all of these childhood conditions.

*Mrs. Rodgers. Thank you very much. And I also wanted to ask if you would just speak to the way that other countries define the value of a life, and how that impacts the availability and also potentially the price of drugs.

*Ms. Davis. Yes. It is based on the quality metrics. And it is used by discounting the value of the patient's life based on how chronically ill or disabled they are, and then multiplying that, the number of years that they anticipate the survival.

And so it is a very discriminatory practice, and it is something that we have acted vigorously to prevent from happening in the U.S., and we have done with ICER. We prevented CVS Caremark from importing ICER's quality metrics, and we also opposed the ventilator medical rationing during

COVID using those measures as well.

*Mrs. Rodgers. Thank you for joining us and speaking out. My time is expired. I yield back.

*Ms. Eshoo. The gentlewoman yields back.

The chair is pleased to recognize the gentlewoman from California, Ms. Matsui, for your five minutes of questions. Great to see you, Doris.

*Ms. Matsui. You, too, Anna, and everybody else. And thank you very much, Madam Chair, for calling this hearing. It is so important. And thank you for the witnesses for being here. It is important to hear about your experiences and your expertise.

I know there has been a lot of conversation on the out-of-pocket cap in around, and I have listened to Professor Sachs. I understand that this is just one tool. But particularly for beneficiaries as they have challenging prescription drug costs, it is really very, very important.

So just a comment, Ms. Ball: Can you share what, say, a $2,000 out-of-pocket maximum in the Part D plan would mean for you? Would this provide you with better certainty for your total drug costs for the year? Ms. Ball? Are you present? She is having trouble. Let me go on here.

*Ms. Ball. I had trouble with unmuting. I am so sorry. Yes. You know, it would benefit me is that I would be able to know exactly what I would need if my pricing went up to

$2,000. But basically, what happens is that I would have the able to receive my drugs, which is the most important part because at the time that it went to $6,000, there was no way that I could have. And that really was devastating to my health and to my family. So it would help a great deal.

I am sorry. We can't hear you, ma'am.

*Ms. Eshoo. Doris, you need to unmute.

*Ms. Matsui. Sorry about that. I got unmuted.

I want to talk about the role of rebates. Reforms like the equation of rebates and insurance premiums were realigned incentives that manufacturers have for raising their prices, but may be limited in their ability to assist Medicare in obtaining lower prices, particularly on specialty drugs.

A similar problem exists with rebates that drug manufacturers pay to PBMs and insurers. Typically, these post-sale rebates or discounts are not available for drugs that lack competition. Professor Sachs, for expenditure drugs that have no manufacturer rebates, what leverage do Part D plans and PBMs currently have to negotiate lower prices?

*Ms. Sachs. They have little to no leverage today.

*Ms. Matsui. Okay. Professor Sachs, inflationary rebates can address the overall growth of a drug's price over time. But what other mechanisms are needed to reduce costs, particularly for specialty drugs with an initial high list

price?

*Ms. Sachs. Exactly as you just said. The inflationary rebates will be important to discourage or prevent drug companies from hiking the list prices of their drugs more quickly than inflation. But the companies that set a high price in the first place, especially where the price is many times what other countries are paying for the same drugs, H.R. 3 gives the Secretary the authority to negotiate for the prices of those drugs and strengthen their hand in that negotiating process.

*Ms. Matsui. Okay. Thank you. I want to go back to -- we were talking about out-of-pocket caps. Professor Sachs, can you briefly describe how H.R. 3's proposal to cap out-of-pocket costs compares to H.R. 19 that we are also considering today?

*Ms. Sachs. Yes. So the ideas are very similar, to help patients afford their out-of-pocket costs. But the details are different in two important ways.

So first, H.R. 3 is more protective of patients and imposes a $2,000 annual limit on points' out-of-pocket costs rather than a $3100 out-of-pocket limit on patients out-of-pocket costs. And then second, H.R. 19 imposes less responsibility on manufacturers in the catastrophic phase, only 20 percent compared to 30 percent in H.R. 3, which will help manufacturers be discouraged from driving patients into

that phase of their benefits.

*Ms. Matsui. Okay. Fine. Thank you, Madam Chair, and I yield back my time.

*Ms. Eshoo. The gentlewoman yields back.

A pleasure to recognize the former chairman of the full committee and the Republican lead author of the Cures -- what is the matter with me? -- the 21st Century Cures Act. I just had a blank moment there. Mr. Upton, you are recognized for your five minutes of questions. Great to see you.

*Mr. Upton. Well, it is. Thank you, Madam Chair, and thanks for bearing with me a little bit for our little issue with WebEx, getting access to what we all are doing. And we all hope that Mr. McKinley's wife, Mary, does well with her surgery this afternoon.

A couple things. It is no secret that all of us on this committee have been very involved in health research. And obviously, 21st Century Cures is a major milestone for us when we passed it back in 2016. President Obama signed it into law. For me, doubling the money for the NIH back in the 1990s, working with Henry Waxman and John McCain, my good buddy, which was successful, and obviously now, as we are beginning to work on Cures 2.0, myself and others very involved in that, as well as wily Pallone and the leadership on both sides .

I just want to thank Ms. Davis. Just a touching story

for me and many on the committee that were on the committee back in 2015. They saw two of my constituents, two little beautiful girls, we actually called Sleeping Beauty and Cinderella, from my district who were impacted with SMA and just so excited about the progress that is being made.

But that is the case with every rare disease. So cystic fibrosis, all of them -- we all want cures for these diseases. We really want to get to the point where we can be the lifeline for those families.

One of the things that also drove us to get 21st Century Cures done was that we realized that venture capital was leaving our company. It dropped by 50 percent back in the early part of the 2010s, the early part of that decade, going overseas because we weren't the leader in innovation. We weren't the leader in getting these drugs approved.

And I have a fear that countries like China and India -- they haven't an explicitly stated that they want to become global leaders in medical innovation yet, although they are trying. But it is often -- those manufacturers that often seem to be cited the most in terms of tainted drugs, quality manufacturing issues, and the policies of H.R. 3 could in fact make those countries potentially more attractive for R&D and manufacturing investments than the U.S.

So Dr. Gupta, do we want to take the chance that we could lose U.S. global leadership in this space and end up

with impure medicines, potentially longer delays in access to new medicines in the laboratory systems which may not have the same gold standard that we have in the U.S.?

*Dr. Gupta. Thank you, Congressman. And I think you have outlined precisely the risk that we face under some of the provisions of H.R. 3. China is signaling to its companies it wants them to catch up, and that they can charge relatively high prices in China. It is expensive to run a clinical drug trial to the FDA standard, and I think you have outlined precisely what we may see if that would happen.

*Mr. Upton. One of the things, too, is that I hear colleagues on both sides talk about where we are. We all want lower drug prices. That is for sure. But we went through this same argument last year by saying we have a bill, H.R. 19, that was actually bipartisan. It was made up of bipartisan bills; every one of them had Democratic and Republican support that we packaged together.

And H.R. 3, we said, isn't going to get to the finish line. And exactly that same thing happened. And that is the fear again in this Congress, that H.R. 3, the way that it is designed now, same bill as last year, isn't going to get to the President's desk whether it be a Republican or a Democrat. So why not take what we know we can agree on and move that, at least do it first rather than wait for H.R. 3?

But I guess in my last minute, I just want to say one of

the provisions in the Cures that was signed into law was the precision medicine initiative at the NIH and many new, innovative therapies, highly targeted, underscoring the importance of patients having access to a range of treatment options.

The future of precision medicine and the highly effective therapies is not for sure a one-size-fits-all. That approach is at odds with how the drug pricing proposal would set prices for medicine. Determining a single price based on the price that we pay for medicines in other countries, and population level compared to the effectiveness of research -- neither of these factors, as I understand it, will account for the value of those treatments to an individual patient.

So are there any recognitions for personalized medicines included in the price-setting in H.R. 3, Dr. Gupta? In my last two seconds.

*Dr. Gupta. Thank you, Congressman. I will be brief. Personally, I am actually unfamiliar with any provisions that might cover that. I will have to review that and get back to the committee. Thank you.

*Mr. Upton. Okay. With that, Madam Chair, I yield back the balance of my time.

*Ms. Eshoo. The gentleman yields back. And it is a pleasure to recognize the gentlewoman from Florida, a

wonderful member of our committee, Ms. Castor, for your five minutes of questions.

*Ms. Castor. Well, thank you very much, Chairwoman Eshoo. Thank you for leadership here. This is a very important hearing on legislation to lower the cost of prescription drugs, so thank you for calling us all together, and thank you for the testimony of our witnesses as well.

I encourage everyone to go back to the memo that summarizes the reason that we are here. Drug prices in the United States continue to soar. The Rand study was cited in that summary memo. Americans pay 256 percent more for their prescription drugs than the average 32 countries. And when you are talking about brand name drugs, it is more than that, 344 percent more.

That is outrageous, and it is exacting a toll on families, all of our neighbors. And it sure impacts the Federal budget and the bottom line because of more extensive outlays for Medicare and Medicare Part D.

This just doesn't make sense any more, that there is a prohibition on Medicare negotiating prices. And I wanted to give a shout-out to our colleague, Peter Welch, who has spent a good bit of his time in Congress fighting for this. And I think, Representative Welch, I think this is our year that we are going to get it done. And I really invite our Republican colleagues to join us on this, to lift that prohibition on

negotiating drug prices. We do it in the VA. It works. And it is really anti-American, isn't it, that we would prohibit anyone from negotiating something in America.

But I would like to spend, Professor Sachs, a little time with you to talk about generic alternative and sole source drugs that don't have the market forces to draw the price down. We have seen, in the current market, we don't have the tools to restrain those costs.

Will you describe for us the way that drug makers often determine a price for sole source products? Is it fair to say that there isn't a lot of leverage for employers or insurance companies to control costs for these drugs, short of excluding coverage, that we don't want to?

*Ms. Sachs. Thank you. As to your question of how companies determine prices for these drugs, it is very common to hear that drug companies charge what the market will bear. They are not looking just to recoup their R&D investments. They are looking at other drugs. They are looking at services, and benchmarking their prices accordingly.

And you are also right to suggest that there isn't a lot of leverage for employers or insurers to control costs for those drugs. But I don't think it is necessarily the case that exclusion or the treat or exclusion is necessary. And so for an example, and I think we can look to Medicaid, Medicaid is required by law to cover essentially all FDA-

approved drugs.

But in exchange, it is a entitled to preferred pricing benefits, including inflationary rebates of the type we are considering today. And different Governmental reports have shown that those inflationary rebates are very effective in helping Medicaid get much better prices than Medicare Part D for the same product.

*Ms. Castor. So given this, you appear to agree that it makes sense to give the Secretary of HHS the power to negotiate prices of certain high-priced drugs that the lack of competition and -- where we have a lack of competition and our neighbors are forced to choose between taking their medications or eating or paying for a roof over their heads. is that right?

*Ms. Sachs. Yes. Yes. Unfortunately, too often, as I mentioned, one in four, almost one in four Americans, 24 percent, including 23 percent of seniors, have difficulty affording these medications.

*Ms. Castor. So some of the bills today do address the issue of generic competition by addressing some of the major barriers to effective, timely generic entry. These policies are crucial to making markets for prescription drugs work more effectively.

However, why is it not enough on its own? Why must we also have a comprehensive solution like what is contained in

H.R. 3 in order to meaningfully bring down drug prices for all Americans?

*Ms. Sachs. Yes. This is such an important question. And these bills promoting generic competition are important. I don't want to suggest that Congress shouldn't pass them. But they are reactive. So as we heard from Professor Carrier's testimony, firms have been engaging in paper delay deals and in petitions. Product helping is another example of this, for years.

And if Congress is now able to crack down on those, industry will develop innovative new ways to extend their monopolies. A comprehensive negotiating strategy would limit, although probably not completely avoid, the need to play this kind of whack-a-mole with pharmaceutical company gaming tactics in the first place.

*Ms. Castor. I agree. I think H.R. 3 is a very important comprehensive approach to controlling drug prices for all of our neighbors.

So thank you, Chairwoman Eshoo, for having this hearing, and I yield back my time.

*Ms. Eshoo. The gentlewoman yields back.

It is a pleasure to recognize Dr. Burgess for your five minutes of questions.

*Mr. Burgess. I thank the chair. And just like in the last Congress, this hearing has been very instructional. And

certainly I have enjoyed the testimony of our witnesses.

Dr. Gupta, if I could ask you, I think we would all acknowledge that the National Institutes of Health is a national treasure, and it has contributed mightily to the basic research and understanding of many diseases. But it doesn't seem to me like the ago was designed with the development of bringing new drugs to market in mind.

So could you elaborate on that a little bit, the process of bringing a new drug to market and the process, for example, in scaling up to coronavirus vaccine?

*Dr. Gupta. Yes. Thank you. Thank you, Congressman, I think that is a very important point. And the NIH is a fabulous organization, world class. But it is not a drug development organization, and the core skill set of biotech and pharma companies is developing medicines, getting them -- manufacturing them, running them through clinical trials, interfacing with the regulators, and then of course actually selling them.

There is no glide path to market a drug once it is approved. There is no national formulary. And it is actually -- and I think big companies are better than small companies. It is actually important to have the ability to make sure that physicians and patients can get them and are aware of them. And the NIH is not equipped to take the prototypes that they sometimes build, or the scientific ideas

they sometimes generate, all the way through that lengthy process.

*Mr. Burgess. All right. When Zika was a concern several years ago, and had multiple meetings with Dr. Fauci of the NIH on this, he did point out that they have a small manufacturing capability, capacity, at NIH. But I would underscore small, and nothing of the sort that would have permitted the rapid introduction of the coronavirus vaccine, for example. That did require the involvement of the private sector. I think we are all grateful that that involvement occurred.

So Dr. Gupta, staying with you for a minute, you actually have some experience in the business world. You have probably been a part of negotiations yourself from time to time. The excise tax that is enumerated in H.R. 3, does that look like a negotiation process to you?

*Dr. Gupta. Thank you. I think that that mechanism would provide a lot of leverage to a party that would disadvantage greatly the counter party to that.

*Mr. Burgess. Well, and again, you also understand the capital, investment of capital, is on a lot of things, and a lot of them are good things. But capital is generally not known for being courageous. And so if capital is challenged in one location, what is likely to happen?

*Dr. Gupta. Well, thank you. I appreciate the chance

to comment on this as well. Just from the laws of economics, I can't think of an example where investors would put their capital at risk in a field that faces price controls. But I think it is also worth sharing a little bit about the odds of a drug making it all the way through the FDA.

Only 1 in 25 drug candidates will make it from pre-clinical studies through FDA approval, and on average, the cost required to support a development program is between 1- and $2 billion. And keeping the incentive structure we have in place is clearly necessarily to continue the outlook that we have.

*Mr. Burgess. I appreciate your input on that. I am going to leave to our colleague, Morgan Griffith, to discuss about the takings clause and the constitutionality of the legislation. I think he tried to rescue it last Congress. I don't know if he is of a mind to try to rescue it this time. But again, I will let him speak to that.

Ms. Davis, if I could just ask you, are there any medications or therapy that your son is currently taking that would not be available in the countries the H.R. 3 international reference pricing is -- that concept is based upon?

*Ms. Davis. So it varies on the type of patients, especially for the patients that are on ventilators. They are not able to access treatments in many of the countries

because the QALY metrics used to develop the inclusion criteria excludes those patients. Their lives are not deemed valuable enough to access the treatment.

*Mr. Burgess. So the calculation of the QALY-adjusted life-year makes them ineligible. And by making them ineligible, what does that do to their -- the outlook for their life span?

*Ms. Davis. It significantly diminishes their life span -- and not only their life span, but the quality of life during that life span.

*Mr. Burgess. We need to be mindful of things like that as we contemplate a bill like H.R. 3. H.R. 19 has a number of great provisions, all bipartisan. A number of them got passed last Congress. A couple of them have passed this Congress and been signed into law. So for my money, we ought to be working on what works, get it done, and let the American people help us sort it out.

I thank the chair for the recognition, and I yield back.

*Ms. Eshoo. The gentleman yields back. Please note I gave you 35 extra seconds there.

The chair is pleased to recognize the gentleman from Maryland, Mr. Sarbanes. You have those shades on. Where are you?

*Mr. Sarbanes. I am over here. Thank you very --

*Ms. Eshoo. There you are. Oh, we can see your whole

face.

*Mr. Sarbanes. Yes. Thank you very much, Madam Chair. Appreciate the opportunity.

Before his passing in 2019, Chairman Cummings, who represented Baltimore, as I do, and for whom this critical legislation is named, as you know, he worked tirelessly to uncover why the prices of lifesaving drugs were so high that people simply could not afford them, why people would need to ration their drugs or go without.

He felt this very, very deeply. I saw that every single day as he moved around his district, his neighborhood. He just couldn't understand why this was the case in a Nation as great as America. We both heard, he and I, and I continue to hear, these stories today from Maryland constituents as to how the high prices of prescription drugs forces them to make impossible choices, endangering their health and their lives.

And all of this is happening while drug companies continue to rake in these incredible profits; between 2011 and 2016, we know that list prices went up 129 percent for 14 of the top-selling drugs -- top-selling because they are so critical for people out there. At the same time, out-of-pocket spending by patients increased by 85 percent for specialty medicines and by 42 percent for non-specialty drugs, even after taking inflation into account. This is just plain wrong.

As former chairman of the Oversight Committee, a committee on which I also served, Chairman Cummings worked tirelessly, as I have said, to fix this problem. The Oversight Committee's work centered on both lowering prices for individuals and families across the country as well as removing waste, fraud, and abuse from Government spending, and our hearing today continues that effort.

Professor Sachs, it seems like we are asking you the same basic questions over and over again. We are doing that because it is really important, because this bill can solve a lot of the challenges that Americans face. So tell me again, why is giving Medicare the power to negotiate such a central tool in effectively lowering drug prices? And maybe focus on the centrality piece of that.

Like there are a lot of other things that we can and we should do to address the high prices. But this specific tool of giving Medicare the opportunity to negotiate is really at the heart of -- it is in the center of our toolkit. So can you speak to that a little bit more?

*Ms. Sachs. Yes, absolutely. And just to clarify, because the prescription drug pricing issue is so complicated, there is not one reason why the price of a drug can be high or why patients might have difficulty affording their medication. It is important to ask and answer these questions in slightly different formats repeatedly, so that

we know what is at stake here for patients and innovation and access.

So to answer your question more specifically, the centrality of negotiation to H.R. 3 is that is gives the Government more authority to have an equal position at the bargaining table with these drug companies, who are the manufacturers of high-priced sole-source drugs.

What do you do for Copaxone? What do you do for Humira? There is a question there about whether companies that have been on the market for a long time, who now recouped their monopolies, but have managed to delay generic competition. And it is really hard to crack down on a hundred patents in a single drug portfolio or on some of these other tactics.

Allowing the Government to negotiate, just as many other countries do, would allow us to lower the prices of some of these drugs and to get more fair prices for patients and payers.

*Mr. Sarbanes. Thank you. And it is so American to allow negotiation in the market. Yes, the Government will be negotiating. Okay. But that is the way it is supposed to work in our system, with two parties bargaining to get to a good result here. And obviously, the Government's hands have been tied arbitrarily for years now.

My understanding is that the CBO estimates a negotiation framework will lower Federal spending by $456 billion -- that

is incredible -- while also saving Medicare $42 billion on other health expenses simply because beneficiaries will be able to fill the prescriptions that will keep them healthy. Let me just emphasize that: Because patients will be able to get prescription drugs that they cannot get right now, they will be healthier, and Medicare will save $42 billion on healthcare costs.

Madam Chair, thank you for this hearing. Very, very important. I yield back my time.

*Ms. Eshoo. The gentleman yields back. Thank you for having us look back at, really, the central work of our -- as I said in my opening statement -- our promoted colleague, Elijah Cummings. In so many ways he set the table for what we are doing today and going forward.

It is a pleasure to recognize the gentleman from Virginia, Mr. Griffith, for your five minutes of probing questions.

*Mr. Griffith. Thank you very much. I appreciate it very much, Madam Chair.

Let me just say that -- and I have got to get this off my chest -- we have been talking about negotiations. But we don't have negotiations in this bill. And that is the problem because what we have is a system that says, if you don't agree to the price dictated by the Government, you can pay a tax of 65- to 95 percent of the gross revenues for that

drug in order to be able to sell it in the United States.

Now, I get very concerned about that, as I did two years ago, because when it comes to the constitutionality of a bill, it is not just the courts that have jurisdiction to determine that constitutionality. This committee and Congress also have a role and have a duty to determine whether or not we are passing bills that are constitutional.

The court may be the final arbiter of that question, but we have a duty to look at it, too. And when you look at the concerns that were raised -- not just by me two years ago, but by owners, including the Congressional Research Service -- we have Eighth Amendment concerns.

While Congress has the power to levy taxes, that levy is -- that ability is not without limitations, especially with regard to taxes that are actually moral penalty fees or fines. And I think a court could reasonably find these taxes are, at least in part, punitive and therefore in violation of the Eighth Amendment of the constitution.

The one that I very first raised was the Fifth Amendment concern, and that is the Takings Clause, because when you say to somebody, you can't sell your intellectual property or your product in the United States unless you give us 65 to 95 percent of your gross sales, you are taking that property away from them. You are taking away fair market earned intellectual property. And I have concerns about that.

Now, I am one of the people on the Republican side of the aisle that actually would consider negotiation, that I think we should have some negotiation ability, and I even have a bill in to do that in certain stressed areas. That being said, we have to do it in a constitutional manner. And Madam Chair, I just don't think this bill is constitutional.

When you limit prices manufacturers can charge and you say -- you are being forced to accept the price for a drug, and that could mean significant economic loss to the developer because you are going to take not of the profit but up to 95 percent of the gross sales, that is a taking, Madam Chair.

And I know that everybody is trying to do the right thing, and you have heard that H.R. 19 has some positives from the witnesses, and we have heard that there are other positives. But if we are going to do the right thing, even when we disagree, let's at least do the constitutional.

Now let me shift -- before I finish my time today, let me shift to H.R. 2843 because I think this one also has concerns. And I think we can all agree that the FDA citizen petition process can be very useful and must be implemented in a way that prevents abuse. And that bill, H.R. 2843, known as the STOP GAMES Act, seeks to address potential abuses. While I admire that goal, I remain concerned that the bill currently does nothing to resolve potential First

Amendment issues, which also were raised back in 2019.

Now, that deals with the First Amendment. It guarantees the right to petition the U.S. Government for redress of grievances. Yet H.R. 2843 would allow the FDA to summarily deny, that is, to not even consider, citizen petitions at its own discretion -- even if they raise valid science -- they think are regulatory concerns.

If there is a scientific basis for petitioning the FDA that has not been considered previously and has been timely submitted, I believe the agency should have a timely process to review the petition and make a decision based on the merits.

Now, Madam Chair, I think we can both agree, and I think all of us can agree, that we need to have a process that is a little quicker. And right now it is being used in games by certain parties in the system to make this process long and drawn out.

But again, let's figure out a way we can fix that without completely eliminating the right to seek redress from the Government by citizens who may have a legitimate concern. And there are bad actors, and we have to figure out how we set that system up. But I will submit to you that H.R. 2843 is not the vehicle, as it is currently written, that we ought to do that with.

So Madam Chair, I hope as we work forward in this, as we

go through subcommittees, we go to full committee with actual bills and the bills that we are discussing today, that we are open to doing some amendments to try to make sure that we can -- even if I don't agree with it 100 percent, let's at least pass a product out of this committee that meets the constitutional test and that we can all feel comfort is actually constitutional.

And Madam Chair, my time is up and I yield back. Thank you so much.

*Ms. Eshoo. Thank you. The gentleman yields back. Always thoughtful.

The chair now, with pleasure, recognizes the gentleman from Vermont, Mr. Welch. And I think I am going to announce who follows so just in case you want to step away, you know that your time is almost at hand -- followed by Mr. Bilirakis from Florida. So Mr. Welch, thank you for all of the work you have done in the whole area of drugs and their costliness. You are recognized.

*Mr. Welch. Thank you very much. First of all, we have got two lawyers following one another, and I disagree with Mr. Griffith on the constitutionality of this. But I do agree with many of the proposals that our Republican colleagues have in their bill.

What the issue here is Government negotiations. And there is a number -- I am going to step back for a minute and

put this in a context. The pharmaceutical industry is dead set against Governmental action through negotiation. And why wouldn't they be? They have record profits. Representative Castor mentioned that we pay two and three times the prices paid for the same drug in other countries.

Pharma is not opposed to Governmental action, and it is Governmental action that provides them with patent protection and the exclusive right to use the product. Pharma is not opposed to Governmental action when it comes to taxpayer financing of the National Institutes of Health and all of the research that taxpayers pay for that then are oftentimes utilized and monetized by the pharmaceutical industry.

Pharma is not opposed to Governmental action when it comes to creating a guaranteed market in Medicare and Medicaid. So pharma has a pretty good arrangement. They have got a guaranteed market. They have got pricing power that is legislative and authorized by the Government. And what we have seen is that it is a model that works, and they make billions and billions of dollars, and the CDOs make millions and millions of dollars in salary.

Pharma oftentimes spends far more on advertising than it does on research and development. And all of these things add up to an incredible, punitive, price-gouging impact on taxpayers, on individuals, and very significantly, on many of our employers, who are doing every single thing they can to

maintain employer-sponsored healthcare for their valued employees.

And when those employers get the notice from the insurance company that premiums are going up 15 and 20 percent, and then talk to their workers about, this year I am afraid we can't have a rise because we have got to keep your insurance, all of that is continuing to occur and will never stop unless we address the cost.

The biggest threat, the biggest threat to access to healthcare is the cost of healthcare. It is the cost. So unless we face this, and the cost of healthcare is most exploding in the area of pharmaceuticals, we are going to allow the erosion of access to healthcare for American workers, American seniors, and American kids.

The argument is being made that if we proceed with price negotiation of any sort, it is going to adversely affect innovation. And I would like to ask -- I would like to ask Professor Sachs to address that directly.

*Ms. Sachs. Thank you, Congressman. I want to say that as a property law professor, I share your skepticism of the takings argument. I would be happy to discuss that in more detail at a later date.

But to respond directly to your question about innovation, you are right. Industry argues that innovation will be harmed no matter what the reform is. They make this

claim without regard to the size of the placing reform, without regard to when in a product's life cycle it would take effect, without regard to what products it would impact.

Today they make this argument about H.R. 3, but they also made it on bills that would crack on pay-for-delay arrangements or product hopping. HHS Secretary Alex Azar called this a "tired talking point,'' and he was right. If industry won't distinguish between the CREATES Act and H.R. 3, then this committee should consider how seriously their arguments should --

*Mr. Welch. I have to interrupt you. Thank you. I just want to make two points. One, we have got to get rid of DIR fees that is hammering our local pharmacies, and they provide good service. And then second, I want to address this question of COVID and us having it and Europe being behind us. We negotiated with pharma to buy, at a reasonable price, the vaccine and refunded them. In Europe their problem wasn't negotiation. They had 27 countries that couldn't come to an agreement on what bid they would make.

I yield back, and I thank the chair and my colleagues for this hearing.

*Ms. Eshoo. The gentleman yields back.

A pleasure to recognize the gentleman from Oregon -- no, the gentleman from Florida, I am sorry, Mr. Bilirakis, followed by the gentleman from Oregon, Mr. Schrader. So you

are recognized for your five minutes. Great to see you, Gus.

*Mr. Bilirakis. Thank you. Good seeing you, too. With all due respect to Mr. Schrader, my good friend, I want to remain in Florida.

I do want to say this: I want to respond to -- my good friend, Representative Castor, with regard -- she brought up the VA. And I understand there is an access issue. I know that the VA does negotiate drug prices. However, 24 of the top 50 drugs on the national formulary are not covered by the VA. And I don't think that is a good thing for our veterans.

And I understand only 63 percent of our veterans actually -- that qualify that are enrolled in the VA use the -- get their drugs from the VA. So that is a big problem, folks, and we need to address that. There is no question.

I want to get into now the rare diseases, if that is okay. And I want to thank the chairman for this hearing. A very informative hearing. And I remain committed to working with my DNC colleagues on both sides of the aisle to put patients over politics by advancing bipartisan solutions.

So that said, I am very concerned about the impact of H.R. 3 on patients with incredibly complex rare diseases. As you know, I am the co-chair of the Rare Disease Caucus, along with Representative Butterfield. We have done some really good things for our rare disease patients the last few years.

So the bulk of R&D for medicines for rare diseases comes from the biopharma industry. In 2018, the biopharma industry invested $102 billion in R&D, 100 percent of which was focused on drug development. Contrast that with the entire NIH budget of fiscal year 2018 which was $35.4 billion, with only 8 percent focused directly on research related to drug development.

We need a robust biopharma industry, and I think everyone agrees to that, investing in rare diseases. If referenced pricing or similar policies are put into place, I worry that direct investment in rare diseases, where the failure rates are high, would diminish, and companies will only again do the safe things, make the safe bets. And our children are suffering. Our people with rare diseases are suffering.

And Representative Butterfield was right about that. ninety-five percent of these rare diseases have no cures or treatments. Very unfortunate. Policies like referencing pricing and Government price-settings will effectively turn our biopharma industry to a risk-averse, think inside the box rather than outside the box, a mod of the industry. And I am concerned. That is not what American citizens want.

Okay. Dr. Gupta, I have a question for you. Can you speak to how H.R. 3 would impact complex rare diseases and investments there due to the economic incentives in H.R. 3,

where the signal to manufacturers to invest in rare diseases are lower cost following up? What kind of an effect would H.R. 3 have on investment, R&D, with regard to rare diseases, please?

*Dr. Gupta. Thank you, Congressman. Well, first I think it is important to recognize that small biopharma companies are the ones driving innovation. They comprise about 70 percent of drugs in phase 3. And they are the ones that primarily serve rare disease patient populations.

So they are the ones that have to seek raising capital from investors. And I think because of that phenomenon and because rare disease populations are of course smaller, meaning that price controls would actually impact them disproportionately in terms of the revenue potential of most things that are being developed, my belief is that price controls, as contemplated by H.R. 3, would significantly negatively impact rare disease patients.

*Mr. Bilirakis. Okay. One last question and then I want to go to Ms. Davis, if I am permitted. Ultimately, would H.R. 3 increase or decrease China and foreign influence over U.S. biomedical research? Yes or no? This is for Mr. Gupta.

*Dr. Gupta. I don't think it would increase influence over U.S. companies. I think it would give China a chance to equilibrate and develop an ecosystem where they could

structure opinion and get a drug to market.

*Mr. Bilirakis. I know I don't have -- well, you know what, Madam Chair? I am sorry. I am not going to go over the time. All right? So I will yield back. Thank you. I just had the vaccine shot, so I am a little bit fatigued. But I apologize for that. But I appreciate your giving me the time.

*Ms. Eshoo. Well, thank you, Gus. And bravo to you for getting the -- for being vaccinated. That was a great thing --

*Mr. Bilirakis. Thank you. My second dose, second dose, so I am very happy.

*Ms. Eshoo. It is a great example to everyone else and the people in our country. And you give my love to Mom and Dad, all right?

*Mr. Bilirakis. That I will. Thank you.

*Ms. Eshoo. It is a pleasure to recognize the gentleman from Oregon, Mr. Schrader. We are all grateful to you for your thoughtfulness, for your work. And he will be followed by the gentleman from Missouri, Mr. Long. So you are recognized, Kurt, for five minutes.

*Mr. Schrader. Thank you very much, Madam Chair. Appreciate it. Appreciate the hearing. This is good stuff.

Dr. Gupta, I am just trying to follow up a little bit on what my good friend and colleague, Gus Bilirakis, was talking

about. But on the flip side, given your role in venture capital, if we were to do H.R. 3, how or would that impact investments in biotechnology startup sector?

*Dr. Gupta. Thank you, Congressman. I think that the impacts would be far-reaching, they would be wide, and they would be generally negative. I think that if there are sectors that could seek that investment that provide safer returns or better returns, the prospect of that, you may see a diminishment of the types of risk that investors are willing to take in biotech.

*Mr. Schrader. Would there be any difference if instead of the benchmarking to set price, we just allowed negotiations on the part of Medicare like with the VA and, in certain States, Medicaid? Would that be different?

*Dr. Gupta. I think that it unfortunately doesn't help address the core issue, which I think remains the various access primarily at the end of the funnel, which is out-of-pocket costs. And price controls of any store do not ensure that the payers will pass those savings on to patients. So I hesitate to suggest that there may be some amount in negotiation without focusing first on what we see as the larger problems.

*Mr. Schrader. Okay. Okay. I just saw negotiation as distinctly different than benchmarking, personally. We do that in so many other areas, and I am that a lot of folks

take that into account when they make their investments going forward.

Ms. Sachs, you mentioned a couple of other topics you would like to see the committee address, maybe at a later data, looking at other parts of the supply chain. I think this committee totally agrees with you. We have had numerous hearings over the last several years on this.

Are there particular policies that address entities beyond pharmaceutical manufacturers that you think we should be really prioritizing?

*Ms. Sachs. Yes, absolutely. So in particular, in thinking about the ways in which different actors have incentives to drive prices up rather than down. I do think it is important to look not just at the pharmaceutical industry but also at the role insurers, pharmacy benefit managers, and even physicians or providers groups in general can play in driving prices up rather than down.

So this committee has already considered some of these proposals. But others would include taking a closer look at pharmacy benefit manager practices and some of these issues in terms of spread pricing. I know this is also a topic of robust interest at the State level, with several State Attorneys General interested in either having already brought lawsuits against the topic certainly we have been discussing so publicly.

*Mr. Schrader. You also discussed a little bit about considering the linking of medical value to price of drugs paid for particularly by a government on any -- do you think that allow governments to craft arrangements for a drug, paying for it over a period of time, or based on outcomes would be beneficial also?

*Ms. Sachs. Congressman, I actually think that is two different questions, so I am going to answer them very briefly because I know we are short on time.

So first, this idea of value investment, if we have two drugs that are treating the same condition, value assessment means we want to pay more for the drug that works better. And if we do that, companies will know that the better the drug they make, the more money they are going to make. They will invest more in products treating unmet needs.

But this idea of value-based pricing, which has come up already in a discussion today, that is what the pharmaceutical industry wants to call it, this idea of outcomes-based contracts. But there is nothing about either the initial or the rebated price of the product, which are necessarily tied to a clinical value. So I like to call them innovate contracting models.

The point I want to make about them is that they are voluntary for industry to engage in. Industry won't engage in these deals unless they think it makes them more money,

not less. Right now they are not required to enter into those deals, and that is certainly of concern for payers.

*Mr. Schrader. That may be something we want to work on in the future, get at those concerns that you have. I am a big supporter of negotiating prices in the arrangement. We already do it in VA. We do it for many States and Medicaid.

But I also want to make sure we get something done. I do have some reservations about the indexing, personally, and so do my constituents. I have heard from a bunch of them of late. But I think there is overwhelming bipartisan, bicameral agreement to work on some sort of solution here and accomplish some of H.R. 19, which is great, but doesn't go far enough, and may be something not quite as robust as robust as our H.R. 3.

But I am feeling good about the opportunity here, and really having you here.

Madam Chair, thank you very much. I yield back.

*Ms. Eshoo. The gentleman yields back. And you have our gratitude for your thoughtful work.

The chair is pleased to recognize the gentleman from Missouri, who is always -- well, there is no one like Billy Long. So you are recognized for five minutes.

*Mr. Long. Thank you.

*Ms. Eshoo. Followed by -- excuse me -- followed by Mr. Cardenas from California.

*Mr. Long. Thank you, Madam Chair, and I appreciate it very much. I am saddened by -- we can't tackle this situation, the drug pricing situation, the same way with the same bipartisanship and the same enthusiasm that we did 21st Century Cures, when you and Chairman Upton worked so hard with the entire committee. And I remember a vote coming out of the subcommittee that was 52 to nothing. Di if that had ever been done before.

And I don't know what it takes to get back to that place in America. I don't know what it takes to get back to that place in Washington, D.C. But we all need to work overtime trying to get back because that was stellar. 10,000 diseases and 500 cures, and we tackled the problem with your help and Chairman Upton's help. The whole committee pulled together. And then we find ourselves in a cantankerous effort like we are here today.

Dr. Gupta, it is clear that everyone on this panel wants to make sure that prescription drugs are affordable to all who need them. While we may strongly disagree on how to achieve the goal, there is bipartisan agreement that the Part D program can be improved. A redesigned benefit that could protect benefits from high drug spending is included in both H.R. 3 and H.R. 19.

I thought that we could seize on this rare bipartisan opportunity to get these important benefit improvements

signed into law this year and do not get bogged down in a partisan fight over other drug pricing reform. Can you please elaborate on why it is important to cap beneficiaries' out-of-pocket costs in Part D?

*Dr. Gupta. Thank you, Congressman. Capping out-of-pocket costs is the key to ensuring access, ultimately, as well as the question of emphasizing that new drugs are created. But patient costs in 2019 were about $82 billion, and we -- that 25 percent of patients will walk away when out-of-pocket costs are above $50. So it is important to eliminate those barriers to access.

*Mr. Long. I have heard from my colleagues on the other side of the aisle about the enormous profits that the biomedical industry purportedly receives at the expense of patients. But many of the same companies, especially smaller startups in places like California and New York, are enormous job-creators and constantly reinvesting their revenue into research and development and cutting-edge jobs.

Dr. Gupta, could you please speak a little more to how H.R. 3's policies might impact the vibrant biotech job growth factor, not only in Silicon Valley but in the rest of the country? And would you say that many of these jobs could move overseas if H.R. 3 were enacted?

*Dr. Gupta. Yes. Well, thank you. That question is reminding [audio drop] 1.4 percent GPDD that we spend on

branded drugs. We get a lot of bang for the buck, not only in the improved [audio drop] was over a trillion dollars and we employ over 800,000 workers in biopharma. One-third of those are in key STEM occupations, and most of the workers are highly mobile Federal workers for any industry.

If H.R. 3 and price controls are set in a way that it has the deleterious effects the industry and we all think it would, I could see an impact on the economic -- a significant impact on the economic output of the SEC, affecting jobs of course in California, Massachusetts, New York, New Jersey, and across the country where the sector is --

*Mr. Long. I don't know if somebody is not muted or what, but I am also on the Telecom Subcommittee and I think I need to get to work on that as much as you were breaking up there on my end. So if anyone is not on mute, you might want to hit mute there.

Dr. Gupta, sticking with you here, your to my emphasizes much of the biotech advances being made in China in recent years. It seems they are already nipping at our heels and see biotech as an industry of enormous strategic importance. How do you expect China's strategy to change if H.R. 3 becomes law?

*Dr. Gupta. Well, I think we have two advantages today in the United States because of the NIH, our tremendous public science funding or tremendous university system. The

only way China will ever catch up -- the only way we will ever fall behind is if we do it to ourselves.

So my sense -- and I am not an expert on China's policies or how they might react -- my sense is that they would really lean in, trying to catch up and trying to siphon as much of the tale, as much of the IP, and as much of the know-how in a very defined way.

*Mr. Long. And if H.R. 3 were to become law, would it be as simple as flipping a switch to turn our biotechnology system back on to follow if investment does move to China and other countries?

*Dr. Gupta. Probably not as simple as flipping a switch. I think that we have tremendous advantages here, such as the NIH and the public university system, that we can always rely on and we can always go back to that well to reclaim our leadership advantage.

*Mr. Long. I hope that everyone got to see 60 Minutes on Sunday, with China's chip development and our lack of chip development. I don't want to see that going to the drug rep phase.

I am over time here, Madam Chair. And thank you for having a great hearing today. And with that, I yield back.

*Ms. Eshoo. The gentleman yields back. And thank you, Mr. Long, for highlighting what the biotechnology industry represents in our country, certainly in my congressional

district. It is a great source of pride to anyone that represents them because of the innovation that they produce. In fact, for big pharma, the big companies look for innovation to the biotechnology industry and acquire them for -- because of their innovation. So thank you.

The chair now has the pleasure to recognize the gentleman from California, Mr. Cardenas, followed by Mr. Markwayne Mullin of Oklahoma. So you are recognized, Tony, for five minutes. Great to see you.

*Mr. Cardenas. Thank you, Madam Chairwoman. And I appreciate you and Ranking Member Guthrie for holding this important hearing. And thank you to all the witnesses for your expertise and opinions today.

We know that lowering prescription drug costs is a priority for all Americans, and I think that lowering healthcare costs overall is a priority as well. Even before the pandemic, one in four Americans reported difficulty affording their medications. Our current economic reality has only made it worse.

As the wealthiest country in the world, the high cost of prescription drugs is unjust, and for too long it literally has become a matter of life and death for many families and many children. No one should be forced to ration or avoid taking medications as to whether or not they can afford it. This is not what Americans or any person deserves, and I am

glad that our committee is working on the solution to address it today. And I hope that we can continue this fight to address the other 90 percent of costs that Americans are concerned about when it comes to healthcare overall.

And as we have prioritized affordability for patients with families. It is also important that we ensure research, development, and production of existing and new medicines can continue to make it to market so that we can have more cures and more lives saved, and also the quality of life of Americans is improved.

Ms. Ball, again thank you so much for your testimony today and for sharing such a personal story, not only about yourself but about the people you care for. Can you please expand on what it felt like for you to know this about patients who are rationing their care or who can't afford to get the care that they need because of prices? And what does it mean to you?

*Ms. Ball. What it meant to me is that not only did I have difficulty with my memory and my physical being, I also had to stop nursing. And that was the love of my life, so that was huge. It also is what I see is all my fellow advocates, people that I have run into in special groups -- they are past the point of what they can do. Their disease is progressing at a rapid pace, and they are not able to get their drugs.

I think that we need to look at this, as you said; that we need to get this bill passed in order for us to save the people in the United States with MS alone. I am sure it is affecting almost every disease, those that are disabled and also for the rare diseases. So it is something that needs to be dealt with.

You can't imagine that 1.1 billion people will die from the fact in the next decade for not receiving their medications. People in the United States should not, one, depend on charity to get their drugs, and people in the United States should be able to take care of themselves without having to depend on either charities or do I get my groceries? You see the imperative that we take this and we take it for -- it is for all of us.

*Mr. Cardenas. Thank you, Ms. Ball. Some bills we are discussing today involve biosimilars, biologics that are similar to other already Food and Drug Administration-approved biologic medicines. I believe biosimilars play a role in helping lower prescription drug costs for patients across the board.

That is why I reintroduced the Increasing Access to Biosimilars Act. By authorizing a Medicare pilot program, this bill would help encourage physicians to prescribe less expensive biosimilars, promoting healthy competition and increasing patient access to lifesaving prescription drugs by

making it more affordable for them.

Professor Sachs, could you please discuss your thoughts on biosimilars and how they could help increase affordability for patients and families?

*Ms. Sachs. Absolutely. And biosimilars and generic small molecule drugs are a key part of the social bargain that we have made with drug companies, where we give them exclusive rights, patents and an FDA exclusivity period, but we expect that at some point, competition through biosimilars and generics will enter and increase affordability for patients, increase our system affordability, and drive down prices.

And the U.S. has yet to realize the full promise of biosimilar competition, and it is very important to consider bills that would increase biosimilar competition in the U.S., as biosimilar competition in Europe is quite ahead of us by points of margin.

*Mr. Cardenas. Well, one of the things that I have a problem comparing us to Europe is that the United States invests more money in R&D in this field than they do in Europe. In addition to that, in the United States we have more talent, thank God. And the reason why we have more talent in this business somehow, some way, we have been able to create that environment. Hopefully we don't have a negative effect on that when we are trying to correct this

issue of drug pricing in America.

My time is expired. I am sorry, Madam Chair. I yield back.

*Ms. Eshoo. The gentleman yields back.

It is a pleasure to recognize the gentleman from Oklahoma, Markwayne Mullin. And we all hope that your son continues to make the progress that he has been making, which is really miraculous. And he will be followed by Dr. Ruiz from California. So you have your five-minute for questioning.

*Mr. Mullin. Well, thank you, Chairwoman Eshoo, and thank you for always being concerned about my son. It is ironic because we are talking about drug pricing, and one that I have to point out, that my son, he has to take a shot every week -- or every day, I am sorry -- and it costs about $4900 a month now because of the --

And sometimes the insurance pays. Sometimes the insurance doesn't. And it is a bit tough for my wife and I, much less thinking about what my son, who is 17 now, what he is going to do. I mean, when my wife and I got married, I was 19 and she was 18 and we were making $500 a week combined. We were just barely going to get by.

And to just think you are going to handcuff -- literally handcuff -- someone like that. So when we are talking about drug prices, I understand it. I get it. It is something

real to us, and we are not going to deal with it. But I still have a little bit of a hard time with H.R. 3. When you start thinking about H.R. 3, it is Government takeover of healthcare because when the Government gets into setting prices, then they are telling the manufacturers -- which is independent from the Federal Government.

They are entrepreneurs; it is what the United States thrives on, not Government takeover but of entrepreneurship -- when you start telling them how much they can charge, it is -- it does affect what they do and what they are willing to invest in because they are going to be capped on what they are able to get reimbursed for, whereas my opinion is we should be looking at what is prohibiting competition from coming into the market.

What is prohibiting individuals from entering the market? Why are we seeing the consolidation of pharmaceutical companies because with more competition, we would see prices come down because they are going to be competing for our pricing.

They are going to be competing for our business. If you are talking about insulin or you are talking about the shot that my son has to take every night because there is only one manufacturer that makes my son's shot, too. And so there is no market. It is either take it or leave it.

Dr. Gupta -- I hope I am saying that right; I know we

have all been using different names to get to you, but Dr. Gupta, is that how you pronounce it?

*Dr. Gupta. Yes, Congressman. Thank you.

*Mr. Mullin. Would you agree that innovation is the best way in the market to control pricing?

*Dr. Gupta. Well, I think that that is exactly right. And I think there are a couple of different aspects to it. As I have mentioned, the value we get from good prescription drugs via pharmaceutical purchasing in terms of improved health outcomes is second to none.

We have to remember that these drugs that we are talking about keep people out of the hospital, thereby saving overall healthcare costs. And I think that is an important point to remember. And I think time into your comments just a moment ago when these drugs go generic, when there is competition, we as a society save over $200 billion a year, $2 trillion a decade. And I think that is exactly the phenomenon that you were referring to.

*Mr. Mullin. So is it fair to say, then, that modernizing and recalibrating the natural price control like the generic drug pricing would help protect innovation and control pricing a little bit better, then?

*Dr. Gupta. It would not just protect it, sir. It would actually stimulate it. The generic -- genericization of medicines is not only a natural price control. It

actually stimulates innovate biopharma companies to develop new medicines. As an investor, that is a process that we support.

*Mr. Mullin. Right. I appreciate that. So with Government control in the market, do you feel like that really creates more partisan regulations that would prohibit new companies from entering into the market, then?

*Dr. Gupta. I think we can all agree that we should be limiting barriers to generic competitors. I think there have been good ideas posited on that. And I wanted to make a quick comment in this regard on biosimilars.

I see evidence of successful biosimilar entry in the U.S. as well. Biosimilars for drugs such as Avastin and Herceptin now have a 50 percent market share. There is a new company in those cases that has started to offer discounts. And that is natural price control in action.

*Mr. Mullin. All right. Well, listen. I appreciate your time. Chairwoman Eshoo, thank you for always being concerned. Thanks for bringing us together, too, because I do agree with a lot of my colleagues that there is room here for us to work on, and I think this affects all of our lives. And there is a lot of opportunity. I just really wish we had a more bipartisan approach.

H.R. 3, I don't think we really had a whole lot at the end; it has almost by my -- the committee is going to take it

or leave it. And this committee has had a history of working together, and ever since we have been on it, we have had a history of working together. And I know you want to work with us. I know there are other people across the aisle that want to work with us.

So I hope this is the beginning of us actually looking for a solution to have H.R. 3 work for all of us, Republicans and Democrats alike. So with that, I yield back.

*Ms. Eshoo. Thank you, Mr. Mullin. And thank you for always sharing your story with us. The American people are tuned in to these hearings. I think they sometimes have a picture that is not quite accurate about individual Members of Congress, the vulnerabilities in our families, what takes place in our lives. It is like holding a mirror up to the country. So I salute you for that. It really is very important.

The chair is pleased to recognize one of the doctors on our committee, Dr. Ruiz of California, followed by one of our pharmacists in the Congress, Mr. Carter from Georgia. So you are recognized, Dr. Ruiz, for five minutes.

*Mr. Ruiz. Thank you. Thank you very much for holding a hearing on this very important issue. And thank you to our witnesses for being here today.

During debate over the drug pricing policies, how Congress should address access and portability, it is

important to remember why we are having this debate in the first place, which is the patient. Unfortunately, the patient and the importance of access to health and life-giving medications sometimes gets lost in the shuffle.

But that is exactly what the core of this debate needs to be about. It is about the dad who can't afford the medication for his child and has to decide every month whether to cut corners on food for the family or medicine for his child.

It is about the mom who is working two jobs to help pay for her aging mother's medicine while also paying for healthcare for her kids.

It is about my patient who told me once that she collected cans to help pay for her insulin, and told me that she figured out a way to afford her medicine by only taking half of the dosage to make it last longer, which makes her medicine, of course, ineffective.

The average American often cannot afford their medication even if they have insurance, even if they have Medicare. So seniors and families all across America are rationing their medications. They are going without them completely because they simply cost too much. And I know I am hearing about it from my constituents, and I am sure that even up here on the dais is hearing similar stories.

For example, David, a senior from Beaumont, California,

in my district contacted my office recently to tell me about the heart medication his doctors want to prescribe but which there are no generic alternatives. The medication is so expensive that after the first three months of the year, David goes into the doughnut hole, where he will remain for the rest of the year, paying $3,294 in nine months just for his heart medications.

For seniors living on a fixed income, this is not affordable and is not acceptable. Individuals and their doctors should choose the treatment based on what is best for the health of the patient, not primarily on whether the patient can afford to pay for the drug out-of-pocket. This system is unacceptable. America can and must do better. And it is time we do something about it.

Healthcare is a right for everyone, and access to prescription medication should not be reserved as a privilege only for the wealthy few. Professor Sachs, thank you again for your testimony. This is a lot of discussion about the most effective way to bring down drug prices, including allowing the Secretary of HHS to negotiate prices directly with manufacturers, much like the VA does.

So H.R. 3 requires the Secretary to negotiate at least 25 of the most expensive sole source drugs in the first year, and at least 50 each year after that, as well as insulin. Would you agree that negotiating eligible drugs is the most

effective way to deliver the greatest amount of savings and best use of resources? And do you think that H.R. 3's mechanism for selecting drugs for negotiation? And do you think that H.R. 3's mechanism for selecting drugs for negotiation provides the most "bang for our buck''?

*Ms. Sachs. H.R. 3 certainly seems to be designed to provide the most bang for our negotiating buck. So the Secretary is explicitly told to select for negotiation the drugs the Secretary thinks will result in the greatest savings to either the Federal Government or beneficiaries throughout the relevant period.

And it makes sense to phase in the program and start with the subset offering drugs most likely to deliver the most savings before expanding.

*Mr. Ruiz. Thank you. And let's translate that to what it means for the patient. So CBO estimates that prices could be reduced by up to 55 percent for the first set of drugs negotiated by the Secretary. So what impact would those price reductions have on healthcare out-of-pocket costs for the patients?

*Ms. Sachs. Well, as the physician, you are an expert, certainly. But the CBO has said that if patients are more easily able to afford their prescription drugs, then they will take those prescription drugs. And in at least some conditions, they will have lower overall healthcare costs.

If you can avoid hospitalizing a patient because they are taking their medication on a regular basis, that is very important and it can lower healthcare costs overall.

*Mr. Ruiz. Thank you very much. This is so important for our Nation. It is not fair that America has to pay three times as much as other countries on the exact same medication. So America can and must do better. And I thank everybody for being here today, and I yield back my time.

*Ms. Eshoo. The gentleman yields back.

The chair is pleased to recognize the gentleman from Georgia, Mr. Carter, followed by our colleague, Congresswoman Debbie Dingell of Michigan. So are you recognized, Buddy, for five minutes.

*Mr. Carter. Thank you, Madam Chair. And thank all of you for being here to the witnesses. And you know, as a pharmacist for over 30 years, this is the one issue that has frustrated me more than any other issue that I have tried to work on while I have been a member of Congress because the answer is so simple and is so clear.

The problem to me, from my perspective, is the vertical integration that exists within our healthcare system. When have the insurance company that owns the PBM, that owns the pharmacy, you have a vertical integration there by which any time you squeeze that balloon, the only thing that is going to happen is it is going to go somewhere else. And what is

what is happening here.

Dr. Gupta, you referenced PBMs and the problems that they had in your opening testimony. And that is the problem. I know. I am a pharmacist. I was a retail pharmacist, an independent retail pharmacist. I am the one who signed the front of the paychecks. I had to make the numbers work. And I know where the problem is.

And the problem right now is that you have three PBMs that are all owned by insurance companies. Someone made the point -- I believe it was you, Dr. Gupta -- that prescription drug prices are only a small percentage of the total healthcare cost. And they are.

But the problem is, the reason that prescription drug prices are so high is because when you have Aetna that owns Caremark that owns CVS, when you have Cigna that owns Express Scripts PBM that owns Express Scripts mail order pharmacy, which by the way is the second busiest in terms of volume in the Nation, when you have United which has the insurance, the PBM, and the pharmacy as well, then you have three PBMs that own -- that cover over 70 percent of the market. There is no competition there.

And that is what has got to be broken up. And yet we tend, in Congress, to try to attack it from a different perspective. And then we have a bill like H.R. 3. I appreciate and I applaud you, Madam Chair, and I applaud the

majority party as well as the minority party, for trying to address this problem. But this is going to hurt more than it is going to help.

I tell this story all the time. When I first started practicing pharmacy in 1980, if you were diagnosed with hepatitis C, it meant you were going to die because we didn't have a cure for it. Now, through research and development by the pharmaceutical manufacturers, you can take a single pill and be cured of it. That is nothing short of phenomenal.

However, if that simple pill costs $85,000 and you can't afford it, it does you no good whatsoever. The problem is, we have got to break up that monopoly, that vertical integration.

Dr. Gupta, I want to ask you: How important do you think this issue is and saving patients would have if PBMs were held accountable, if the middlemen, who bring no value whatsoever to the healthcare system, if they were made to be transparent and accountable?

*Dr. Gupta. Well, Congressman, there is a [audio drop] in the PBM industry and in general among prescription drug middlemen, in fact, of what we spend on prescription branded drugs. Only 53 percent is estimated to actually make it back to manufacturers, and the middlemen are not just taking a small cut. They are taking, in many cases, a substantial cut. And transparency --

*Mr. Carter. I am sorry, Dr. Gupta. What are they doing with that 47 percent? Are they putting it back into research and development? At least the pharmaceutical manufacturers are putting it back into research and development.

*Dr. Gupta. You are right, Congressman. I think that the middlemen have consolidated, and three entities have really outsized market power right now because they represent sha vast proportion of lives.

*Mr. Carter. And my concern with H.R. 3 is it is going to stifle innovation. I mentioned hepatitis, and I mentioned all the other things that I have seen nothing short of miracles come out of research and development over my many years of practice in pharmacy.

I think about my friends that suffer and that have family members that suffer from Alzheimer's. Right now there are currently estimated to be almost six million Americans with Alzheimer's. But by 2050, the Americans age 65 and older with Alzheimer's is projected to be as high as 14 million.

We have had 146 unsuccessful attempts to develop medicines to treat Alzheimer's. Dr. Gupta, what is H.R. 3 going to do to research and development for potential cures for Alzheimer's?

*Dr. Gupta. I think it could be done, not just

Alzheimer's but these -- ALS and similar diseases, where we haven't, unfortunately, made very much progress. We continue to try. We continue to take the best and purpose resources into them. But eliminating the potential for incentivizing that innovation, I think, could be devastating.

*Mr. Carter. Madam Chair, I appreciate your indulgence. I am just telling you: The solution is simple. It is right before us, and we are not getting it. We are not understanding that it is right -- all we have got to do is break up this vertical integration that exists within the healthcare system. If we break it up, we can do something about prescription drug prices. We can do something about healthcare costs.

Thank you, Madam Chair, and I'll yield back.

*Ms. Eshoo. Thank you, Mr. Carter. And I agree with you on the issue of PBMs. I really think that we miss an opportunity for very important reform, and I have held that view for some time. So thank you for your constituent passion about that.

The chair now has the pleasure to recognize the gentlewoman from Michigan, a name that is honored over decades in the Congress, Congresswoman Dingell, followed by one of our distinguished doctors on the committee. Dr. Neal Dunn of Florida will follow her.

Debbie, you are recognized for five minutes.

*Mrs. Dingell. Thank you, Madam Chair. And my heart is with my friend and colleague, too. We do need to talk about that. But I don't want to draw attention from some of the issues that we are talking about today. And Ranking Member Guthrie, thank you, too, because this hearing is just so important because so many of us have constituents who simply can't afford their medicine.

We have heard some arguments here today that if H.R. 3 were to become law, then there is a likelihood that innovation would be driven to China. I think that this is a red herring, let's be clear, because absolutely nothing in H.R. 3 is closing the U.S. market for drug manufacturers or drug development.

The fact is that the United States is the largest pharmaceutical market in the world, and the pharmaceutical industry relies heavily on the premium academic institutions for their R&D work. There is no reason to believe H.R. 3 will fundamentally alter this dynamic. Innovate occurs where the best science is done, and the best science happens here in the United States of America.

And there is no doubt that the U.S. will continue to be the world's leader in funding for basic medical science. And H.R. 3 provides additional resources to NIH to maintain our Nation's role as a global leader in innovation.

So Professor Sachs and Professor Carrier, we have heard

claims today that China can run clinical trials faster than U.S. counterparts. But does that mean they are better? Americans expect that the drugs that they and their families are going to take should meet rigorous review standards in order to ensure they are safe and effective.

Do you agree that the Food and Drug Administration is the gold standard for drug approvals in the world? And whichever one of you wants to go first.

*Mr. Carrier. Yes. I do think that the U.S. FDA is the gold standard for the world.

*Mrs. Dingell. Professor Sachs?

*Ms. Sachs. I agree completely.

*Mrs. Dingell. Additionally, Professor Sachs and Professor Carrier, isn't it fair to say that China pays relatively low prices for drugs? Why would we expect the Chinese market to have greater innovation potential than the United States?

*Ms. Sachs. That is absolutely correct. China pays lower prices for drugs than we do. And I think you put it well when you said that innovation occurs where the best science is done, not where the drug prices are the highest.

*Mrs. Dingell. Professor Carrier, any comments?

*Mr. Carrier. Sure. I think that one issue that we haven't talked enough about is the type of innovation that would be affected by H.R. 3. So we are not talking about

that many drugs. It is only 8 to 15 fewer drugs out of a total of 300, according to the studies.

And if you look at the type of drugs here, they are not the most revolutionary drugs. So for example, there is one study that has come out that looked at 122 ultra-expensive drugs in Medicare annual spending of $63,000 a year, and found that 73 to 85 percent of them have no or low additional added value. And so when we are talking about this, we are not talking about the blockbuster drugs. We are talking about a lot of "me, too'' drugs.

*Mrs. Dingell. Well, let me ask you about that because I hear from my constituents about the high cost of older drugs like albuterol. I mean, everybody on the committee knows that I cannot get the story of the mother out of my head who has to pay $800 for an inhaler. And so, for example, inhalers to treat asthma can cost hundreds of dollars, but they are decades-old drugs.

Professor Sachs and Professor Carrier, how the H.R. 3 framework incentivize new innovative frontline research rather than the ultra "me, too'' drugs that you just discussed?

*Mr. Carrier. Well, it will force pharma to create new innovations. Pharma has played all sorts of anti-competitive games, and they have relied on those games, and they have relied on charging whatever price they want in the U.S. so

they don't have to do quite as much innovation.

Sure, innovation of the revolutionary kind is hard, but to the extent you can rely on these tricks that have gotten you to this point, then there is no need to go beyond that.

*Mrs. Dingell. Professor Sachs?

*Ms. Sachs. I agree -- yes. My apologies. I agree. If you look at the top-selling drugs in Medicare right now, Part B and Part D, most of them are over a decade old. These are drugs that have recouped their investment and have had plenty of protected time on the market.

Negotiating for the prices of these drugs won't harm innovation in the future. It will make space for future innovation in just the way Professor Carrier said.

*Mrs. Dingell. Thank you both. Madam Chair, with 12 seconds left, I guess I will yield those back.

*Ms. Eshoo. The gentlewoman yields back.

It is a pleasure to recognize Dr. Dunn of Florida. And he will be followed by our colleague, Congresswoman Kuster. Dr. Dunn, you are recognized.

*Mr. Dunn. Thanks very much, Madam Chair.

*Ms. Eshoo. Thanks for your patience.

*Mr. Dunn. Appreciate it. No, no, I appreciate your having this hearing.

We all know that the policies we make in Washington can have tradeoffs, both good and bad. But any policy that will

choke off investment in an entire industry, and an industry that is in the industry of making cures, is bad policy.

I want to associate myself with Dr. Gupta's testimony. I think we are living in a truly fascinating age with medicine and cancer treatments, gene therapies, CAR T therapies, monoclonal antibody treatments, and many more are in development or recently hit the market.

And we all want Americans to have access to these new, innovative cures. Americans already have access to more cures than do the citizens of the nations that H.R. 3 seeks to tie our drug prices to. Why take a step backwards and restrict access to cures for sick Americans?

The quality of life metric, so-called QALYs or quality-adjusted life years, are built into the prices some of our European friends pay for their prescription drugs. By these calculations, a treatment that extends the life of a disabled patient is worth less than a treatment for a young, healthy patient. This is not an attitude we should be importing, and it flies in the face of the Americans with Disabilities Act.

In Florida, the estimated impact of H.R. 3 is a loss of nearly $7 billion in economic output; 300,000 jobs, many of them at small and medium-sized biotech companies, and doing clinical research. H.R. 3 is an industry-killing proposal at a time when so many cures are on the horizon, and it is strikingly short-sighted in the wake of a global pandemic.

To be clear, I think Americans should have access to the kinds of cures I am talking about at an affordable price. We all want the prices to come down. I associate myself with Buddy Carter's remarks on that. But let's not destroy the American pharmaceutical industry and strangle innovation in the process.

H.R. 19, the Lower Costs, More Cures Act, is full of bipartisan provisions to achieve just that. Fully 17 of these provisions were signed into law last year after careful bipartisan reaction. We passed transparency. We classified insulin as a biologic, improved generic medicines. Forty more bipartisan provisions are included in the H.R. 19 bill this Congress.

And it includes provisions to reduce out-of-pocket costs, learn more about the costs of middlemen in the pharmaceutical industry, combat shady practices, extending patents, et cetera. I am disappointed by this shortsighted effort to control prices at the cost of tradeoffs that are just too harmful to patients suffering from many diseases.

Dr. Gupta, I would like to direct my questions to you. We just witnessed the incredible speed at which vaccines were developed in COVID. Can you think of any control on H.R. 3's international reference price list that produced and delivered multiple COVID vaccines to market over the last year? And do you relate that to the relative capabilities of

the pharmaceutical industries in those countries before the pandemic arrived?

*Dr. Gupta. Absolutely. Thank you, Congressman. I think it is important to recognize that, for instance, there were certain therapies such as dexamethasone, which was a generic drug which ended up being effective. Perhaps we would have been able to develop the monoclonal antibodies -- I think we would have -- that serve for acute patients. And certain types of the vaccines, including the antivirus vaccines, may have been developed as well.

But the mRNA vaccines, I think it is important to recognize thought it was biotech investment over the preceding several years that laid the foundation that allowed them to be positioned and rapidly developed an effective vaccine in under a year.

*Mr. Dunn. Thank you. So let me charge ahead with our limited time. Dr. Gupta again, it takes 10, 15 years for new treatment to make it through the pipeline. There are currently over 250 cell and gene therapies in early clinical stage trials, 17 for ALS, 16 for MS, and 300 for rare pediatric diseases. What happens to these potential cures if H.R. 3 is signed into law? And do you think the manufacturers will pursue approval for these drugs if H.R. 3 is enacted?

*Dr. Gupta. I think some of them may. I think some of

them try to do the math and realize that there is no longer an argument to be made to pursue it. I think that the longer extreme danger is that it will close up the funnel at the top end and we might never get to 1,000, 2,000, or 10,000 cell and gene therapies in the pipeline, which is where we should be headed.

*Mr. Dunn. Good. So I want to relate a quote from an Australian physician in the last few seconds here. He said, "I disagree with Government decisions often because I want to use a medication which is shown to be of benefit and is the standard of care in the United States that I just can't use.'' That was by an Australian hematologist.

This is what we risk if we go down the path of H.R. 3. Why on earth would we want to import these frustrating, tragic stories to our practices?

With that, Madam Chair, I yield back. Thank you again for having this important hearing.

*Ms. Eshoo. I thank the gentleman and he yields back.

The chair is pleased to recognize a good friend to all of us, the gentlewoman from New Hampshire, Ms. Kuster, being followed by Mr. Curtis of Utah.

Annie, you are recognized for your five minutes of questions.

*Ms. Kuster. Thank you so much, Chairwoman Eshoo, for holding this important hearing today to discuss legislation

to lower the cost of prescription drugs for the American people.

For too long Americans have been grappling with the skyrocketing costs of prescription drugs, and the current trajectory for what Americans, and particularly seniors on Medicare Part D, pay is simply unsustainable, and the status quo is simply unacceptable.

For years, since I began running for Congress, I have been calling on Medicare to be able to negotiate the price of prescription drugs, a policy that has broad support amongst the American people and would generate literally billions of dollars in savings. So I am so pleased to see this provision included in the Elijah Cummings Lower Drug Costs Now Act.

Legislative reforms to how we price drugs and medication in America should be a nonpartisan issue. It doesn't matter what your party affiliation is or where you live. Americans in every corner of our country are seeing more and more of their hard-earned dollars going to prescription drugs and lifesaving treatments.

And that is why I am so pleased to partner with my friend and colleague, Republican Congressman David McKinley, on bipartisan legislation to create billions in savings for Medicare Part D beneficiaries. Last week we introduced the Ensuring Access to Lower Cost Medicines for Seniors Act, which aims to ensure Medicare beneficiaries receive the full

benefit of affordable generic drugs.

The placement of generic and biosimilar medicines in the same pricing terrace, more expensive brand drugs, has led to seniors paying more out-of-pocket costs for their medicine. Our bipartisan bill seeks to reverse this trend by ensuring automatic coverage of lower-cost generic medications immediately after launch, and the creation of a dedicated specialty tier for specialty generics that offer lower-cost sharing for seniors.

The Ensuring Access to Lower Cost Medicines for Seniors Act could save seniors $4 billion per year through reforms to how generics and biosimilars are covered. And I want to thank Chairwoman Eshoo for including this bipartisan bill in today's hearing.

Ms. Sachs, thank you for your testimony and for discussing how some of the misaligned incentives. It is how Medicare Part D operates. In your opinion, does Medicare Part D's design currently incentivize the coverage of brand-name drugs even when lower-cost generic medicines might be available?

*Ms. Sachs. I would agree that there are elements of the Part D design which contribute to this. But it is also really about the relationships between the Part D plans and the PBMs as well.

*Ms. Kuster. So thank you. Several Part D plans offer

more favorable formulary placements to branded drugs than they do to lower-priced generics. Would the creation of a separate specialty tier for generic drugs in Part D have the possibility of lowering out-of-pocket costs for seniors?

*Ms. Sachs. It would absolutely have the possibility of doing that. And the reason is that today, a lot of seniors' out-of-pocket costs are based on the list price of the drugs even if the negotiated net price is much lower than that. And so giving them those generic prices would be very helpful.

*Ms. Kuster. And do you have any sense of what the savings could be for seniors across this country?

*Ms. Sachs. I don't. That would be a question for CBO. But more generally, you are right to say that this is the type of bill which responds to some of the misaligned incentives, particularly involving the PBM-insurance plan relationship.

*Ms. Kuster. Great. Well, thank you very much. I appreciate it.

And Madam Chair, let the record reflect I yield back with a minute to go.

*Ms. Eshoo. You go. Thank you. The gentlewoman yields back.

A pleasure to recognize the gentleman from Utah, Mr. Curtis, followed by our colleague, Ms. Barragan from

California. So you are recognized for five minutes, Mr. Curtis. Nice to see you.

*Mr. Curtis. Thank you. Yes. Very good to see you. Thank you, Madam Chair. It has been a very great hearing. Appreciate the comments of all my colleagues. And I would particularly like to associate myself with the representative who referred to this as "good stuff.'' That is a great way to describe it.

Mr. Guthrie, I love to brag about the startup economy here in Utah, which is largely responsible for us being on the forefront of economic development and recovery. I'm aware of 20 startup biotech companies that are working on cures for deadly diseases like COVID-19 and rare forms of cancer.

To bring this home, in Utah alone it is estimated that H.R. 3 would result in the loss of nearly 20,000 jobs and a loss of over $4 billion in economic output. My experience tells me that regulations like what we're looking at in H.R. 3 are disproportionately hard and hurt small businesses.

Could you share how you feel smaller biotech companies would access funding that they need in order to do the drug discovery and eventually drug development if H.R. 3 becomes law?

*Dr. Gupta. I'd be delighted to, Congressman. And that's particularly the intersection of biotechnology and

finance in which I find myself, which is to say that reminding ourselves that it's smaller biotech companies that are primarily charged with bringing innovative products forward and represent about 70 percent of innovative drugs in phase 3 today.

With price controls, I think that the smaller biotech companies will be disproportionately impacted, which is why the overall impact on innovation will be high. There might be large organizations that will have other access to capital or be able to reprioritize from large budgets. But small biotech companies will be very vulnerable to this legislation.

*Mr. Curtis. Thank you. Ms. Davis, while we were all touched by your story of Hunter, I am told that many companies have patient assistance programs that help patients pay for costs of medications at little or actually no cost. They also have cost-sharing programs to assist the insured patients pay for out-of-pocket costs.

I am curious: Have you or any of your families you know benefitted from these programs?

*Ms. Davis. Yes. In my testimony I discussed Ben, who participated in a free drug patient assistance program. I also know a number of patients that participate in patient assistance programs that provide assistance towards their copays, deductibles, and coinsurance, which have risen so

high in recent years.

Sadly, insurers have enacted copay accumulator programs which make the benefits of patient assistance programs really inapplicable to patients.

*Mr. Curtis. Thank you. And quickly, Dr. Gupta, as a followup, is it fair to say that if H.R. 3 is enacted, this charity care would be among the first things that we would see going?

*Dr. Gupta. You know, Congressman, I haven't contemplated that in the past, and I think I would have to get back to you, actually.

*Mr. Curtis. Okay. I would love to know that. Let me also point out, Dr. Gupta, we know these rare diseases strike in an unpredictable and very cruel way. As an example, I have lost three neighbors -- and by neighbors, I am talking within two blocks in my home -- to ALS over the last several years, and currently another neighbor and a very close friend of mine is an ALS patient. Fortunately, he has the resources to enroll in clinical trials for experimental therapies to treat his ALS. And quite frankly, he credits these trials for the very, very small progression of the disease, which is unusual.

If H.R. 3 were to pass, there are studies that indicate that there would be a 90 percent reduction in drugs developed by small biotech companies over the next decade, some of

which could help ALS patients. Do you share the same belief, that H.R. 3 would lead to reductions in competition and overall reductions in drug development?

*Dr. Gupta. Absolutely. And I think it is something that we heard earlier, was that types of drugs that would be eliminated would be primarily non-innovative drugs. I don't agree with that. I think that the types of drugs we would lose out on would be the most innovative, the most risky, and for the diseases where we have made the least progress, and that includes ALS, Parkinson's, and Alzheimer's disease.

*Mr. Curtis. Yes. Just in the few seconds I have left, can you explain the impact of H.R. 3 on clinical trials that have helped my friend?

*Dr. Gupta. Very briefly I would say that I think it will reduce the incentive to fund the clinical trials, which are expensive, and therefore reduce the number of innovate medicines available via clinical trials.

*Mr. Curtis. Very good. And Madam Chair, thank you very much. I yield my time.

*Ms. Eshoo. The gentleman yields back.

It is a pleasure to recognize our colleague form California, Ms. Barragan, followed by one of our distinguished doctors on the committee, Dr. Joyce of Pennsylvania. So you are recognized, Annette. Great to see you.

*Ms. Barragan. Thank you, Chairwoman Eshoo, for holding this important hearing on legislation to lower prescription drug prices, including H.R. 3.

The last Congress, we took some of the savings from this bill and reinvested them to expand Medicare. I hope that we decide to do that again, and this time to expand things like access to dental coverage for Medicare beneficiaries.

Two-thirds of seniors and individuals with disabilities in the Medicare program do not have oral health coverage. Oftentimes these individuals are living on a fixed income, and beneficiaries struggle to be able to afford and receive dental care.

I currently have a bill, the Medicare Dental Benefit Act, which is H.R. 502, which would expand Medicare Part B benefits to cover dental and oral health services, including things like routine cleanings, exams, fillings, crowns, major services such as root canals and extractions, emergency dental care, and other necessary services. I am hopeful that my bill, as well as other proposals by my colleagues to expand Medicare services, can be considered as we move forward.

Now I want to talk a little bit about labeling exclusivity. In addition to H.R. 3, today we consider my legislation to bring more competition to the drug market. The bill is called the Prompt Approval of Safe Generic Drugs

Act. We know that as more generic drugs come into the market, prices drop dramatically. However, throughout our system, small hurdles remain for generic competition, and my bill addresses one example of how we can address that.

Under current law, generics can be blocked from entering the market if safety information on a brand drug label is protected under exclusivity but no other hurdles remain. My bill would create a path forward for generic competition in these instances, by allowing the Food and Drug Administration to allow a statement of appropriate safety information to the generic drug's label to assure safe use.

My bill stands for something quite simple: Safety information should be a feature of drug labels, not a bar to competition. The FDA supports this legislation, and the CBO recognizes this is a problem, estimating that fixing it would save $164 million.

Professor Carrier, I recognize this is just one issue we are discussing here today. But can you discuss how regulatory issues like this can promote competition and lower drug prices for consumers?

*Mr. Carrier. Yes, I can. Thank you for the question. And you are absolutely right that this is an important issue. There are many ways in which generics are not able to enter the market, and you put those all together and American consumers suffer because they are not able to afford their

drugs.

And so I appreciate your leadership on this piece of legislation. You are right that generics should be able to enter the market if the only thing that is blocking them is the label from the brand company. And so this would be one piece of legislation that could bring generics to the market faster.

*Ms. Barragan. Great. Thank you. Another issue that we've been hearing a lot about today is, just let the market do its thing and that will take care of itself. And that hasn't worked. That's why Congress has to step in and do something. Just taking a look at things like insulin, where it started and where it has gone is a good example of why we need H.R. 3 and why we need action.

Communities of color, including my community, that has a very high rate of diabetes -- my district is almost 90 percent Latino, African American, low-income -- have really high rates.

Professor Sachs, what will be the impact for diabetics, especially communities of color, if insulin prices are negotiated?

*Ms. Sachs. It could be very significant for health and for closing health disparities because we have these decades-old drugs whose prices continue to rise year after year, seemingly without justification. So by lowering those

prices, we can improve adherence and help mitigate some of those racial disparities.

*Ms. Barragan. Thank you. And thank you to our panelists and to the chairwoman. With that, I yield back.

*Ms. Eshoo. The gentlewoman yields back.

The chair now is very pleased to recognize the doctor, a gentleman from Pennsylvania, Dr. Joyce, followed by our colleague from Delaware, Ms. Blunt Rochester. So you are recognized, Doctor. Good to see you.

*Ms. Joyce. Thank you for yielding, Madam Chair and Ranking Member Guthrie. Thank you for all the witnesses for being here with us today to discuss this incredibly important issue.

I want to first talk about a case that I personally was involved with. Ten years ago I diagnosed Charlie, a 62-year-old man, with melanoma on his right thigh. And at diagnosis, the disease was only found locally, and further evaluation showed that there at that time was no spread of the disease.

Two years later, he developed evidence of metastatic melanoma involving internal organs. And then he received what was at that time standard of care therapy with interferon, and unfortunately, his melanoma progressed. Subsequently, he was started on one of the new immunotherapies approved for metastatic melanoma, Similar to what we know President Carter has subsequently received as

well.

Initially his disease did respond to the therapy. But within weeks, the melanoma continued to spread. My then-64-year-old patient was started on a different immunotherapy to treat his melanoma. His response was remarkable, and it was significant. He continued on that therapy until complete remission of the disease was attained.

Today, ten years later, he is symptom-free. He is disease-free. His imaging studies, which include CAT scans, MRIs, PET scans, show no evidence of disease. Last Friday, April 30th, I talked to Charlie on the phone, and he has such great insight on how the opportunity to have tried two different immunotherapies as the treatment for metastatic melanoma have allowed him to be completely cured.

During that phone call I asked Charlie if he had been given the opportunity to have tried a second immunotherapy but not have had that cure in the United States, he said, "I would have pursue it wherever I could.'' But given the opportunity to have tried a second immunotherapy after the first one failed, I asked Charlie, "What does that mean to you?'' Charlie is very blunt and straightforward with me. He said, "Without the opportunity to have tried two immunotherapies to treat my metastatic melanoma, I would be dead.''

The drugs that he was allowed to use were Opdivo and

Keytruda, and they presented huge advancements in the treatment of metastatic melanoma. The chance to have two therapies for metastatic melanoma has allowed today for patients to be cured.

My questions first are for Dr. Gupta, Knowing that there are countless tragic stories of physicians in other countries who cannot allow their patients to have these innovations because they don't have access to them because of their Government authority.

Opdivo is only approved for five of the 14 indications in Australia, and in France, only four of the 14 indications are approved. This frustration we should receive as a warning to all of us -- to American patients, to American physicians -- that if we go down the path of H.R. 3, we are going to lose access, innovation, and cure.

Dr. Gupta, as a physician, can you tell us more about what H.R. 3's foreign price controls would mean for U.S. physicians and for the patients that you serve and the patients that need these innovations?

*Dr. Gupta. Well, thank you, Congressman, for the opportunity. And I think it is actually right that other countries have shown a willingness to block groundbreaking medicines from reaching their citizens. And I think that is morally indefensible. I think that is the last thing that we should be trying to import from another country.

As a physician, having had the privilege of practicing medicine like yourself, what I most wanted for my patients was for them to get the medications that were prescribed for them. And there should be nobody coming between a patient and their doctor. And I think that we should not be emulating the systems that other countries have to blockade innovations from getting to patients.

*Ms. Joyce. So is it fair, Dr. Gupta, to say that American doctors could be put in that position where they wouldn't be able to prescribe what they know their patients need and what they know could cure their patients?

*Dr. Gupta. I think that is possible, yes.

*Ms. Joyce. And does that mean that these patients, particularly our most vulnerable, may be at risk for worse health complications, worse outcomes, if restricted access to drugs and therapies were implemented?

*Dr. Gupta. Absolutely. As we have heard, not just days but human resources and minutes can matter, and it is a matter of getting innovative drugs to patients as fast as possible to help the most number of people. And I think that is what we all are attempting to do.

*Ms. Joyce. I thank you for your answers.

Madam Chair, I thank you for allowing us to present and talk about access, innovation, and cure. And I yield my remaining time.

*Ms. Eshoo. The gentleman yields back.

And it is a pleasure to recognize the gentlewoman from Delaware, Congresswoman Blunt Rochester. And she will be followed by the gentleman from North Carolina, Mr. Hudson. So you are recognized, Lisa. Great to see you.

*Ms. Blunt Rochester. Good to see you, Madam Chairwoman. And thank you so much, Madam Chairwoman, for your leadership on this issue. I know we have talked many times about it on the floor as well as in committee, and I know this is a priority.

And thank you especially to our ranking member and the witnesses for joining us here today. As evidenced by the interest and ideas of my fellow members, you can see that we all know that the current system is not sustainable, and that the focus really needs to be on making sure that Americans are well and safe.

And Ms. Ball, I essentially want to thank you for sharing your story with us. As someone who has both spent much of your life caring for others as a registered nurse and as a multiple sclerosis patient yourself, today you represent millions of Americans who are struggling to afford medications that improve their health and save their lives. The pandemic has been hard on many families like yours, and it is unacceptable that you and so many others should have to really choose between thinking medications and paying your

bills while the prices continue to rise.

And so, Ms. Ball, you mentioned that the cost for your medication has gone up substantially over time. What did that means for your out-of-pocket spending when your drug cost increased? How did it impact your monthly budget for other things, like groceries and gas?

*Ms. Ball. When I received the information that I had the grant, it was $6,000. I called so many pharmacies to see if it could be less. So basically, we tried to rearrange everything that we could as far as groceries, and going to live at my daughter's house; also, having the fact that I wasn't able to practice anymore, so there was no income coming in.

As far as groceries and such, when I made the final decision that I couldn't take the drug, that kind of put it back a little bit into perspective. But in essence, it is very difficult. Very difficult. When I did my $1800 at the very beginning of my diagnosis, it was -- I had to move to a smaller place. I had -- there was many, many, many things. And I had the advantage of having a family that could help me. And there are many of us out here that don't.

*Ms. Blunt Rochester. I know you talked about the increase in the price year after year. What sticks out to you the most about that experience?

*Ms. Ball. I guess what sticks out to me is that if

they would have been doing something innovative, if they were doing something that was reaching to a cure, I could have understood, even for a small amount of time, because they have to pay for what they are doing.

But the fact that all it was anymore a way of them to take the price up for something that is absolutely the same -- it wasn't really approved in the sense that they didn't think it made the FDA and people from NIH didn't feel that it had given any kind of improvement. And it didn't. So that is a lot of money that people are putting out for something that is not coming close to a cure.

*Ms. Blunt Rochester. And what do you think that this means for retired Americans who live on fixed incomes? And lastly, from your perspective, could you also talk about the inflation rebate proposal included in H.R. 3, and if you think that that would help you afford the prescriptions that you need?

*Ms. Ball. Well, for people that have a -- that are retired, such as myself, it is very difficult because you only get so much in Medicare. So if you have a $2,000 cap, which would be great, and you don't have the amount of money as far as negotiating the money for us to get the right amount of money to pay for it, the $2,000 cap would help. So we need to be able to do that.

And I must apologize. I am not very well-versed on that

part of that because I have never had to work with it. But thank you for asking me.

*Ms. Blunt Rochester. No problem. Thank you.

Ms. Sachs, I just had a question for you. What do you say to people who say that H.R. 3 won't actually lower the cost of drugs?

*Ms. Sachs. I think it absolutely will lower the cost of drugs, not only for patients but also for payers. And here, I think the CBO's estimate of how much it will save, $456 billion over a decade -- if that's off even by a little bit, it would be a tremendous savings for American patients, savings which could be used to expand access to insurance more generally.

*Ms. Blunt Rochester. Thank you so much. I think what we have heard today is that this is a complex issue, that we need to be comprehensive in our approach, and that we need to make sure that we are watching out for our constituents as well as not stifling innovation. I believe that we can do it, and we need to do it.

Thank you so much, Madam Chair, and I yield back.

*Ms. Eshoo. The gentlewoman yields back.

It is really a pleasure to welcome back to the committee our wonderful colleague, Mr. Crenshaw. A lot of us prayed for you. It is great to see you. Hope you are feeling 100 percent better, and that what you endured has brought you

back to full eye strength. And I am so happy to see you. I hope you got my message, too. So you are recognized for five minutes, Mr. Crenshaw. And you'll be followed by our colleague from Minnesota, Ms. Craig. Mr. Hudson had to leave, so that's why you're next. Really nice to see you.

*Mr. Crenshaw. Well, thank you for the kind words, Madam Chairwoman. It is a pleasure to be with you all. I still can't see you, but I do feel better.

I should see normally in a few weeks, I hope. I have got to wait for this procedure to sort of follow its actual path. But we are optimistic that I will have some sense of normal in a few weeks to a month.

*Ms. Eshoo. Great. Great.

*Mr. Crenshaw. Thanks for all the good wishes. Really appreciate it. But like I said in the last hearing, even a blind knuckle-dragger can do hearings. So here we are.

Look, this bill is really important. I've been talking about this bill for a long time, and I appreciate us doing a hearing on this really important topic. I think we all want lower drug prices. I think the question is: How do we get there without killing the goose that lays the golden egg?

There has been a lot of concern about innovation. There has been a lot of concern about the fact that when we reverse incentives to invest, one study shows that this will directly hit the smaller biotech firms. Over 90 percent of them will

reduce their investment. We will see a massive decrease in new cures, cures that could save lives, that could reduce healthcare costs in the long term.

And we talked a lot about negotiation. Ms. Sachs, this question is for you. Is it really fair to call the process laid out here a negotiation?

*Ms. Sachs. Yes. I believe it is. Nothing in H.R. 3 tells a pharmaceutical company what they can and can't charge. They limit how much those companies are able to demand those prices of the Federal Government.

*Mr. Crenshaw. Right. But if they don't come to the table with the Federal Government, they are levied a 95 percent tax on their revenues. Correct? That doesn't seem like a negotiation. It seems like extortion.

*Ms. Sachs. And right now Medicare is a price taker. They have to accept the prices being demanded by pharmaceutical companies, and have relatively little ability to push back on those prices. That is not how the free market negotiation works.

*Mr. Crenshaw. Right. But if I am the Government and you are a private citizen and I want your services. And you say, well, for that price that you are offering me, sir, I won't give you my services. And I say, if you don't give me your services, I am going to levy a tax on you, 95 percent of your revenues from now on. That is not a negotiation.

Nothing close to it.

The other problem I see with the process laid out here is that again, it is called a negotiation, but that is not how bureaucrats work. It can't work that way because of the Administrative Procedures Act, because of Section 1871 within Medicare. It can't possibly work that way. It can only work as a formula. So it's just simply false to say it is a negotiation. Isn't it just price-setting?

*Ms. Sachs. I would welcome more details on how the Administrative Procedures Act is a barrier here. It is not entirely clear to me how it would be. What I will say is that CMS and --

*Mr. Crenshaw. I will tell you. Let me -- I will explain it really -- what it basically says is that you have to have an objective way of setting a price. It cannot be subjective. And of course this makes sense because we can't give one company a subjective negotiation and say, hey, you know what? We will give you 90 percent of your costs. And then we, say, give another company only 80 percent of the cost. You are a lawyer. What would happen? You would have lawsuits. You would have endless lawsuits. That is why we have these procedures in place.

*Ms. Sachs. So we have here is a clear delegation to the Secretary of the criteria they should use in engaging in negotiation.

*Mr. Crenshaw. Exactly. And every lawyer we have talked to, every single one, says there is only one outcome that will happen here. The Secretary will set up a formula. It is not going to be the Secretary talking to the CEO of Pfizer, is it? No. It is going to be a midlevel bureaucrat. That midlevel bureaucrat isn't allowed to think subjectively about how they negotiate. Right? They have to follow a formula. It is going to be a failure --

*Ms. Sachs. No. That is a mischaracterization of H.R. 3.

*Mr. Crenshaw. But that is exactly now it will be interpreted into the rulemaking, wouldn't it?

*Ms. Sachs. No. I think there is no reason to believe that that would be --

*Mr. Crenshaw. Well, every other lawyer we talked to, the counsels from CMS, counsels from CRS, say that that is exactly how this would be interpreted. In fact, it has to be, according to Section 1871 from Medicare.

*Ms. Sachs. I think what is important here is to remember that we are talking about paying prices that are closer to the much lower prices that are being paid abroad. And that is setting up the framework for this broader negotiation. And the Secretary is given the discretion to use different criteria to negotiate within that framework.

*Mr. Crenshaw. That may be the case for older drugs.

But newer drugs will simply not be invested in. Again, I don't dispute your earlier comments that it would immediately lower drug prices. Of course. I mean, by law it is making their drug prices lower. The concerns we have are, of course, with innovation.

And look, let's get philosophical for a second. I think that if we had all the cures, all the drugs that we would ever want for the human race right now, they existed, you could make a good moral argument that the Government could just confiscate them and deliver them to people. Right? You could make a moral argument that way.

But of course, that is not the situation that we are in. The situation we are in is that we want more drugs available to us. In America, we have access to a lot more innovative drugs than any other country. There is a study of the over 300 new drugs approved since 2011. America has access to 87 percent, and something like

*Ms. Eshoo. [Audio interference] that is left.

*Mr. Crenshaw. Australia has 39 percent access. The U.K. has 50 percent. Canada has less than 50 percent.

So innovation is a big deal. I don't know who was just talking, but I reclaim my time. Ms. Davis --

*Ms. Eshoo. Mr. Crenshaw, your time -- I am sorry, your time is expired. You are over by --

*Mr. Crenshaw. Oh, thank you, Madam Chairwoman. Sorry.

Can't see the timer. I apologize.

*Ms. Eshoo. No. That is all right. Thank you. I gave you a little more time so you could finish a couple of your sentences there. And again, we are really thrilled that you are back. Keep making progress.

*Mr. Crenshaw. I appreciate it, Madam Chairwoman. Thank you for indulging me. I am sorry. I can't see the time.

*Ms. Eshoo. That's all right. That is okay.

Now it is a pleasure to recognize the gentlewoman from Minnesota, Congresswoman Craig, to be followed by -- we don't have any Republicans left. So there is going to be a string of Democrats following. The gentlewoman from Massachusetts, Mrs. Trahan, will follow Congresswoman Craig.

So great to see you, Angie. You are on.

*Ms. Craig. Thank you so much, Madam Chair. And thank you to our panelists for your patience and resilience here today in this hearing.

Look. The burden of high out-of-pocket costs of drugs on Medicare beneficiaries is significant. Over the next decade, approximately 1.1 million older adults are predicted to die prematurely due to this cost burden. One study found that if Medicare is able to negotiate, lower drug prices and cost-sharing responsibilities for beneficiaries are reduced. It may decrease premature deaths by about 94,000 per year,

and generate nearly $500 billion in savings by the year 2030. This is particularly important for those today who must choose between filling their prescriptions and treating their illnesses or paying their bills.

Bob Miller is a constituent of mine living with MS. Over the course of 12 years, the list price of his medication rose from $13,000 a year to over $103,000. While on his employer's coverage, Bob was able to get copay assistance to make the drug affordable for him. but under Medicare, he is now ineligible for that same type of assistance.

Faced with the reality that the cost of his drugs would jeopardize his retirement security, Bob opted to stop taking the drug. He understood he was rolling the dice on his health, and he wants Congress to act so that no one else must make this life-threatening decision.

So let me start with Professor Sachs. Can you generally describe how HR 3 will benefit low-income people in particular, recognizing that some people have access to cost-sharing assistance through the low-income subsidy; they already have some help. But what about others who don't qualify for this extra help? How would their out-of-pocket expenses and premiums potentially be low?

*Ms. Sachs. Thank you. And this is an important question, to think about where the low-income subsidy phases out and how it isn't helping enough seniors who may be on a

fixed income, especially. So this out-of-pocket cap would be particularly helpful for seniors who are just out of low-income subsidy qualification but who have these expensive out-of-pocket costs.

*Ms. Craig. Professor Sachs, you heard my statistic that I have cited there. Do you agree that lowering drug costs and reducing out-of-pocket expenses could prevent premature death, as recent studies have shown?

*Ms. Sachs. Yes, relying on those studies. And it is really easy to see how something like that is true for something like insulin.

*Ms. Craig. Absolutely. Additionally, the Congressional Budget Office has estimated that the Medicare program will save billions because people can finally afford to take their medications. Do you expect H.R. 3 will also lead to better health outcomes?

*Ms. Sachs. Yes. Especially -- or potentially for low-income beneficiaries, given those high out-of-pocket costs that they face today.

*Ms. Craig. Thank you so much. I recently introduced H.R. 2464, the More Help for Seniors Act, that would expand the ability for seniors to receive extra help under the Part D low-income subsidy program. Not only do we need to provide more help to low-income seniors so more could take advantage of the program, we need to effectively reduce drug

costs for everyone.

That is why I personally believe H.R. 3 is so important. It is clear that lowering costs for seniors will not only improve their lives, but research has shown that for thousands of people each year, it will also save lives.

And I have got just a little more than a minute left, and I just want to say that much of the question and discussion here today, as someone who spent more than 20 years working in medical technology, for a company that had to compete to be on the VA contract every couple of years -- some years we were, some years we weren't, for the technology company that I worked for -- I just have to say that the "the sky is falling'' dynamic here is just, frankly, unbelievable.

And if you look at net operating profit for any large brand A pharmaceutical drug company in this country, it is really hard for me to believe that this sector that has continued to just increase price, increase price, has never really been held to account here -- look. We know, we all agree, that we have to balance innovation. But at the end of the day, I think this sector in healthcare has been able to escape any, or much, of the accountability in this country for what has happened with drug costs.

And let's talk about -- we don't have time today, but specialty drugs, and compound drugs. Look. This sector

needs more competition, not less. And at the end of the day, Medicare, just like the VA, should be able to negotiate its drug pricing in the United States of America.

And with that, Madam Chair, I yield back.

*Ms. Eshoo. The gentlewoman yields back. We all benefit from your membership on our subcommittee.

And now the chair with pleasure recognizes the gentlewoman from Massachusetts, another new member to our subcommittee -- all of our new members are just such value added. I keep saying this every time I introduce them. But I think that it is important to reiterate -- the congresswoman from Massachusetts, Mrs. Trahan. And she will be followed by our colleague from Texas, Mrs. Fletcher.

So Lori, thank you for your patience.

*Mrs. Trahan. Thank you so much, Chairwoman Eshoo.

*Ms. Eshoo. I love seeing the backgrounds of everyone. They're so varied. Yours looks especially lovely.

*Mrs. Trahan. Thank you. I appreciate that.

*Ms. Eshoo. Well, good.

*Mrs. Trahan. And I appreciate this hearing, our ranking member, certainly our witnesses who are with us today.

I did want to respond to my colleagues' argument that if H.R. 3 was in effect, we would not have COVID-19 vaccines and treatment, which I find to be misguided and would like to

just spend a bit of time clearing, or setting the record straight.

As my colleagues will remember last Congress, we passed billions of dollars of funding for NIH and BARDA to aid in the research, development, manufacturing, and purchase of COVID-19 vaccines and therapeutics. We just followed that up with even more in the American Rescue Plan a few months ago. That funding, along with the hard work and expertise at NIH and BARDA and, yes, our private pharmaceutical manufacturers, led to the development of several safe and effective vaccines.

This has been a collaborative effort. Take the Moderna vaccine, for example, the first product the company has ever commercialized. The United States invested $2.5 billion in clinical research, development, manufacturing, and purchase of just that vaccine, removing almost all of the risk for the pharmaceutical manufacturer. And before last year, Moderna was already relying on the work of the NIH to help develop its mRNA technology. Almost all of the company's investment in its vaccine came from these federal dollars.

I will also note for the Pfizer vaccine and all of the authorized vaccines, the Federal Government negotiated the price it would pay. These resources went to manufacturers due to the bipartisan work of Congress, which paid off massively for the American people.

So negotiation never would have hurt the ability for vaccines to come to market. And using that as a scare tactic just doesn't stand up to the facts.

Professor Sachs, I would love for you to just comment on this. It might be helpful just to hear unequivocally, if H.R. 3 had been enacted prior to the emergence of COVID-19, would it have impacted the ability to bring COVID-19 vaccines to market?

*Ms. Sachs. Absolutely. And I want to be clear: Nothing about H.R. 3 would have impacted the creation of Operation Warp Speed or development of vaccines and treatments for COVID-19. And in fact, Operation Warp Speed, as you said, it helped encourage the development of new vaccines. That is exactly the type of Government initiative which disproves the idea that there is a tradeoff between innovation and access.

And then just one more brief comment. This is what is important. Congress made the decision that patients could not be charged out-of-pocket for these products. They were to be provided free at the point of sale or treatment to those patients. So we have both innovation and investment from the Federal Government and no-cost access for patients.

*Mrs. Trahan. Thank you for that. Well, H.R. 3 takes a bold step to flip the status quo in a system that has made billions in profit while working families, like the one I

grew up in, are struggling to pay for their lifesaving medicines.

Ms. Ball, I just want to thank you once again for coming here today. Your story is one that resonates personally. My father has had MS for the past 27 years, and in the early days, when he was healthier and could walk, he would come to Capitol Hill for Patient Advocacy Days. And I have seen the sacrifices that he and my mom have had to make for his treatment and care. MS is unpredictable and it is a costly disease, and your testimony today was so helpful.

In my remaining time, one critical area that I think must remain at the center of our policy discussions is health equity. We have had so many hearings that have highlighted the disparities that exist across our healthcare delivery system, and prescription drugs are no exception.

Given the disproportionate impact that the pandemic has had on communities of color, Congress does have an urgent responsibility to address those disparities that have long predated COVID-19. And so, Ms. Sachs, with the remaining time, it is common-sense that if people can afford to take their medications, that they will remain healthier. How will the policy in H.R. 3 lead to better health outcomes for low-income communities and people of color?

*Ms. Sachs. Yes. It is certainly my hope that the lower drug prices created by H.R. 3, both through the

Medicare out-of-pocket cap and the negotiation provision, will allow for increased adherence, increased affordability, especially in low-income communities and in communities of color, and can help really mitigate some of these racial disparities.

*Mrs. Trahan. Thank you. I appreciate that. I will yield back the no time I have left.

*Ms. Eshoo. [Laughing.] I want to thank the gentlewoman. Excellent line of questioning and observations. I am proud of all of the members of our subcommittee. I think that it is the best subcommittee at Energy and Commerce -- how about in the whole House, everybody? That is how proud I am of you.

Okay. Now, the chair is going to recognize the gentlewoman from Texas, Mrs. Fletcher. And then following her, there are four members that are waiving on, and then our colleague, Dr. Kim Schrier, has asked to be last because she has a conflicting event. So I don't want anyone to think that I am leapfrogging over her.

So a pleasure to recognize you, Lizzie, and you have five minutes. And then we will take the members that waiving onto our subcommittee today.

*Mrs. Fletcher. Wonderful. Thank you so much, Chairwoman Eshoo, for holding this hearing today. Bringing down the cost of pharmaceutical drugs has been one of my top

legislative priorities, and it obviously is one of this Congress. As we have heard today, there has been a bipartisan priority for many, and many of the bills being considered today have bipartisan support.

But a lot of the questions and comments in today's hearing seem to have presented us with a false choice between lowering drug prices for Americans and developing innovative treatments. So I am really grateful to our panel for insights, all of your insights today, and I would like to focus a little bit on this issue, the idea that high drug prices provide a funnel for innovation, and if profits decline, it will impact efforts to find new cures.

At the same time we hear that, industry experts have noted that the pharmaceutical industry is one of the most profitable sectors, and sees greater profits than other industries on the S&P 500, for example.

So Professor Sachs, can you briefly discuss whether there is evidence for the claim that high drug prices are truly the conduit for innovation? Would the pharmaceutical industry continue to invest in R&D if H.R. 3 became the law, or would it no longer invest in R&D if we were to pass H.R. 3?

*Ms. Sachs. They absolutely would continue to invest in R&D. Now, to be sure, there are projections that there would be a small decrease in the number of drugs coming to market

over the next decade or more as a result of H.R. 3.

But I want to emphasize that it is not just the amount of drugs we get, it is the kind. We have heard a lot of discussion about the importance and the need for cures. And I absolutely agree with that. We don't just want new drugs. We want good new drugs that fulfill unmet needs for our patients.

And economists looking at the creation of Medicare Part D found that it gave a large new subsidy to pharmaceutical companies to do innovation, but that most of that innovation was concentrated into these classes with lots of existing treatments. So if we are lowering prices a little bit in Medicare Part D, we might be taking away some of those "me, too'' drugs, but there is no reason to think that we would be limited incentives for companies to develop these truly new cures because these are actually the products that command very high prices in other countries against which we would be referencing.

*Mrs. Fletcher. Well, thank you for that. And your answer touches on another issue that we have sort of covered a little bit today. But I think when it comes to research and innovation, we have talked a little bit about the funding that we have done recently, and there is funding in H.R. 3 for research and development and innovation. There is $10 billion of direct funding to the NIH to bolster research

in cancer, rare diseases, regenerative medicine, antibiotic resistance, and treatments for substance use disorder, among others. There is also, in H.R. 3, $2 billion to the FDA to enhance drug development, review, and safety, including investing further in activities authorized under the 21st Century CARES Act.

So I think that is important when we talk about research. And Ms. Sachs, would you agree that investments in the NIH and FDA, like the efforts I just described, would help enhance research and development on new drug therapies?

*Ms. Sachs. Absolutely. And one example of that is we have heard somewhat today about the fact that we really want new drugs for conditions like Alzheimer's. But we have also heard about the fact that even today, we have hundreds of candidates which have failed clinical trials. So even today, without H.R. 3, we don't have these effective new therapies.

What we really need is some public investment and figuring out more about how some of these diseases work, about what approaches might be important for private pharmaceutical companies to pursue. So H.R. 3, developed in 2019, isn't the reason that companies have failed over the last decades to find new drugs for Alzheimer's, and it is not going to prevent us from finding a solution, either.

*Mrs. Fletcher. And thank you. With the little bit of time I have left, there is also some recent research that

shows that many of the patented prescription drugs, like some of the innovative things we are talking about today, were actually first discovered through taxpayer-funded NIH research and grants. Is that your understanding?

*Ms. Sachs. Yes. And I think we also just heard a little bit about the Moderna vaccine, where there was a huge amount of public investment, not just in the development but the partnership with the NIH in completing those clinical trials. So that is a very recent example where that is absolutely the case.

*Mrs. Fletcher. Well, thank you so much, Ms. Sachs. And in the time I have left, I just want to thank all of our witnesses. This is clearly a really important topic for our constituents and for people across the country. So in addition to supporting innovation, H.R. 3, as well as some of the other legislation we are discussing, is really the critical legislation we need to lower prescription drug prices so Americans can live longer, healthier lives.

And Madam Chairwoman, I yield back.

*Ms. Eshoo. The gentlewoman yields back, and we thank her.

How we will go to four members that are members of the full committee of Energy and Commerce, and they are waiving on today and we welcome them. The first will be the gentleman from Illinois, Mr. Rush, followed by the

gentlewoman from Colorado, Ms. DeGette, followed by the gentlewoman from Illinois, Ms. Schakowsky, followed by the gentleman from Florida, Mr. Soto.

So do we have the gentleman from Illinois, Mr. Rush?

*Mr. Rush. Madame Chair, so delighted to see you once again. I want to thank you for allowing me to participate in today's important hearing on H.R. 153. I am also very pleased several speakers, if you will, like myself in many -- and once again considering H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, which I am proud to cosponsor. Madam Chair, these bills would take [audio drop] to ensure fundamental drug pricing for Medicare recipients and patients of all ages throughout the country.

Professor Carrier, it is nice to see you once again. And I appreciate your coming back to once again testify on my bill, the Protecting Consumer Access to Generic Drugs Act. You and I want to stop these insidious practices of what is called pay-for-delay for far too long, it is inarguably a complete and complex instrument. Can you walk us through an example of a time when this practice has hurt consumers and led to higher drug prices for American patients?

*Mr. Carrier. Sure. Thank you so much, Representative Rush, for your leadership on this issue now and your leadership going back for years. You have discovered the problem of pay-for-delay settlements as early as anyone has.

The problem with pay-for-delay is a brand company pays a generic to stay off the market, and that generic could be delayed for years.

And so there are multiple examples involving drugs like Impax and Loestrin and the antibiotic Cipro, many drugs that are worth a lot in terms of revenue where the consumer is delayed getting an affordable drug for years.

*Mr. Rush. Thank you very much. Also, Professor Carrier, I appreciate the suggestion that to be sure certain this was taking place. Can you please, or would you please, walk us through it, each amendment, and explain why they are needed to stop the practice of pay-for-delay once and for all?

*Mr. Carrier. Sure. So for starters, I think that your bill is an excellent approach to the problem. The Supreme Court in 2013 said that pay-for-delay settlements could violate antitrust law. But the settling parties -- and here we include the generics, because the settling generics are just as bad as the brands here -- they do everything in their power to muddy the waters, to say that it is not really a payment, or it is a payment for generic services, not really for delay, or that there is no delay because the patent is good.

And so your bill would really solve this problem by dealing with the FTC and giving the FTC the power to go after

this in court to fix some of these mistakes that courts have done, like not recognizing payment, like adopting the scope of the patent test. And so if you were to consider other changes to the legislation, I suggested things like applying it to the patent trial and appeals court.

So this is one place where the settling parties are trying to hide payments. Detail of settlements, patent trial and appeal board settlements, are not reported to the FTC. So that would be one place to start. Don't let them hide it there. Include that in the bill.

*Mr. Rush. Thank you so very much. Let me move on to Professor Sachs.

Professor Sachs, in your testimony, you discuss various mechanisms other countries have implemented to strengthen the hands of their payers, too, and their classes than they are now presently -- present, rather. Are these classifications lifesaving prescription drugs battling COVID in other countries? And real importantly, are there [audio drop] between insured, Medicare pending strengthening, negotiate without prices, losing access to the medications and [audio drop]?

*Ms. Sachs. Thank you, Congressman. And to your question about how H.R. 3 would protect Medicare beneficiaries access to these medications, it is important that nothing in H.R. 3 changes that Medicare is obligated to

cover at least two drugs per class, all drugs in the six protected classes. Nothing about H.R. 3 changes that.

*Mr. Rush. Thank you very much.

Madam Chairwoman, again, thank you for your kindness, and I yield back no time because I don't have any time.

*Ms. Eshoo. [Laughing.] Well, thank you, Mr. Rush. You are always welcome at the subcommittee. And thank you for your important legislation.

The chair now has the pleasure to recognize the gentlewoman from Colorado. She is the chair of the Energy and Commerce Subcommittee on Investigations and Oversight. Great to have you with us, Diana. And she will be followed by Congressman Soto of Florida because Jan Schakowsky had to drop off. And then we will have, I believe, the last member, last but not least, Dr. Schrier.

So there is some light at the end of our hearing tunnel here. And so great to have you, Diana. Your five minutes of questions -- and thank you for your patience in joining us.

*Ms. DeGette. Well, thank you so much, Madam Chair, for allowing me to waive on. I feel like I should be an adjunct member of the committee anyway, and I really want to thank all the witnesses for your tenacity in holding on. And I really want to thank you, Anna, for considering this H.R. 3 because the Oversight Subcommittee, as you know, has had a number of investigations over the last number of years on the

broad issue of drug pricing, and this really is a national crisis, as we keep hearing, and it is not going to be getting any better.

[Audio drop] on this committee know that I am the co-chair of the Congressional Diabetes Caucus, and this is the largest issue-based Congress. We heard about the MS drugs. But diabetes drugs are probably the biggest textbook example of what has happened to patients in America because if you are Type 1 diabetic and you take insulin, if you don't get your insulin, you die.

And in the past two decades, prices for most commonly prescribed insulins went up from $20 to over $200 -- $250 -- a vial, which is more than 700 percent increase. And the drugs were the same drugs. And the reason is the way that these drugs are marketed, and because of the inherent markup in the system.

And I found this out. The problem is, Members of Congress are actually healthcare consumers themselves. Everyone, all the members on this committee, know my daughter Francesca and have known her since she was like four years old, some of them.

Well, she was on my insurance, and her insulin cost about $30 a bottle. Then when she turned 26, she went off of my insurance, of course. She had insurance provided for her by her employer. And she went over to get her insulin after

she went on the new insurance; well, her insulin was not listed on this formulary. So guess what? When she went to get her insulin, it was $312 a bottle for a 26-year-old young woman.

And I have had so many people tell me they were working four jobs to get their insulin. They didn't know what to do. And by the way -- [telephone rings] -- excuse me -- and by the way, when my other daughter, who is a doctor, tried to get her a coupon to get her that insulin, the coupon only took $20 off. So anybody who says the coupons fix this situation, it is untrue.

So I have a couple of questions for our witnesses. The first one is for Dr. Sachs. Dr. Sachs, how would the negotiation process in H.R. 3 bring down the price of drugs like insulin, which is listed in H.R. 3, for patients who need them to survive?

*Ms. Sachs. Congresswoman, I want to thank you for your leadership on this important issue of insulin because, as you know, H.R. 3 specifically instructs the Secretary to negotiate for the price of insulin. And we have these decades-old drugs whose prices continue to rise. They cost many times more here than they do abroad. Bringing down those prices would be particularly important for patients.

*Ms. DeGette. Tri. And Ms. Ball, I just want to tell you I thought your testimony was very, very moving because

you had the same kind of experience that my daughter and many other -- millions of Americans have in trying to just live, just to be alive. So what would the impact have been for you if an out-of-pocket cap existed for your medications?

*Ms. Ball. Thank you, Representative DeGette. I am saying that if I would have had that, my life in the five years after I was diagnosed, before I had to quit working, it would have been much easier for me to pay for them. It also is the fact that, when you not getting your drug because of this cost, you have to pick: eat, pay your rent, or get the drug that is going to keep you walking and thinking?

So that is what the impact was for me. If we had the H.R. 3, I would have been able to probably afford my drugs. And that is what is most important.

*Ms. DeGette. Well, that's right. I met a young woman who was working four jobs to get her insulin.

*Ms. Ball. Yes.

*Ms. DeGette. And she was living in her car. That is exactly to what you are saying.

Madam Chair, once again, thank you so much. This is such a critical issue. And I would hope that our Republican colleagues across the aisle. If they don't like H.R. 3, then work with us to find something that is for real because just having a Band-Aid that we say is going to solve something

isn't going to actually solve issues like Ms. Ball's. And I yield back.

*Ms. Eshoo. We all thank you, Diana, especially for your leadership in so many areas, but most particularly in always highlighting the issue of diabetes. And we see you or hear your name, right next to it is "diabetes.'' So thank you.

Now I have the pleasure of recognizing the gentleman from Florida, Mr. Soto, again another member that has really brought high value to our committee, and we are thrilled to have you waive on. You are recognized for five minutes.

*Mr. Soto. Thank you, Chair Eshoo. Let's start with the facts.

Americans pay more for prescription drugs than any other nation in the world. Many can't afford those drugs, and so they go without. What good is having amazing drugs if many of my constituents can never afford them?

Here is another fact: The VA Hospital, Medicaid, both negotiate their drug prices. They have done so for decades. Yet Medicare cannot. That is why we are here today, because you have this big gap between VA and Medicaid negotiations. But why doesn't Medicare? And that leads to higher prices for our seniors.

This makes no sense. And a lot of our colleagues across the aisle talk about competition, for years, except for right

now. Why? Why are we not talking about how -- competition is not good for Medicare but it is good for all these other programs? That makes no sense.

And then I hear all the scare tactics today, and it reminds me of what we heard back in the 1960s at the founding of the Medicare program. Ronald Reagan said, "If you don't stop Medicaid, one of these days you and I are going to spend our sunset years telling our children and our children's children what it was once like in America when men were free.'' Wow. Well, that didn't happen.

George Herbert Walker Bush described Medicare in 1964 as "socialized medicine.'' Yet you all are rigorously defending the program today.

Barry Goldwater, having given our pensioners their medical care in kind, why not food baskets? Why not public housing accommodations? Why not a vacation resort? Why not a ration of cigarettes for those who smoke and beer for those who drink? Ridiculous things were said during this Medicare debate, and Bob Dole -- I was there -- fighting the fight, voting against Medicare. Scare tactics didn't work back then and they are not going to work now.

We have to go forward to make sure that we can increase the access to lifesaving drugs for all Americans. And that is what this is all about. I know I have had countless town halls in my district with Democrats and Republicans in

liberal and moderate and conservative areas in my district.

And seniors of all stripes, of all political persuasions, tell me they are paying way too much, and many of them have to ration their drugs. They have to make sure at the end of the month -- they take a half a pill or half of what their doctor said because they are waiting for their Social Security check to come in at the end of the month, at the end of the month for the beginning of the second month. So they are rationing that. Some of them are even forgoing groceries in the most prosperous Nation in the world. That is what the issue is today.

I have a question for my fellow Scarlet Knight, Professor Carrier. One of the areas we have heard some abuses about is in the petitions at the FDA. Professor Carrier, I would like to follow up on the portion of your testimony in which you discuss a number of reasons why we should move forward with stopping abuses to the citizen petition process.

Can you explain why it is difficult for the FDA to dismiss a citizen petition currently? Why is it difficult for them to prove that a petition's purpose is primarily for delay and that there are no valid scientific or regulatory issues raised in the petition? And could FDA's resources be better used if we change that?

*Mr. Carrier. Absolutely. Thank you for the question,

Representative Soto. And you are right that a lot of these citizen petitions are filed just to delay generic entry. Everybody knows it. The FDA knows it. But the FDA cannot summarily dispose of these petitions.

Why? Because the standards are too high. The standards are, as the FDA says, "Extremely difficult to meet.'' That is the FDA talking. Why? Because the FDA has to show two trainings, both of them:

First, if there is a primary purpose of delaying the generic. How is the FDA going to know what the brand company's primary purpose is? It is not going to say in the petition, "Oh, by the way, we are doing this to delay the generic.'' So it doesn't really know that.

And then the second one is: The petition doesn't, on its face, raise a valid scientific or regulatory issue. There is so much scientific legalese in all of these documents, but it is really hard for the FDA to conclude, right off the bat, that there is no issue at all.

And so when you put these two things together, the FDA has never used this power. In its annual reports to Congress, it says that the provision "has neither curbed the filing of provisions'' submitted with a price purpose of delay, or "permitted FDA to dispose of petitions without expending substantial amounts of resources.''

It is important for FDA to summarily deny frivolous

petitions. FDA has never done so. That is why switching and/or could make a really big different.

*Mr. Soto. Thanks so much. And there is the appearance of creating a manufacturer's delay to petition the FDA. In your opinion, if this is enacted, would a manufacturer stakeholder still be able to use the petition for legitimate scientific or regulatory issues? Yes or no?

*Mr. Carrier. Yes. Absolutely. And there is always a sham exception to petitioning. That is what is going on.

*Mr. Soto. Thank you. My time is expired.

*Ms. Eshoo. The gentleman's time is expired, and we thank you again for waiving on.

Now, last but certainly not least, one of the fine doctors that is a member of our subcommittee and we are thrilled that she is, the gentlewoman from Washington State, Dr. Kim Schrier. Thank you, Kim, for your patience.

*Ms. Schrier. Thank you, Madam Chair. Thank you for your patience. And thank you to our witnesses.

This is such an important discussion, and while much of our work this past her was really focused on the immediate needs to come at the pandemic, the urgent need to bring down the cost of prescription drugs has not gone away for my constituents or any others.

And like so many of my colleagues have already highlighted, many of our prescription medications cost far

too much, and their prices have continued to increase, for no reason, far faster than the rate of inflation, even when nothing about them has changed. We heard about Copaxone, and Humira, and insulin is another classic example. I have Type 1 diabetes, and so I just want to show you how tiny this little bottle is.

Twenty years ago, this bottle of insulin cost $40, and now it costs over $300. And nothing has changed about it. That holds ten milliliters, two teaspoons of medicine that I can't live without, and most insulin users use two or three bottles a month. So this is just one example of why this issue of drug pricing is so important.

And that example is particularly egregious, kind of the poster child for price gouging. But the issue is nuanced. And Professor Sachs, you were quoted a couple years ago as saying, "We probably are under-rewarding drug innovation for some types of diseases, such as early stage cancers requiring long clinical trials, and then over-rewarding it for others.''

And I was hoping we could talk a little bit about innovation and that point because there is a big difference between new, lifesaving, curative, truly transformational treatments and a second, third, or fourth drug in a class that doesn't really represent a big therapeutic advantage over existing therapies.

And I am from Washington State. Here are a couple things that have happened in my home State, which is a hub for cancer treatments, cell therapies like CAR T, gene therapies. One local company spent more than eight years pioneering personalized cancer immunotherapy for patients with lymphoma that hadn't responded to anything else by going to a special manufacturing facility, changing cells, re-engineering them to fight cancer.

There is also a one-time gene therapy that has shown promise for patients with thalassemia, potentially freeing them from a lifetime of transfusions. And there are countless oncology treatments that meaningfully extend survival and improve quality of life.

But research and development is not easy, and there is no guarantee of success, and it could take many, many years. And so I want to talk about the nuance and the use of a scalpel instead of a hatchet in these conversations.

Can you tell me, Professor Sachs, how can we better incentivize innovation that represents these therapeutic advances instead of the "me, too'' drugs that just follow on what we already have?

*Ms. Sachs. Thank you for this very important question. I think you are absolutely right to quote my own words back at me because I don't think that all drug prices are too high and should just be decreased. I think some drugs are priced

too high, but others are not. I think we need more investment in certain areas, but we probably have to much investment in some of the "me, too'' areas like you mentioned.

So in my opinion, this isn't just about the number of drugs that we get. It is about the kind. We want innovation that works for patients. We want cures. And the better the drug is, the more we will pay for it and the more we should pay for it.

And so all of that really matters in thinking about competitive clinical effectiveness, which is something not just many countries but also U.S. payers do. We say, is this drug better than the current drugs we have for treating the same condition? If it is not better, maybe we don't want to pay more for it. But if it is better, we should pay more for it.

And so thinking --

*Ms. Schrier. Right. The notion of what would it cost us over the long run for this patient to have all of these horrible consequences? How much time would they spend in the hospital who didn't have it? And that is a way to think about whether the cost of a drug is justified.

I was just going to ask about H.R. 3. Can you tell me what guard rails are already in H.R. 3 or could be added in order to ensure that those innovative treatments are treated

differently, that we take into consideration the big benefit? How can we make sure that happens?

*Ms. Sachs. Absolutely. So H.R. 3 already instructs the Secretary to think about comparative clinical effectiveness. Right? Is this drug better than other drugs for the same condition? If so, that matters as to how we think about negotiating and setting a fair price for that product.

H.R. 3 is also limited to the top spending drugs in Medicare and more generally. So a lot of rare disease drugs won't even be eligible for negotiation, and rare disease patients should have -- be concerned about the impact of negotiating on the price of those drugs.

*Ms. Schrier. And they will take it into consideration when. We have a treatment for Alzheimer's, for example, that will be worthy and valuable and will be treated as such.

Thank you, and I yield back.

*Ms. Eshoo. We all pray for that day. Thank you, Dr. Schrier.

Well, I think that that -- we have heard from 41 members, witnesses. So you have really held our attention. I want to thank each one of you on behalf of all my colleagues today. Each one of you brought great value in your testimony. So a great shout-out and enormous thanks to each one of you, Therese Ball, Michael Carrier, Dr. Gupta,

Khrystal Davis, and Rachel Sachs. You really got a workout there, Rachel, from both sides. But very sincerely, thank you to each one of you. And on behalf of the American people because they are listening in, and I think that this was a 101 on the subject matter.

Now, I need your help, Mr. Guthrie. We have coming -- we have 90 documents that I would like to move to place in the record. I don't think that you want to stick around to help me read 90 of them.

*Mr. Guthrie. Yes. I won't do that. So I'll give you unanimous consent not to read.

*Ms. Eshoo. All right. Okay. So as ordered, and all the documents that have been submitted to the subcommittee will be made part of the record.

[The 90 documents submitted during the hearing follow:]

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

*Ms. Eshoo. Now, pursuant to committee rules, members have, as you know or may not recall, you have ten business days to submit additional questions for the record. As I said to the witnesses, you will be hearing from members. Many of them will submit a written question. And we ask the witnesses to please respond as promptly as you can to any questions you receive. So with my thanks to each one of you both to the tone, the value of your observations, your questions, the answers of the witnesses, I think you have just been terrific. This has been a great experience.

*Mr. Guthrie. Might we share?

*Ms. Eshoo. Yes. Certainly.

*Mr. Guthrie. I think I said I will give unanimous consent. I actually can't do that. So I will move unanimous consent --

*Ms. Eshoo. I asked for unanimous consent --

*Mr. Guthrie. Okay. I will not object. [Laughs.]

*Ms. Eshoo. Thank you. Thank you, Mr. Guthrie. Appreciate it. You are wonderful. Can you imagine if we had to sit here for -- listen to me read out 90.

Where was I? I think at this time I can say that the Health Subcommittee meeting of today is adjourned with my thinks to all of the members and our superb witnesses.

Thank you.

Everyone stay healthy, please.

[Whereupon, at 3:41 p.m., the subcommittee was adjourned.]