MAKING HEALTH CARE MORE AFFORDABLE: LOWERING DRUG PRICES AND INCREASING TRANSPARENCY

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH, EMPLOYMENT, LABOR, AND PENSIONS

COMMITTEE ON EDUCATION AND LABOR
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C O N T E N T S

MAKING HEALTH CARE MORE AFFORDABLE: LOWERING DRUG PRICES AND INCREASING TRANSPARENCY

Thursday, September 26, 2019
House of Representatives,
Subcommittee on Health, Education, Labor, and Pensions
Committee on Education and Labor
Washington, D.C.

The subcommittee met, pursuant to call, at 2:01 p.m., in Room 2175, Rayburn House Office Building. Hon. Frederica S. Wilson [chairwoman of the subcommittee] presiding.

Present: Representatives Wilson, Norcross, Morelle, Wild, McBath, Underwood, Stevens, Courtney, Fudge, Harder, Shalala, Levin, Trahan, Scott, Walberg, Roe, Allen, Banks, Taylor, Watkins, Wright, Meuser, Johnson, and Keller.

Also Present: Representatives, Davis and Foxx.

Staff Present: Ilana Brunner, General Counsel; Emma Eatman, Press Assistant; Daniel Foster, Health and Labor Counsel; Carrie Hughes, Director of Health and Human Services; Ariel Jona, Staff Assistant; Stephanie Lalle, Deputy Communications Director; Jaria Martin, Clerk/Assistant to the Staff Director; Max Moore, Office Aide; Merrick Nelson, Digital Manager; Veronique Pluviose, Staff Director; Banyon Vassar, Deputy Director of Information Technology; Joshua Weisz, Communications Director; Cyrus Artz, Minority Parliamentarian; Courtney Butcher, Minority Director of Member Services and Coalitions; Cate Dillon, Minority Staff Assistant; Rob Green, Minority Director of Workforce Policy; Jeanne Kuehl, Minority Legislative Assistant; John Martin, Minority Workforce Policy Counsel; Hannah Matesic, Minority Director of Operations; Alexis Murray, Minority Professional Staff Member.

Chairwoman WILSON. I note that a quorum is present. The subcommittee on Health Employment Labor and Pensions will now come to order. Welcome to everyone.

I note that the subcommittee—for the subcommittee: Mr. Grijalva, Ms. Davis of California, Mr. Castro of Texas, and Ms. Jayapal of Washington and Ms. Schrier of Washington are permitted to participate in today's hearing with the understanding that their questions will come only after all members of the subcommittee on Health, Employment, Labor, and Pensions, on both sides of the aisle who are present and have had an opportunity to question the witnesses.

The subcommittee is meeting today in a hearing to receive testimony on making health care more affordable, lowering drug prices and increasing transparency.

Pursuant to rule 7(c), opening statements are limited to the Chair and the Ranking Member. This allows us to hear from our witnesses sooner and provides all members with adequate time to ask questions.

I recognize myself now for the purpose of making an opening statement.

Today, we are gathered to discuss policy solutions to reduce prescription drug prices for consumers, businesses and taxpayers. Prescription drug prices are out of control. More than $450 billion or about $1,100 per person is spent across the healthcare system every single year.

Pharmaceutical companies are charging American prices that are three, four, or in some cases, dozens of times higher than what they charge for the exact same drugs they sell in other countries.

As a result, Americans across the nation are struggling to afford the medication they need to maintain their health. In fact, in the past three years, in ten adults decided—in the past year, three in ten adults decided to forego taking their prescribed medications because of the cost.

We must act on behalf of people like Azima, a social worker in my home state of Florida who struggles to make monthly co-payments for her prescription drugs which cost more than her rent, electricity, cell phone bill and car payment combined, and Jesimya David Scherer-Radcliff who tragically died from rationing the life-saving insulin he needed to treat his diabetes.

As our witnesses will share, exorbitant drug prices place a significant burden on workers and their families. Employer health plans spend nearly $84 billion annually on drugs alone. As drug companies continue to raise prices with no end in sight, seniors, taxpayers, workers and our economy are all footing the bill. That is why we must take bold action by passing the Lowering Drug Cost Now Act, an ambitious plan to lower drug prices and increase transparency in five key ways. First, the bill ends the ban on Medicare negotiating directly with drug companies to get a fair deal for American consumers. Second, the bill makes the lower drug prices negotiated by Medicare available to all Americans, which will cut costs for both employers that provide their workers healthcare and workers covered by employer provided healthcare. Third, the legislation caps negotiated drug prices at prices charged in similar countries so that drug companies stop ripping off Americans while charging other countries less for the same drugs. Fourth, the bill creates a new out-of-pocket limit, on drugs for Medicare beneficiaries and ends unfair annual price hikes by prescription drug companies for 8,000 drugs.

Finally, the Lowering Drug Cost Now Act reinvests the savings from negotiated drug prices in research and innovation to make new medical breakthroughs.

My Republican colleagues have responded to this proposal with the same tired rhetoric, labeling it a socialist takeover of our healthcare system but the central provisions in this proposal have been endorsed by President Trump himself.

We even put together a few video clips of the President promising to negotiate prices and align the prices Americans pay with what consumers in other countries pay. Play the video.

[Video plays]

Chairwoman WILSON. On the day the Lowering Drug Cost Now Act was introduced, the President tweeted: "It is great to see Speaker Pelosi's bill today." My Republican colleagues claim cutting the cost of drugs will stifle research and innovation, but nine out of ten big pharmaceutical companies spend more on marketing, sales, and overhead than on research.

Each of us has a responsibility to serve our constituents and address the unsustainable cost of prescription drugs.

Today's hearing is an important step towards that goal, and I want to thank each of our witnesses for being with us to discuss this comprehensive solution to one of our nation's most pressing crises.

I now recognize the distinguished Ranking Member for the purpose of making an opening statement. Mr. Walberg.

[The statement of Ms. Wilson follows:]

Prepared Statement of Hon. Frederica S. Wilson, Chairwoman, Subcommittee on Health, Employment, Labor, and Pensions

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As a result, Americans across the nation are struggling to afford the medication they need to maintain their health. In fact, three in ten adults decided to forgo taking their prescribed medications in the past year because of the cost.

We must act on behalf of people like Azima, a social worker in my home state of Florida who struggles to make monthly copayments for her prescription drugs, which cost more than her rent, electricity, cell phone bill, and car payment combined.

And Jesimya David Scherer-Radcliff, who tragically died from rationing the life-saving insulin he needed to treat his diabetes.

As our witnesses will share, exorbitant drug prices place a significant burden on workers and their families. Employer health plans spend nearly $84 billion annually on drugs, alone.

As drug companies continue to raise prices with no end in sight, seniors, taxpayers, workers, and our economy are all footing the bill.

That is why we must take bold action by passing the Lower Drug Costs Now Act, an ambitious plan to lower drug prices and increase transparency in five keyways.

First, the bill ends the ban on Medicare negotiating directly with drug companies to get a fair deal for American consumers.

Second, the bill makes the lower drug prices negotiated by Medicare available to all Americans, which will cut costs for both employers that provide their workers health care and workers covered by employer-provided health care.

Third, the legislation caps negotiated drug prices with prices charged in similar countries so that drug companies stop ripping off Americans while charging other countries less for the same drugs.

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Each of us has a responsibility to serve our constituents and address the unsustainable cost of prescription drugs. Today's hearing is an important step toward that goal.

I want to thank each of our witnesses for being with us to discuss this comprehensive solution to one of our nation's most pressing crises. I now recognize Ranking Member Walberg, for an opening statement.

Mr. WALBERG. I thank you, Chairwoman and I appreciate the opportunity today to have a hearing on this bill. Also to make it very clear that the President hasn't yet called upon us to support it and his statements were that he was glad to see a bill talking about doing things we all want to do. He did not say that he supports this bill as written and I would think that he, as he said, in one of the videos up there, together we will stop it. Together—there has been no togetherness in putting this bill together, even from my Democrat colleagues in working with the speaker who put it together. I just wanted to make that notation as well. There is no question that healthcare costs are at the top of the minds for many Americans—most Americans and the cost of prescription drugs are a concern for workers and families.

According to a recent report on medicine use and spending in the U.S., patients paid 61 billion dollars in out of pocket drug costs in 2018. So it is not surprising that a recent poll found 1 in 4 Americans worry about affording their medication. Sadly, individuals and families are being let down by Democrat leadership. Instead of working on this serious issue in a bipartisan manner, Speaker Pelosi's radical, partisan bill was drafted in secret, I think for a purpose, without member input or the regular committee process.

The public leader McCarthy accurately described H.R. 3 as a "Step towards nationalizing the drug industry and opening the door to a one size fits all government-controlled rationing of prescription drugs."

This bill is a political ploy that will not be considered in the Senate or become law. When asked about the bill, Senate Majority Leader Mitch McConnell said, and I quote: "Socialist price controls will do a lot of left-wing damage to the healthcare system and of course we are not going to be calling up a bill like that."

We shouldn't be surprised that once again, Democrat leadership is pushing far left politics over policy. From taking over all student lending to mandating wage hikes, Democrats are pushing an agenda that strips hardworking taxpayers of their rights. H.R. 3 is just the latest in this string of aggressive socialist policies introduced by Congressional Democrat leadership. Over half of the Democrat Conference supports Medicare for all. A government-run single payer healthcare system that would eliminate private health insurance, including employer sponsored coverage, something that is admired by most everyone who has that opportunity and ought to be expanded. This is a jurisdiction of our committee. Congressional ef-

forts to bring down drug prices for American people have been and should continue to be a collaborative and bipartisan effort.

In 2016, a Republican Congress passed the 21st Century Cures Act. Bipartisan legislation, I might add, that was signed into law by President Obama, which accelerated discovery and development of new cures and treatments. Additionally, we reauthorized a generic drug user fee program and last year, the FDA approved a record number of generic drugs, driving up competition and giving consumers more affordable choices. And this year, and I know this for a fact as I sit on the House Energy and Commerce Committee. This year's House and Senate Committees have worked together on bipartisan bills to address the cost and transparency of prescription drugs.

Two of these bills, bipartisan bills have become law and others are awaiting further action in both chambers. There is a common thread there in bipartisan efforts.

Governments don't negotiate, they dictate. The radical approach taken by H.R. 3 includes troubling and unprecedented government interference in private market negotiations which will eliminate choice and competition and jeopardize innovation investment and access to future cures. Countries that have adopted drug pricing systems like those included in H.R. 3 face decreased access to innovative new medicines, increased wait times for treatment and supply shortage for in demand drugs. H.R. 3 will negatively impact investment and research and development of future treatments putting breakthrough cures for diseases like Alzheimer's, cancer, sickle cell anemia, and others at risk.

Instead of holding a hearing on this socialistic agenda drug pricing scheme that will hurt the development of money saving treatments and more importantly, people's lives. The committee's time would be better spent finding bipartisan solutions to our Nation's problems.

Republicans stand ready to work with Democrats to push for legislation that promotes competition, lowers out of pocket cost for consumers, and establishes transparency and accountability in drug pricing and might I add, that has a chance for a two-chamber solution that would get to the President's desk. With that, I yield back.

[The statement of Mr. Walberg follows:]

Prepared Statement of Hon. Tim Walberg, Ranking Member, Subcommittee on Health, Employment, Labor, and Pensions

"There's no question that health care costs are at the top of the minds for many Americans, and the cost of prescription drugs are a concern for workers and families. According to a recent report on medicine use and spending in the U.S., patients paid $61 billion in out-of-pocket drug costs in 2018. So, it's not surprising that a recent poll found one in four Americans worry about affording their medication.

Sadly, individuals and families are being let down by Democrats. Instead of working on this serious issue in a bipartisan manner, Speaker Pelosi's radical, partisan bill was drafted in secret, without Member input or the regular Committee process. Republican Leader McCarthy accurately described H.R. 3 as 'a step toward nationalizing the drug industry and opening the door to a one-size- fits-all, government-controlled rationing of prescription drugs.'

This bill is a political ploy that will not be considered in the Senate or become law. When asked about the bill, Senate Majority Leader Mitch McConnell said, 'Socialist price controls will do a lot of left-wing damage to the healthcare system. And of course, we're not going to be calling up a bill like that.'

We shouldn't be surprised that once again Democrats are pushing far-left politics over policy. From taking over all student lending to mandating wage hikes, Democrats are pushing an agenda that strips hardworking taxpayers of their rights. H.R. 3 is just the latest in this string of aggressive socialist policies introduced by Congressional Democrats. Over half of the Democrat Conference supports Medicare-for-All, a government-run, single-payer health care system that would eliminate private insurance, including employer-sponsored coverage, which is in the jurisdiction of this Committee.

Congressional efforts to bring down drug prices for the American people have been, and should continue to be, a collaborative and bipartisan effort.

In 2016, a Republican Congress passed the 21st Century Cures Act, bipartisan legislation signed into law by President Obama which accelerated discovery and development of new cures and treatments. Additionally, we reauthorized the generic drug user fee program – and last year the FDA approved a record number of generic drugs, driving up competition and giving consumers more affordable choices.

And this year, House and Senate Committees have worked together on bipartisan bills to address the cost and transparency of prescription drugs. Two of these bills have become law, and others are awaiting further action in both chambers.

Governments don't negotiate, they dictate. The radical approach taken by H.R. 3 includes troubling and unprecedented government interference in private, market negotiations, which will eliminate choice and competition, and jeopardize innovation, investment, and access to future cures.

Countries that have adopted drug-pricing systems like those included in H.R. 3 face decreased access to innovative new medicines, increased wait times for treatment, and supply shortages for in-demand drugs.

H.R. 3 will negatively impact investment in research and development of future treatments, putting breakthrough cures for diseases like Alzheimer's, cancer, sickle cell disease, and others at risk.

Instead of holding a hearing on this socialist agenda drug-pricing scheme that will hurt the development of money-saving treatments and—more importantly——people's lives, the Committee's time would be better spent finding bipartisan solutions to our nation's problems. Republicans stand ready to work with Democrats to push for legislation that promotes competition, lowers out-of- pocket costs for consumers, and establishes transparency and accountability in drug pricing."

Chairwoman WILSON. Without objection all other members who wish to insert written statements into the record may do so by submitting them electronically to the committee clerk in Microsoft Word format by 5:00 pm on Wednesday, October 9th, 2019. I will now introduce our witnesses: Frederick Isasi is Executive Director of Families USA. Welcome. Bari Talente is Executive Vice President of the National MS Society. Welcome. Dr. Mariana Socal is Assistant Scientist at Johns Hopkins University, Bloomberg School of Public Health. Welcome. Dr. Craig Garthwaite is Associate Professor of Strategy at Northwestern University's Kellogg School of Management. Welcome. Christopher Holt is Director of Health Care Policy at the American Action Forum. Welcome, Mr. Holt. David Mitchell is Founder and President of Patients for Affordable Drugs. Welcome.

We appreciate all of you coming today and look forward to your testimony. Let me remind you that the witnesses—let me remind the witnesses that we have read your written statements and they will appear in full in the hearing record, pursuant to Committee Rule 17 and committee practice, each of you is asked to limit your oral presentation to a five minute summary of your written statement.

Let me remind the witnesses that pursuant to Title 18 of the U.S. Code, section 1001, it is illegal to knowingly and willfully falsify any statement, representation, writing, document or material fact presented to Congress or otherwise conceal or cover up a material fact.

Before you begin your testimony, please remember to press the button on the microphone in front of you so that it will turn on and the members can hear you. As you begin to speak, the light in front of you will turn green. After four minutes, the light will turn yellow to signal that you have one minute remaining. When the light turns red, your five minutes have expired, and we ask that you please wrap it up or I will have to wrap it up for you.

We will let the entire panel make their presentations before we move to member questions. When answering a question, please remember to once again turn on your microphone. I will first recognize Mr. Isasi.

TESTIMONY OF FREDERICK ISASI, J.D., EXECUTIVE DIRECTOR FAMILIES USA

Mr. ISASI. Chairwoman Wilson, Congressman Walberg, Members of the subcommittee, thank you for the opportunity to testify today. I am Frederick Isasi, the Executive Director of Families USA, a non-partisan, non-profit that for nearly 40 years has served as one of the leading national voices for the health care movement in Washington D.C. and on the state level. Thank you very much for holding this hearing on lowering drug costs. We are meeting at an extraordinary time for our Nation's family.

Do you realize that about 1/3rd of Americans report not taking their prescription drugs because they are too expensive? Of these, more than 2/3rds are engaging in the terrible gamble of either skipping doses or cutting their pills in half.

Think of the life these Americans are living. In last fall's Congressional elections, the American people sent a strong signal to all of you. An astounding 82 percent of Republicans and 90 percent of Democrats said taking action to lower the price of prescription drugs should be a top priority for this Congress.

Despite all the conflicts, legal and economic discussions and the alarmist and false arguments of the drug industry, at its core, the problem of out of control drug costs is very simple. Congress created a system that provides a government-granted monopoly to drug makers, and many within the industry are abusing Federal law.

Let me explain what I mean. Over time, so much of the industry's focus has shifted from creating innovative drugs that can save lives to doubling down on high-powered lawyers to help find loopholes, sue competitors and generally abuse the spirit in which Federal prescription drug laws were created. It is time for Congress to reexamine and rewrite patent exclusivity laws to stamp out these abuses and actually incentivize innovation.

In the absence of this wholesale reform, we at Families USA are strongly supportive of the committee acting to mark up and move forward H.R. 3 the Lowering Drug Cost Now Act. It represents bold Congressional action that would require the government to defend our families and negotiate directly with drug manufacturers to curb abusive practices and price increases. These are policies supported by more than 2/3rds of Americans. The bill uses savings and reduced drug costs to invest in research and development for new cures as well as capping out of pockets costs for Medicare beneficiaries. It also could support much needed improvements in Medi-

care, such as dental, hearing and vision benefits and support for low-income Medicare beneficiaries.

We also recommended several critical improvements to strengthen the bill, such as expanding the selection of drugs that are subject to negotiations, expanding mandatory price hike protections to private payers and allowing uninsured patients to get negotiated prices. So what will the fate of this legislation be? You are all up against one of the most profitable industries in the world with revenues in access of $1 trillion and half of its profits are generated in the U.S. and Canada alone.

And industry spending, at least $133 million to lobby Congress, all of you, with over 800 lobbyists in D.C. Members of the committee, I ask you, does our democracy work? Will this committee, will Congress, will the President act to support our Nation's families or will the drug companies win yet again?

Let me tell you about one person, perhaps, who can steady your resolve to get this legislation enacted. Her name is Katherine from Wheeling, Illinois. Her story tells her own struggle but also the struggle of millions of other Americans. Katherine worked very hard. She had a career as a secretary and then in her late 50s, she developed a cough. It wasn't going away. Within three months of going to the doctor for a cough, however, she was told she had a rare lung disorder and that without a lung transplant, she wouldn't live to see the end of the year and then her condition worsened.

Her doctors prepared her to die and Katherine prepared herself to die, and then she got the call. A new lung had been found and she was going to live. This all happened about five years ago. This incredible gift and a new chance at life, but unfortunately her experience has turned into something else.

Katherine takes 36 pills every day, including anti-rejection and pain medications. Each year, the cost of her medication overwhelms her. Katherine has to ration her medications to make them last. She spends an astounding $1,000 each month on her medications, despite being a Medicare beneficiary, which is exactly half of her monthly income. Think about what this means.

Katherine, after living through the experience of almost dying, receiving a lung transplant, fighting for her life is left to spend half of her income to pay for medications. You won't be surprised to know that Katherine sold her home, moved in with her parents, her mom is 86 and her dad died this year at 89.

She lives an extremely frugal life but as her drug costs escalate year over year, she moves closer and closer to financial ruin and deep poverty. At the end of each year, she finds herself thousands of dollars short. She lives each day with the anxiety of wondering how will she find the money to pay for her drugs.

Despite being one of the wealthiest nations in the world, despite spending two or three times more than the rest of the world, this is the life we give to Americans. Thank you for holding this hearing, thank you for considering this legislation.

[The statement of Mr. Isasi follows:]

Testimony of Frederick Isasi, JD, MPH
Executive Director
Families USA

Before the House Education and Labor Committee
Subcommittee on Health, Education, Labor, and Pensions

Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency

September 26, 2019

Families USA
1225 New York Avenue, NW
Suite 800
Washington, DC 20005

Chairwoman Wilson, Ranking Member Walberg, and members of the House Education and Labor Committee, Subcommittee on Health, Education, Labor, and Pensions: Thank you for the opportunity to speak with you today. I am Frederick Isasi, the Executive Director of Families USA. For nearly 40 years, we have served as one of the leading national voices for health care consumers both in Washington, D.C. and on the state level. Our mission is to allow every individual to live to their greatest potential by ensuring that the best health and health care are equally accessible and affordable to all.

I am delighted to be speaking to this subcommittee at such a pivotal time. After decades of outrageous price increases, Congress is finally taking meaningful action to reduce the staggering price of prescription drug costs for America's families. On behalf of the millions of families struggling every day to afford basic prescription drugs, thank you for your leadership.

The Impact of High Drug Costs on Families

While high drug prices are a source of seemingly constant debate in Washington, D.C., for millions of America's families, they are a painful and burdensome reality and can impact the basic necessities of life. For example, consumers facing increased drug costs report cutting-back on key areas of their budget, such as buying food.[1] And for some, the choice is even more dire. Incredibly, nearly three in ten adults – approximately 80 million people – in our country have not taken required medicine due to its costs.[2] Another one in ten cut their pills in half or skip dosages to stretch the limited supply of drugs they can afford to buy.[3] And, approximately one in five forgo essential medications altogether because they can't afford to fill their prescription.

While people who need high-cost drugs face the most significant financial pain from high and rising prices, the impact of the skyrocketing cost of drugs is spread across all consumers. In fact, almost 25 percent of a privately-insured health care consumer's monthly premium goes to prescription drugs.[4]

Please allow me to share the story of just one of the millions of consumers struggling under the burden of high drug costs – a woman named Catherine, a 63-year-old with disabilities from Wheeling, Illinois:

> *Within three months of going to the doctor with a cough that wouldn't go away, Catherine was told that, without a lung transplant, she would not live to see the end of the year. Her condition worsened. Her doctors prepared her to die — she prepared herself to die. Catherine was eventually able to receive a new lung in November 2014.*
>
> *Because lung transplants have a high risk of complications, Catherine must be constantly monitored by doctors. Catherine takes 36 pills every day, including anti-rejection and pain medications. Each year, her medication costs put her in the Medicare Part D coverage gap — the doughnut hole. In fact, before each year ends, Catherine starts to ration her medications to make them last until*

her benefits are renewed at the beginning of the year. She spends $1,000 each month on her medications, which is exactly half of her monthly income. Catherine sold her home and moved in with her parents to reduce her living expenses. She lives an extremely frugal life, but as her drug costs escalate year over year, she moves closer and closer to financial ruin and deep poverty. At the end of each year, she finds herself several thousands of dollars in the negative, wondering how she will make up the shortfall.

Catherine lives every day with a serious chronic illness. It is unconscionable that she should simultaneously deal with the stress and hardship that comes with such a significant financial burden.

Exploitative pricing is more than academic for those who rely on lifesaving drugs. Ten years ago, Naloxone, a life-saving drug used to treat opioid overdoses, cost just one dollar for a nasal spray. Now, it costs $150, and the auto-injectable version costs $4,500.[5] EpiPen — a drug intended for emergency allergic reactions, and essential in childcare settings and schools. About a decade ago, after Mylan acquired the EpiPen, they sued generic companies trying to produce it and increased costs from $100 to over $600.[6] After a great deal of public outcry the company introduced a generic version of the EpiPen priced at $300 in the U.S. , while its price is $100 in Canada, and $38 in the UK.[7]

Debunking the Innovation Canard

Despite pharmaceutical industry claims that high prices are fueled by the risk and cost of drug research and development (R&D), recent evidence suggests these costs make up a small share of their spending. In 2017, drug makers spent a fraction -- 22% of their revenues -- on R&D.[8] Meanwhile, taxpayer-funded research contributed to every one of the 210 drugs approved between 2010 and 2016.[9]

For decades, drug makers have systematically abused patent and market exclusivity rules to quell product competition.[10] For example, AbbVie has nearly 250 patent applications around a single product – Humira – helping it to generate $100 billion from this drug alone.[11] And AbbVie is not alone in these abusive practices. The makers of the top 12 best-selling drugs in the United States have filed, on average, 125 patents per drug, resulting in an average 38 years of blocked competition, far in excess of the exclusivity envisioned under Federal law.[12] Instead of investing in real innovation, drug makers would rather make outsized profits on minor tweaks to existing drugs, which is why more than three quarters of new patents are for existing drugs.[13]

When patents on blockbuster drugs do finally expire, brand name manufacturers have turned toward increased prices on their remaining products to maintain and expand high revenues.[14] According to a 2017 study, revenues generated by new drugs failed to make up for loss in revenues due to expiration of patents. Increases in invoice prices for current drugs under exclusivity, however, generated $187 billion in revenues.[15] Were it not for these price increases, revenues for name brand pharmaceutical companies would

have been flat over the last decade, and overall spending on drugs would have fallen due to increased utilization of generic drugs.[16]

And, even when drug manufacturers do allocate a small percentage of their revenue toward *bona fide* innovations, all too often they focus their resources on drugs that don't address the most urgent needs of families and instead focus on niche drugs that yield the greatest profit.[17] For example, experts agree that across the world there is an urgent need for new antibiotics to combat increasing drug resistance, but major pharmaceutical corporations continue to step back from that life-saving research.[18]

Current Medicare Drug Payment Policy Represents Total Market Failure

Critics of H.R. 3 and other legislation to allow Medicare to negotiate on prices claim that these bills will "would end the current market-based system.[19]" To suggest that the current way in which brand name drugs are purchased by Medicare as "market-based" is utterly absurd. In truth, Medicare payment for brand name drugs is as far from a competitive marketplace as can be imagined. First, the Congress has granted government-sanctioned monopolies on brand name drugs through patent and market exclusivity laws. Second, Congress tied Medicare's hands by barring it from negotiating on prices for these drugs. Finally, Congress has kept the government from refusing to buy drugs at exorbitant prices. ***Let us be very clear: this is not a competitive market. It is a hostage situation.***

State Remedies are Limited without Action by Congress

Many states are doing everything in their power to address the drug affordability crisis for their consumers but they need the federal government to take action if they are to have the ability to fully address high and rising drug prices. During the 2019 legislative session, 44 states have filed 244 bills to control drug costs.[20] Precedent-setting legislation in Maryland will create a Prescription Drug Price Review Board to determine the appropriate price for government payers in the state to pay for high-cost drugs.[21] Additionally, Oregon, California, Connecticut, Nevada, and Vermont, recently enacted drug price transparency laws to require drug makers to justify dramatic price increases.[22] These state efforts are almost always challenged by lawyers from the pharmaceutical industry. And, without action from the federal government, state legislation can only do so much. Congress created the rules that drug manufacturers have so blatantly abused, and it alone has the power to change those rules.

Legislation Under Consideration

One option Congress is currently considering to reduce drug costs is to allow Medicare to negotiate the price it pays for pharmaceuticals. H.R. 3, *the Lower Drug Costs Now Act*, represents a critical and clearly necessary step in addressing the rapidly-growing crisis around prescription drug costs.

The *Lower Drug Costs Now Act* represents is the kind of legislation consumers are demanding—it requires government to take action so that they can afford their

medicines without bankrupting themselves in the process. And it does this without risking access to lifesaving medicines through a restrictive formulary. Specifically, the *Lower Drug Costs Now Act*:

- Authorizes and mandates that the Secretary negotiate directly with drug manufacturers on insulin and at least 25 other drugs that lack competition with the greatest costs to Medicare and the U.S. health system.
- Establishes a maximum negotiated price of no more than 1.2 times the average price offered in six other countries (Australia, Canada, France, Germany, Japan, and the United Kingdom).
- Requires manufacturers to make the negotiated price available to other purchasers.
- Provides a strong incentive for manufacturers to negotiate in good faith and to provide the negotiated price to Medicare and other purchasers through the use of an escalating excise tax and civil monetary penalties.
- Limits manufacturers' ability to hike the price of drugs year after year by imposing inflation rebates in Medicare Parts B and D.
- Caps out-of-pocket spending for seniors in Part D at $2000.

When enacted, the *Lower Drug Costs Now Act*, will significantly improve the affordability of prescription drugs for consumers and produce substantial savings in the Medicare Program. A preliminary analysis from the Congressional Budget Office found that the Senate's *Prescription Drug Pricing Reduction Act*, which includes an inflation rebate and Medicare Part D out of pocket cap, but not Medicare price negotiation, would save Medicare beneficiaries $27 billion in out-of-pocket costs and would save the Medicare program $85 billion over ten years.[23] With a lower out-of-pocket cap for Medicare beneficiaries, an earlier baseline year for the Medicare inflation rebates, and real negotiating authority for the Secretary, the savings for both beneficiaries and the Medicare program from the *Lower Drug Costs Now Act* promise to be much larger.

These savings can then be reinvested in ways that promise to improve health and health care for all consumers. Families USA strongly supports using savings generated by the *Lower Drug Costs Now Act* to support the research and development of new treatments and cures, particularly for diseases and conditions that have been ignored by private industry. Additionally, Families USA supports using these savings to provide much-needed Medicare dental, hearing, and vision benefits and improved support for low-income Medicare beneficiaries.

While Families USA strongly supports the passage of the *Lower Drug Costs Now Act*, we recommend several critical improvements to strengthen the bill to ensure that it fully delivers on its promise to make prescription drugs affordable. These improvements include:

- **Expanding the selection of drugs subject to negotiation:** The minimum number of drugs for which the Secretary must negotiate a fair price annually should be increased above 25 over time and there should be stronger criteria in place to ensure that it is the costliest drugs that are negotiated. Additionally, the

definition of a negotiation-eligible drug should be expanded to include drugs that face competition from less than three generics, as it is at this level of competition that prices are significantly reduced.[24] The Secretary should also have the discretion to select additional drugs for negotiation if the manufacturer is engaging in particularly abusive pricing practices.

- **Ensuring all consumers and purchasers are protected by price spikes:** It is not only Medicare beneficiaries who are harmed when manufacturers decide to increase their prices year over year. There should be strong incentives and/or penalties in place to ensure that manufacturers cannot raise prices above the rate of inflation for non-Medicare purchasers as well. This is particularly critical for drugs which have a relatively low exposure to Medicare – such as pediatric drugs.

- **Protecting uninsured consumers:** Though under this bill manufacturers would be required to make the negotiated price available to other health plans, this leaves uninsured consumers subject to high prices. As the consumers most vulnerable to high and rising prices, Congress should ensure that uninsured consumers can purchase drugs at no more than the prices negotiated for Medicare.

The American People – Across the Political Spectrum – Want Action

In last fall's midterm Congressional elections, the American people sent a strong signal to Capitol Hill. Sixty-three percent of voters cited health care as an important issue facing the country.[25] Even more to the point, an astounding 82 percent of Republicans and 90 percent of Democrats said, "Taking action to lower prescription drug prices" should be a top priority for the new Congress.[26]

Perhaps surprisingly to those in the political trenches, various solutions to solving the problem of high drug prices have public support across the political spectrum. Public polling finds that:

- 86 percent of Americans favor allowing Medicare to negotiate with drug companies to get a lower price on medications – particularly salient for today's conversation.[27]
- 75 percent of Americans favor shortening the length of monopoly granted on prescription drugs so that cheaper generic drugs are made available sooner.[28]
- 86 percent of Americans support requiring drug companies to release information to the public on how they set their drug prices.[29]

Given these findings, it is perhaps not surprising that a recent Gallup poll found that the

pharmaceutical industry is the *least popular* industry in America, with 58 percent of people in the United States holding a "totally negative" view of the industry.[30]

Now is the time for Congress to act boldly on behalf of their constituents. I ask you today, will you support this common sense legislation to protect taxpayers and your constituents from profiteering by the least popular industry in the country, or will you side with drug makers, who hope to continue to exercise unfettered and unregulated monopolies over their products?

Thank you for your time today. I look forward to continuing to work with this committee and your colleagues across Capitol Hill to bring real relief from high drug prices to America's families.

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Chairwoman WILSON. And thank you. We will now recognize Ms. Talente.

TESTIMONY OF BARI TALENTE, J.D., EXECUTIVE VICE PRESIDENT, ADVOCACY, NATIONAL MULTIPLE SCLEROSIS SOCIETY

Ms. TALENTE. Thank you. Good afternoon, Chairwoman Wilson and Ranking Member Walberg. Thank you for the opportunity to participate in this hearing on lowering drug prices and increasing transparency. My name is Bari Talente and I am the Executive Vice President of advocacy with the National Multiple Sclerosis Society. The Society works to ensure that the nearly 1 million people with MS in the United States have what they need to live their best lives.

People with MS are typically diagnosed between the ages of 20 and 50, making MS a disease that hits people during their prime employment years. In fact, nearly 60 percent of people living with MS have employer-sponsored health insurance. We hear from people with MS who are reluctant to disclose their diagnosis publicly because they feel their job may be in jeopardy or they don't want to be that person with their coworkers, the one who is responsible for driving up health insurance costs.

There are now more than 15 FDA-approved disease modifying treatments, referred to as DMTs, that help manage disease progression for relapsing forms of MS. No single DMT is best for all people living with MS so these treatments are not interchangeable.

The first—unfortunately, the price of these DMTs has dramatically increased since the first treatment was approved in 1993. That DMT came to the market at approximately $11,500 and now has a list price of more than $98,000. Imagine how this has felt for someone who has been on this treatment since it first came out.

In 2013, the annual median price for the MS DMTs was less than $60,000 dollars. Today, in 2019, that median price for brand MS DMTs is over $88,000 dollars.

We have seen escalating prices for products already on the market, some for a considerable amount of time.

In fact, a recent study by Health Affairs shows that price increases of brand name drugs are largely driven by year over year price increases of drugs already on the market and not by new products.

We have recently asked people with MS about the impact of the cost of these DMTs on them. 40 percent of those who took our survey shared that they have altered their use of their DMT because of costs. They are stopping treatment, skipping or delaying filling a prescription or not taking the medication as prescribed to try and make it last longer.

Due to the price, people with MS often face prior authorization and step therapy in their health insurance, which can delay care. Each time a person with MS experiences a gap in care or fails on a medication, they are at risk for a relapse, disease progression, and worsening of symptoms from which they may not fully recover.

Here are just two of the direct experiences people with MS have shared with us. Jenna from Massachusetts is worried about affording her DMT. Her husband's insurance currently covers it, but not

all insurances will. Jenna says, "we are terrified for him to change jobs because we cannot afford my medication if it is not covered. He has had to turn down a better paying job with better hours in order to keep our insurance."

Over the last decade, Keysha from Pennsylvania has tried many DMTs. She has commercial insurance through her employer and receives financial assistance through a manufacturer sponsored program, but she notes "If I am on super-expensive meds, I am hurting my company's bottom line in the end. I would choose a different medicine if there was one that was significantly lower in price."

Medications cannot change lives if people cannot access them. We must look at solutions across the entire prescription drug supply chain. Additional information about legislation we support is in our written testimony. We do support the goals and many provisions of the Lowering Drug Cost Now Act of 2019 and applaud this effort to lower drug costs. We appreciate this legislation does not establish a formulary and includes an out-of-pocket cap in Medicare part D.

We believe the bill could be strengthened by beginning the out-of-pocket cap earlier and expanding competition to be more than one single generic. I would like to conclude with a message from Keysha to all of you and your colleagues: "Do something to help with the cost. It is not a selfish thing to want to be well. To want to contribute. All people deserve a chance to be contributing members of society." Thank you, and I look forward to your questions.

[The statement of Ms. Talente follows:]

Written Statement of Bari Talente, J.D.
Executive Vice President of Advocacy
National Multiple Sclerosis Society
Before the Committee on Education and Labor
Subcommittee on Health, Employment, Labor, and Pensions
United States House of Representatives
Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency
September 26, 2019

Background and Introduction:
Good Afternoon. Chairwoman Wilson and Ranking Member Walberg, thank you for the opportunity to participate in this hearing on lowering drug prices and increasing transparency. My name is Bari Talente, Executive Vice President of Advocacy with the National Multiple Sclerosis Society. I think it is important to note who is not here today – the many people living with MS who have employer sponsored insurance and who because of high drug costs are worried about the cost to their employers and the effect that has on co-workers in the form of higher premiums, increased cost sharing, lost wages, or reduced benefits. In fact, we hear from many with MS who are reluctant to disclose their diagnosis publicly because they don't want to be "that person" with their coworkers or they fear their job may be in jeopardy because they are a driver of rising health insurance costs.

Nearly 1 million people are living with MS in the United States. Given that the average age of MS diagnosis is between the ages of 20 and 50, this is a disease that hits people during prime employment years. In fact, various surveys and studies tell us that nearly 60% of people living with MS have employer sponsored insurance.

But before we get into that let me tell you a little bit about multiple sclerosis, the Society and the impact of high drug prices, affordability and access for people living with MS. MS is an unpredictable, often disabling disease of the central nervous system that disrupts the flow of information within the brain, and between the brain and body. Symptoms vary from person to person and range from numbness and tingling, to walking difficulties, fatigue, dizziness, pain, depression, blindness and paralysis. The progress, severity and specific symptoms of MS in any one person cannot yet be predicted but advances in research and treatment are leading to better understanding and moving us closer to a world free of MS.

The National MS Society's vision is a world free of MS. Our mission is to ensure that people affected by MS can live their best lives as we stop MS in its tracks, restore what has been lost and end MS forever. We work with all ethical stakeholders, companies, organizations and individuals that share our mission to end MS forever. To that end, in 2018, the Society received $7.5 million USD from the pharmaceutical industry. This represented less than 4% of the organization's revenue in 2018. As we call for transparency across the prescription drug supply chain, we live this value and post this information on the Society's website. **It is important to note that we do not accept pharmaceutical support for our advocacy work**.

The Society is also an employer, with nearly 1,000 staff across the country. It should not surprise you that we have a higher percentage of employees living with MS than many employers. People directly affected by MS- whether they themselves live with MS or a loved one does- are drawn to our work. We also provide robust benefits to our staff and have also been directly impacted by rising health insurance costs due to the high price of drugs and the costs of treating MS. Over the past two years, our

organization's health insurance has increased by about 15% each year- after negotiating down from initially proposed increases of 19% and higher. Our leadership has affirmed our commitment to living our health care principles and ensuring our staff and their family members living with MS have affordable access to the medications they need. Choosing to support our employees has consequences and our organization has had to shift resources from priority work that benefits all people living with MS in the United States.

Cost of MS Disease Modifying Therapies & Impact on People with MS

A growing body of evidence indicates that early and ongoing treatment with a Food and Drug Administration (FDA) approved Disease Modifying Therapy (DMT) is the best way to manage the MS disease course, prevent accumulation of disability and protect the brain from damage due to MS. These medications have transformed the treatment of MS over the last 25 years. Fortunately, there are now over fifteen FDA-approved DMTs for relapsing forms of MS. No single agent is 'best' for all people living with MS. As MS presents differently in each individual, every person's response to a DMT will vary and these treatments are not interchangeable. It is not uncommon for people to work their way through several of the medications as they find the one that stabilizes their disease, or as different medications stop working for them.

Unfortunately for people affected by MS, the price of MS treatments has dramatically risen since the first DMT was approved in 1993 (appendix 1). The first medication, so anxiously awaited for, was approximately $11,500 when it came on the market. That same medication today has a list price of more than $98,000. It's not the only one. In the MS DMT market, price increases occurring one or more times per year for almost all DMTs have become the norm. Between 2004 and 2015, the average price of MS disease modifying treatments increased 300%. Those trends have continued. In 2013, the annual median price was less than $60,000. In 2019, the median price for brand MS DMTs is $88,853. While some of these increases are associated with new treatment options entering the market, the MS space is a prime example of escalating prices for products already on the market- some for a considerable amount of time. For almost all of these medications, they must be taken continuously. For a person with MS diagnosed at age 25, they could experience 50 plus years of DMT costs.

Today, people with MS report high and rapidly escalating medication prices, increasing out-of-pocket costs, confusing and inconsistent formularies, and complex payer approval processes that stand in the way of getting the treatments they need. Many people with MS tell us that without copay assistance, they would not be able to afford their medications to slow the progression of their disease. Further, we hear from healthcare providers and people with MS about barriers to treatment imposed by insurers rather than a shared decision-making process between the person with MS and their healthcare provider. One of these examples is so called "co-pay accumulators", which prohibit the application of copay assistance from counting towards an individual's deductible or out-of-pocket maximum.

Additionally, we have seen increased use of step therapy, or fail first, people have to "fail" on a medication that is preferred by an insurer before moving to a medication that is right for them. We have heard of people required to fail on treatments they already know don't work for them, or to try multiple similar treatments before being able to move to a different mechanism of action or route of administration. These policies are designed to discourage the use of costly medications. People with MS also report delays in treatment as they wait for prior authorization, or approval from their insurer for their medication. Each time there is a gap in care or someone fails on a medication, they are at risk for a relapse, disease progression and worsening of symptoms from which they may not fully recover.

Medications do not work if people cannot access them. In a recent survey of people with MS conducted by our organization, 40% shared that they have altered their use of their DMT because of costs. They may have stopped treatment for a period of time, they may skip or delay filling a prescription, maybe they skip or delay a treatment, or they don't take the medication as prescribed to try and make it last longer.

I would like to share just a few of the direct experiences of people with MS, who have shared with us the impact the cost of their medications have on their lives.

- Kristine from Georgia, who after her divorce, was forced to switch insurance plans. Her new plan required her to fail on some treatments before she could access the more aggressive treatment that her doctor prescribed. Because the average price of MS therapies is around $88,000 a year, it is common for insurers to implement utilization management practices like step therapy in order to control costs. Kristine shared the impact failing on a drug had on her life - "There were several times I was hospitalized for days at a time receiving high doses of IV steroids and unable to work. My symptoms ranged from electrical shock type pain in my face to having trouble walking to losing my speech for almost six months."
- Jenna from Massachusetts told us that after her medication stopped working for her, her doctor prescribed a different, more aggressive medication. This medication worked for her but is extremely expensive at over $80,000 a year. She wrote to us about the worry she felt about affording this medication if her insurance didn't cover it and about the terror she and her husband face about having to change jobs – and therefore change insurance. She wrote "My husband and I are both hard workers. He is a building maintenance tech in a union, and I am self-employed, helping other small business owners with their marketing. His insurance currently covers my medication, but not all insurances will. In fact, we are terrified for him to change jobs, because we cannot afford my medication if it is not covered. We struggle financially and he has to weigh new opportunities for employment, which would pay more and help us greatly, over the issue of health insurance coverage. Because all health insurances won't cover my treatments, he has had to turn down a better paying job, with better hours, in order to keep our current insurance."
- And Keisha from Pennsylvania, who was diagnosed with MS as a sophomore in college. Over the last decade, Keisha has tried many disease-modifying therapies to help manage her MS. She has commercial insurance through her employer and receives financial assistance through a manufacturer-sponsored program, but the expenses still add up because of copays and needing to meet deductibles. Keisha is especially concerned about the rising costs of disease-modifying therapies. She says, "If I'm on super expensive meds, I'm hurting my company's bottom line in the end. I would choose a different medicine if there were one that was significantly lower in price". Keisha has a message for you- as policymakers and decisionmakers: "do something" to help with the cost. It's not a selfish thing to want to be well, to want to contribute," she says. "All people deserve a chance to be contributing members of society, they need to be able to function just as much as I do."

Solutions for People with MS

Drug prices, affordability and access are complex problems that will require multiple solutions and shared commitment by all stakeholders. There is no silver bullet solution and we have to look at solutions across the entire prescription drug supply chain. The Society has advocated for Congress to

advance policies that will lower drug costs and improve access for those living with MS. The current trajectory is unsustainable for government, taxpayers, and those living with chronic conditions such as MS.

In 2016, the National MS Society released comprehensive recommendations to Make MS Medications Accessible (Recommendations), which call on all stakeholders across the healthcare and drug supply chain system to work together **to make medications more affordable, and the process for getting them simple and transparent**. We believe there is no single solution that can fully reverse the trend toward ever-increasing drug prices and payer policies that inhibit or delay access to medically necessary therapies. We have consistently called on all stakeholders to engage in conversations to drive solutions and to bring forward solutions for their industry. Congress is one of these stakeholders that must act.

Current Legislative Proposals

Reining in Price Increases

As shared above, price increases in the MS space have been particularly problematic. The National MS Society supports various proposals to address price increases.

- The CURE High Drug Prices Act (S.637/H.R.4158), introduced by Sen. Richard Blumenthal and Representative Pingree, would require pharmaceutical manufacturers to justify to the Department of Health and Human Services price increases of 10% or more within the previous year; 20% or more over 3 years; and 30% or more over the preceding 5 years. If the increases are found unreasonable, HHS could require the company to reimburse consumers and payors (including Medicare & Medicaid); provide the product for the price before the increase for up to one year; and pay civil penalties if the price gouging was done knowingly.
- The Fair Accountability and Innovative Research (FAIR) Drug Pricing Act (S.1391/H.R. 2296), sponsored by Representatives Jan Schakowsky (D-IL) and Francis Rooney (R-FL), and U.S. Senators Tammy Baldwin (D-WI) and Mike Braun (R-IN). The bipartisan, bicameral legislation would require transparency from pharmaceutical manufacturers who increase drug prices by more than 10% per year or more than 25% over a three year look-back period and justification for each price increase, including manufacturing, research and development costs for the qualifying drug and other information that is deemed appropriate.
- The Prescription Drug Sunshine, Transparency, Accountability and Reporting (STAR) Act (H.R. 2213), which includes the Stopping the Pharmaceutical Industry from Keeping Drugs Expensive (SPIKE) Act of 2019. The SPIKE Act requires manufacturers to report detailed information to the Secretary of the Department of Health and Human Services (HHS) for certain drugs if their prices exceed certain thresholds. Beginning in 2021, if a drug price increases by more than 10 percent or $10,000 over one year, 25 percent or $25,000 over three years, or has a launch price higher than $26,000, pharmaceutical manufacturers would be required to submit a justification for the price or price increase to the HHS Secretary. This justification would have to explain the causes of a price increase or high launch price, which could include information on expenses pertaining to developing, manufacturing, licensing, and marketing the drug. The STAR Act also includes language that would make information on PBM rebates public on the Department of Health and Human Service's website.

While thee FAIR Drug Pricing Act and the SPIKE Act legislation have similar intent, the Society believes that the language in the FAIR Drug Pricing Act will go further to level the playing field in regard to information that people with MS need to make more informed choices. While the SPIKE Act requires the

manufacturer (once a SPIKE is triggered) to submit information on individual factors that have contributed to the increase in the cost of the drug, the manufacturer would be able to make the determination on what factors have contributed to the price increase of the drug and submit information only on those factors. The Society's recommendations call for increased transparency in all levels of the prescription drug supply chain, so that all stakeholders are operating with the same information and we believe that the requirements outlined in the FAIR Drug Pricing Act move us closer to that goal.

Incentivizing generics and promoting competition
The Society is concerned with anticompetitive practices that may be delaying the entry of lower cost generics into the market and we have supporting the following legislation to help put an end to these practices.

- We support the Creating and Restoring Equal Access To Equivalent Samples Act (CREATES) Act, (S.340/H.R.965), which allows the FDA more discretion to approve alternative safety protocols, rather than requiring parties to develop shared safety protocols. It also creates a mechanism by which the generic manufacturers can seek a civil action against the brand company if that company refuses to provide samples within commercially reasonable, market-based terms. This legislation has bi-partisan, bi-cameral support, and we have urged Congress to swiftly pass it to ensure that bad actors cannot further delay needed therapies to the market.
- Additionally, the Society believes that Congress should pass legislation that prohibits "pay-for-delay" settlements and other anticompetitive tactics that prevent lower-cost generic medications from coming to market.
- We support the Preserve Access to Affordable Generics and Biosimilars Act (S.64) from Senators Chuck Grassley and Amy Klobuchar. This bill would prohibit brand name drug companies and biologic manufacturers from compensating generic companies or biosimilar manufacturers to delay the entry of a generic drug or biosimilar into the market. According to a recent Kaiser Health News data analysis the FDA has approved over 1,600 generic drug applications since January 2017, yet more than 700 (43%) were not on the market as of January 2019.vi According to that same analysis, 36% of generics that would be the first to compete in the marketplace against the branded drug are not yet for sale. FDA approval is one important step to improving access to lower cost medications, but these products need to be available for patients and the healthcare system to benefit and we urge you to consider this legislation for inclusion in your larger drug pricing package.
- The Society also supports the Biologic Patent Transparency Act (S.659), sponsored by Senators Collins and Kaine. This bill aims to provide transparency around patents, promote competition in the biosimilar space in order to expedite lower cost biosimilar treatments. The Society believes that issues surrounding patents need to be examined more broadly, and we urge Congress to thoroughly examine patent issues and the role they play in high prescription drug costs. The Society believes that novel innovation and intellectual property must be protected in order to foster better therapies, but that protection needs to be balanced with the goals of the Hatch-Waxman act to ensure that after the protection period, that both biosimilar and generic therapies have an uninterrupted pathway to market.

The Prescription Drug Pricing Reduction Act of 2019
The Society supports provisions within the Senate Finance Committee's *The Prescription Drug Pricing Reduction Act of 2019 (PDPRA)* to reduce beneficiaries' out-of-pocket drug costs in Part D. Medicare

beneficiaries living with MS have high out-of-pocket costs and typically reach the catastrophic phase early in the year (appendix 2). Once they reach the catastrophic phase in Part D they are still responsible for 5% of the costs of their medications.

The Society also supports provisions to require drug manufacturers to pay additional rebates if they raise prices above the inflation rate. Studies have indicated potential shadow pricing in the MS DMT class over the past several years[i], and we urge Congress to include provisions to help alleviate it. We believe that this legislation will help limit price increases for existing MS medications.

As people with MS need relief now from high out of pocket costs, the Society have urged implementation of this provision before 2022. Further, we encourage Congress to consider options such as a monthly cap or other alternatives to smooth out-of-pocket cost burdens for beneficiaries throughout the year. We also urge that Congress consider equalizing manufacturer liability in both the catastrophic phase and the coverage gap. Placing manufacturer liability in just the catastrophic phase could have unintended and unforeseen effects on the market for specialty medications.

Lower Drug Costs Now Act of 2019 (H.R. 3)

The National MS Society supports the goals and many provisions of the Lowering Drug Costs Now Act of 2019 (H.R. 3) and applaud Chairmen Scott, Pallone and Neal for their leadership in advancing policies that will result in lower drug costs for many Americans.

The Society's 2016 recommendations to make MS medications accessible for people with MS called for Congress to allow the Secretary of Health and Human Services to negotiate the prices of medications. We are pleased that this is a fundamental provision of H.R. 3 and is a positive step to address high drug prices. It's important that those negotiated prices will be offered to commercial plans. MS DMTs are some of the most expensive medications. In 2017, two of the MS disease-modifying therapies (DMTs) rank in the top 25 medications by total spending and accounted for over $2.5 billion in total spending, according to the Centers for Medicare and Medicaid Services (CMS) dashboard. The idea of negotiating prices for Medicare Part D could have a real-life impact on people living with MS on Medicare, because the actual price of medications matters to them. Depending on how much a person has paid towards their drug costs for the year, they could be paying coinsurance based on the price of the drug. Negotiating a lower price on their behalf could yield real savings for both individuals and the health care system.

We do have a suggestion related to medications eligible for negotiation. According to the Food and Drug Administration, "On average, the first generic competitor prices its product only slightly lower than the brand-name manufacturer. However, the appearance of a second generic manufacturer reduces the average generic price to nearly half the brand name price. As additional generic manufacturers market the product, the prices continue to fall, but more slowly. For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower."[ii]

We have noted above our support for bipartisan legislation that will promote bringing additional generics to the market. Currently, only one MS brand DMT has generic competition. There are two generics for this DMT, which are also expensive (especially when considered in price with traditional generics) and to date, these generics have had little impact on both overall costs within the class or on people's out-of-pocket costs. These generics entered the market with list prices more than $60,000 per

year, and though one drastically reduced its list price more than a year ago, access to this generic has not followed general market trends for generics. Additionally, the cost of these generics often means that they are placed in the specialty tier of a formulary, removing any incentive for their use. As more specialty medications go generic, it is important to ensure access to these generics can drive prices downward. Therefore, we urge that H.R. 3 is modified so that competition from a single generic is not a sole reason to exclude a drug from consideration in negotiation. It is also unclear if complex/specialty generics work as traditional generics, and the legislation may want to include flexibility to address this group of medications.

We appreciate that H.R. 3 does not include a formulary. As stated previously, MS medications are not interchangeable and a formulary could restrict access to certain medications. We also appreciate that that those on commercial and employer sponsored plans could benefit from the negotiated price. However, we urge that the inflation rebates in Parts B and D be applied to commercial plans as well.

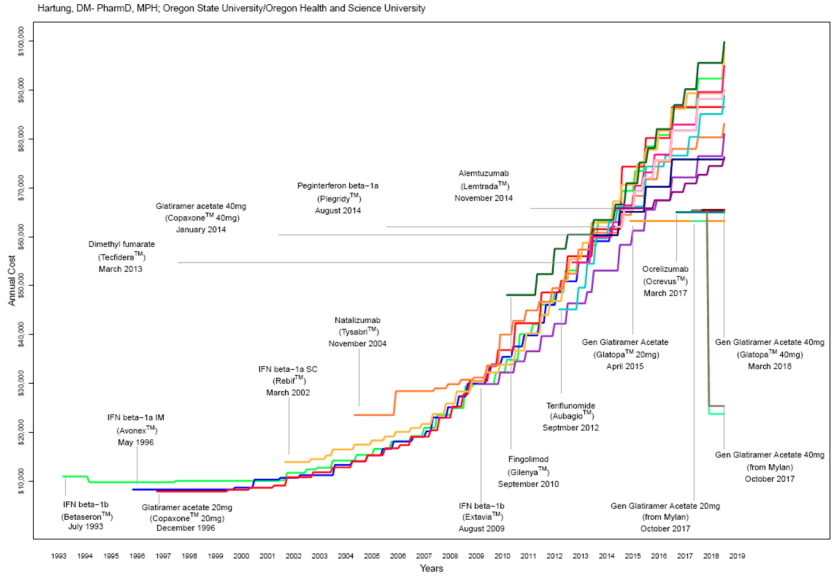
We also support the provisions to establish an out-of-pocket cap in Medicare Part D and are encouraged by the significant bipartisan support for this cap. We appreciate the various legislative efforts to ease the burden on Medicare beneficiaries and that H.R. 3 includes a Medicare Part D out of pocket cap of $2,000 in 2022. As stated above, we believe that this could be implemented earlier and that smoothing out-of-pocket costs throughout the year be considered. As you can see from appendix 2 those living with MS face high out-of-pocket costs at the beginning of the year and smoothing these costs along with an out-of-pocket cap could provide predictability for those Medicare beneficiaries living with MS. People with MS on Medicare currently pay approximately $6,0000 out-of-pocket just for their MS DMT. Then, there are symptom management medications for MS and medications for other health conditions an individual may have. An out-of-pocket cap is needed to bring predictability, affordability and access to Medicare beneficiaries.

Much discussions has been raised around the impact of any sort of legislation to address prescription drug prices on innovation in drug development; however, recent analysis shows that price increases of brand name drugs are largely driven by year-over-year price increases of drugs that already in the market vs. new products.[iii] We recommend that H.R. 3 be amended to include the FAIR Drug Pricing Act, to address this issue.

We thank the Committee for your attention to these important and complicated issues that cross all types of health insurance, employers and all aspects of individuals trying to live their best lives. The National MS Society is committed to working with all committees of jurisdictions to find solutions for people with MS.

I look forward to your questions on this important issue.

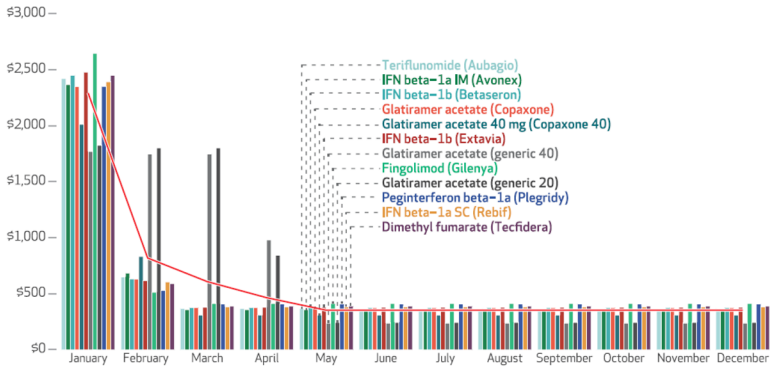
Appendix 1


Hartung, DM- PharmD, MPH; Oregon State University/Oregon Health and Science University
Annual Cost
$10,000
$20,000
$30,000
$40,000
$50,000
$60,000
$70,000
$80,000
$90,000
$100,000
1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019
Years
IFN beta−1b (Betaseron™) July 1993
IFN beta−1a IM (Avonex™) May 1996
Glatiramer acetate 20mg (Copaxone™ 20mg) December 1996
IFN beta−1a SC (Rebif™) March 2002
Natalizumab (Tysabri™) November 2004
Glatiramer acetate 40mg (Copaxone™ 40mg) January 2014
Dimethyl fumarate (Tecfidera™) March 2013
Peginterferon beta−1a (Plegridy™) August 2014
Alemtuzumab (Lemtrada™) November 2014
IFN beta−1b (Extavia™) August 2009
Fingolimod (Gilenya™) September 2010
Teriflunomide (Aubagio™) Septmber 2012
Gen Glatiramer Acetate (Glatopa™ 20mg) April 2015
Ocrelizumab (Ocrevus™) March 2017
Gen Glatiramer Acetate 20mg (from Mylan) October 2017
Gen Glatiramer Acetate 40mg (Glatopa™ 40mg) March 2018
Gen Glatiramer Acetate 40mg (from Mylan) October 2017

Appendix 2

EXHIBIT 4

Projected out-of-pocket spending for beneficiaries without a low-income subsidy for multiple sclerosis disease-modifying therapies, by month, 2019



SOURCE Authors' analysis of data from the Prescription Drug Plan Formulary files of the Centers for Medicare and Medicaid Services (CMS), and CMS enrollment data in 2016 (the most recent data available); and 2019 basic Part D benefit plan parameters. Drug prices are derived from the Medicare Plan Finder, using the nationwide plan that reported the lowest retail costs in the Portland, Oregon, metropolitan area. **NOTES** The solid line is average projected out-of-pocket spending across drugs. Appendix exhibit A6 shows details by drug (see note 20 in text). IFN is interferon. SC is subcutaneous. IM is intramuscular.

[i] Hartung, DM, Bourdette DN, Ahmed SM, Whitham RH. "The cost of multiple sclerosis drugs in the US and the pharmaceutical industry: Too big to fail?". Neurology. 2015 May 26;84(21):2185-92. doi: 10.1212/WNL.0000000000001608. Epub 2015 Apr 24. https://www.ncbi.nlm.nih.gov/pubmed/25911108. (Accessed 9/24/2019).

[ii] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices

[iii] Hernandez, Inmaculada. et. al. The Contribution of New Product Entry Versus Existing Product Inflation In The Rising Costs of Drugs. Health Affairs. January 2019. https://doi.org/10.1377/hlthaff.2018.0514 . https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2018.05147. (Accessed 9.24.2019)

Chairwoman WILSON. Thank you, Ms. Talente. We will now recognize Dr. Socal.

TESTIMONY OF MARIANA P. SOCAL, MD, MS, MPP, PH.D., ASSISTANT SCIENTIST, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH, DEPARTMENT OF HEALTH POLICY AND MANAGEMENT

Dr. SOCAL. Good afternoon. Thank you, Chairwoman Wilson, Ranking Member Walberg and Members of the Committee. It is a great honor and It is a great pleasure to be talking to you today.

For over a year, I have been researching America's largest employers and trying to help them improve the drug benefit that they offer to their workers. In one of these initiatives and partnering with the Pacific Business Group on Health, a coalition of more than 50 large public and private employers to identify and remove wasteful spending from their drug formularies.

I am also leading a research project in which I partnered with ERIC, the ERISA committee. This committee represents nationwide self-insured companies with more than 10,000 employees. In this project, I am examining the prices that some of the largest U.S. corporations are paying for their drugs.

The first thing I learned in my research is that employers want to provide their workers with the best benefits that they can. Companies want to attract and retain the best workers in offering good benefits is key for that.

The second thing that I have learned is that companies are spending a lot of money hiring specialists to help them manage their drug benefit, but they are not always getting the best deals that they can. Typically, employers hire pharmaceutical benefit managers, a PBM, to negotiate drug prices on their behalf. The PBM also designs the drug formulary that goes to the employer's plan.

So here is how the negotiation works. The PBM offers to cover a drug on the formulary in exchange for lower prices. When the PBM has a choice and can pick between a few drugs, which one will go into the formulary, then the market can work. The problem occurs when a drug has no competition. If the PBM cannot say no to a certain drug and then choose a different one, then the PBM cannot negotiate a lower price, and there is no incentive for manufacturers to lower the price.

As a result, for certain drugs without competition, the U.S. pays three to four times more higher prices than in other countries.

For these cases, a different type of negotiation is needed. In the absence of product to product competition in the U.S. market, the price comparison between the U.S. and other countries can offer an alternative pathway for this negotiation. My colleagues and I examined the 79 top spending drugs in the Medicare part D program, and we found that if the U.S. paid the average price of the countries that we studied, Medicare part D alone could have saved $73 billion in 2018.

If employers adopted the same approach, the savings would be similar. H.R. 3's proposal of having the secretary negotiate on behalf of all Medicare beneficiaries and those covered by private insurance is likely to succeed in lowering drug prices because of two

main reasons: first, because it includes everyone in the negotiation. The more people included in the negotiation, the greater the negotiating power and the greater ability to lower prices.

Second, because it incorporates a transparent benchmark into the negotiation, the prices paid in other countries. U.S. companies, especially the very large employers, they like to think that they are getting the best possible deals in drug pricing, but we found that sometimes, the employers don't even have the information that they need to understand if they are getting the good deal or not.

It is very hard, for example, for an employer to know how much they are paying for a drug. The net price, after the rebates and discounts can be only known sometimes weeks or months after the drug bill was paid and there is very little transparency in this process.

The negotiation proposed in H.R. 3 would benefit employers by providing them with a transparent maximum price. It will also allow employers to opt out of the price so that they can choose what's the best deal for them. For patients, lower and transparent prices will help reduce cost-sharing. Patient's cost-sharing is typically calculated over a drug's list price. Having a transparent and lower drug price available to all patients will allow them to benefit directly from the negotiations. This is also very important for the 30 percent of American workers who are currently enrolled in high-deductible health plans. These patients pay the drug's full cost. Today, over half of all Americans obtain health coverage through their employer, most of them through self-insured employers which the employer will pay the drug's bill.

In response to rising drug costs, many companies are pushing more of the cost of prescription drugs onto the employees, either in the form of high deductibles or by charging a percentage cost-share, especially for high-cost drugs. This is one of the reasons why many Americans are not able to afford the drugs they need, even if they have health insurance.

Thank you so much for your time, and I look forward to your questions.

[The statement of Dr. Socal follows:]

JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

Department of Health Policy and Management

BEFORE THE U.S. CONGRESS
HOUSE COMMITTEE ON EDUCATION AND LABOR

Subcommittee on Health, Employment, Labor and Pensions

Congressional Hearing, September 26, 2019

"MAKING HEALTH CARE MORE AFFORDABLE: LOWERING DRUG PRICES AND INCREASING TRANSPARENCY"

Statement of

Mariana P. Socal, M.D., M.S., M.P.P., Ph.D.

JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

Department of Health Policy and Management

Chairmwoman Wilson, Ranking Member Walberg, and members of the Committee, good afternoon. It is a great honor to be speaking with you today. My name is Mariana Socal, and I am a medical doctor. I have a Ph.D. in Health Systems from the Johns Hopkins University and a master's in Public Policy from Princeton University.

I am currently a faculty member in the Department of Health Policy & Management at the Johns Hopkins Bloomberg School of Public Health. My primary research interest is how to improve access for people who need prescription drugs to improve their health and quality of life.

For over a year, I have been partnering with the Pacific Business Group on Health – a "purchaser coalition representing 60 public and private organizations across the U.S that collectively spend $40 billion a year purchasing healthcare services for 10 million Americans"[1] - to improve the drug benefit that they provide to their members by identifying and removing wasteful drug spending from their drug formularies.

I also lead a research project in partnership with ERIC – The ERISA Committee. ERIC represents large plan sponsors - generally nationwide companies with over 10,000 employees—that "provide comprehensive employee benefits to workers

[1] http://www.pbgh.org/about/members

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and families across the country."[2] In this project, we are examining prices paid by 10 of the largest US corporations for biologic and biosimilars. These companies have asked us to analyze their information because they are concerned that they may not be getting the best deals that they can.

I am speaking today on my own behalf. The opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University.

I would like to provide commentary on how high drug prices impact American employers and their workers, and American retirees.

PART I – HOW HIGH DRUG PRICES IMPACT AMERICAN EMPLOYERS AND THEIR WORKERS, AS WELL AS RETIREES

Most Americans obtain health coverage through their employers

Currently, 55% of all Americans obtain health coverage through their employer[3] and 61% of those individuals are covered by employer self-

[2] https://www.eric.org/about-eric/

[3] US Census Bureau - Health Insurance Coverage in the United States: 2018 https://www.census.gov/content/dam/Census/library/publications/2019/demo/p60-267.pdf

sponsored insurance plans.[4] This means that the prescription drug costs of most American workers are paid directly by their employer.[5] However, recently many companies are pushing more and more of the costs of prescription drugs onto the employees. This one of the reasons why members of Congress are hearing more about the cost of prescription drugs.

Self-insured employers take a financial risk to cover their employees

Given the high number of Americans who depend on self-insured employers to obtain their coverage, and the financial risk that these employers and employees are taking, it is imperative to keep prescription drug costs under control. Today, prescription drug prices are on the rise and this means that many Americans are not able to afford the drugs they need, even if they have health insurance.

Today, most employers negotiate drug prices through a PBM

The typical self-insured employer hires a pharmaceutical benefit manager – PBM – to manage their drug benefit. The PBM negotiates prices with the

[4] Kaiser Family Foundation Employer Health Survey 2018
https://www.kff.org/health-costs/report/2018-employer-health-benefits-survey/
[5] Self-insured employers may purchase stoploss insurance, which may cover varying portions of the risk. (reference: Kaiser Family Foundation survey)

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drug manufacturers and, based on these negotiations, the PBM designs the drug formulary that determines the employer's drug benefits.

PBMs must have the ability to say "no" in order to successfully negotiate

In order to obtain a lower price for a certain drug, the PBM will offer to place that drug in a favorable position in the formulary – at lower cost sharing or without any clinical requirements for utilization. Often, in exchange for a lower price, the PBM will also agree to exclude the drug's competitors from the formulary. Thus, the ability to say "no" and exclude certain products from the formulary is *crucial* for the success of most price negotiations performed in America today. When the PBM has a choice, and therefore the ability to negotiate, the market can work. This occurs when there are both branded and generic products available in the market for the same drug, or when there are many similarly effective drugs available in the same therapeutic class.

The market fails when there is no competition

The problem occurs when there is no competition because the drug is the only option available in the market. This may occur even for drugs that have been on the market for a long period of time. Drugs can keep their competitors off the market by instituting pay-for-delay agreements, for

example, or by extending their patent life by implementing tweaks to their chemical composition, to their administration mechanism, and so on. Insulin, for example, is an unpatented drug, but its administration devices are protected by patents. In some cases, the market is small and even if the drug is not protected by a patent, there is not enough incentive for a competitor to enter the market. In these situations, especially if the drug is the only one that treats the disease, prices remain high because the PBM cannot negotiate lower prices and drug manufacturers do not have an incentive to offer a lower price.

The US pays much higher drugs prices than other countries for certain drugs

My colleagues and I examined the 79 top-spending drugs in the Medicare that had no generics or biosimilars available.[6] These drugs alone were responsible for over 50% of the total part D program spending in 2016. We compared the U.S. prices of these drugs to the prices in the UK, in Japan and in Ontario, Canada. We found that, on average, U.S. prices were 3 to 4 times higher than the prices in other countries, for the same drugs. Interestingly, drugs that were "older," i.e., were available in the US market for longer, had higher price differentials when compared to other countries.

[6] Kang SY, DiStefano MJ, Socal MP, Anderson GF. Using External Reference Pricing in Medicare Part D To Reduce Drug Price Differentials With Other Countries. Health Aff (Millwood). 2019 May;38(5):804-811.

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US drug rebates do not offset the price differential with other countries

In our analysis, we accounted for drug rebates paid by drug manufacturers. We found that, in order for the US price to match the average price of the other countries, drug manufacturers would have to offer an average rebate of approximately 78% for the drugs that we studied in the US. Drug rebates are confidential, and so we could not verify manufacturer's actual behavior. However, it is unlikely that drug manufacturers would provide such high rebates to all drugs that we studied because these drugs lacked direct competition. The numbers published by Medicare show average rebates for branded drugs in the low 20%[7], and an independent analysis by the IQVIA institute found average rebates in the Medicare program of approximately 35% for branded drugs.[8]

List prices, <u>before</u> rebates, determine Americans' cost-sharing amounts

Even if a manufacturer were to offer a large rebate to the PBM or self-insured company on one of these high-cost drugs, the problem is that the level of cost sharing by the American worker is determined by the drug's list prices before rebates are applied. The Associated Press reported in the first 7 months of 2018 that drug companies were 96 times more likely to increase the list price

[7] CMS. 2014 Part D Rebate Summary for All Brand Name Drugs. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/PartD_Rebates.html
[8] IQVIA institute. Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates. October 2016. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/estimate-of-medicare-part-d-costs-after-accounting-for-manufacturer-rebates.pdf

than to lower the list price.[9] Today, American workers are increasingly required to pay a percentage of the list price of their drugs, especially for high-cost specialty drugs.

In the Medicare program, it is estimated that 63% of beneficiaries are enrolled in a plan that charges a percentage coinsurance for specialty drugs.[10] The result is that, on average, patients pay approximately 22% of the final cost of any given drug.[11] This is why it is becoming increasingly hard for Americans to afford drug prices. Patients do not directly benefit from drug rebates because their out-of-pocket payment is typically calculated over the drug's list price.

Out-of-pocket caps alleviate, but do not necessarily resolve the problem

Fortunately, there are out-of-pocket maximums for most employees with employer-sponsored coverage. However, in about 20% of cases, the out-of-pocket maximum is equal to or higher than $6,000 a year.[12] This amount represents almost 10% of the median household income in America (which,

[9] https://www.apnews.com/b28338b7c91c4174ad5fad682138520d
[10] Medicare's Part D Drug Benefit At 10 Years: Firmly Established But Still Evolving. Hoadley J.F., Cubanski J., Neuman P. Health Affairs 34, No. 10 (2015): 1682–1687
[11] IQVIA institute. Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates. October 2016. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/estimate-of-medicare-part-d-costs-after-accounting-for-manufacturer-rebates.pdf
[12] Kaiser Family Foundation Employer Health Survey 2018 https://www.kff.org/health-costs/report/2018-employer-health-benefits-survey/

according to the US Census Bureau, was $61,372 in 2017).[13] In addition, patients pay full list price for their drugs while they are on their deductible phase; this is extremely important for the American workers enrolled in high-deductible health plans. As of 2018, this represented 29% of workers with health insurance.[14]

Medicare beneficiaries do not have an out-of-pocket maximum

It should also be noted that, while most employees covered by employer-sponsored health insurance are protected by an out-of-pocket maximum, once they become Medicare beneficiaries they lose this protection. Medicare beneficiaries obtain their drug benefit through the part D program, which does not have an out of pocket limit. There have been multiple proposals to limit the out-of-pocket liability for Medicare beneficiaries, such as a proposal by the Trump Administration, the Senate Finance Bill that passed, and HR 3; these proposals simply disagree on the amount.

PART II – HR3 AND OTHER POLICY CONSIDERATIONS

In sum, high drug prices strain American employers, workers, and retirees. The market does not work for certain drugs because the PBMs have limited

[13] US Census Bureau https://www.census.gov/library/publications/2018/demo/p60-263.html

[14] Kaiser Family Foundation Employer Health Survey 2018 https://www.kff.org/health-costs/report/2018-employer-health-benefits-survey/

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negotiating power when there is no competition. For these cases, alternative negotiation pathways are greatly needed. The negotiation mechanisms outlined in HR3 target these drugs for which there is a market failure. In the absence of product-to-product competition within the US market, the price comparison between the US and other countries can offer an alternative pathway for negotiation.

Using international prices as a benchmark can bring the US price back to international norms

Currently, most pharmaceutical manufacturers are global companies and they rely on sales in both US and international markets to obtain their revenue.[15] Using average international market prices as benchmarks for US price negotiations has the potential to generate significant savings for US employers and their employees. Our analysis of the 79 top-spending drugs in Medicare part D found that, if the US paid the average price across the countries that we studied, the Part D program alone could have saved $72.9 billion dollars in 2018.[16] If employers adopted this approach the savings would be similar

Which countries should be included in the international price?

[15] https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf

[16] Kang SY, DiStefano MJ, Socal MP, Anderson GF. Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials With Other Countries. Health Aff (Millwood). 2019 May;38(5):804-811.

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It is important to select countries that have similar per capita incomes and large pharmaceutical markets like the US to be included in the international price. Ideally, these countries would also have diverse price-setting approaches. For example, some countries such as the UK have value-based pricing, whereas other countries such as Germany have market-based pricing. Our research found no major differences when prices from other countries were compared with each other. The patterns that emerged in our data suggest that, although countries may have different mechanisms for setting or negotiating drug prices, ultimately they obtain drug prices within the same range.

There is strength in numbers: price negotiations involving more individuals result in lower drug prices

Currently, negotiations for most covered Americans are fragmented between drug manufacturers and each one of the PBMs, Medicare prescription drug plans, Medicare Advantage plans, and so on. HR 3's proposal of having the HHS Secretary negotiate on behalf of all Medicare beneficiaries and those covered by private insurers, including by self-insured employers, would greatly increase the negotiation power because it would cover the vast majority of Americans. Combining larger numbers of individuals in a single negotiation has been shown to increase negotiating power and result in lower drug

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prices.[17] In addition, companies can opt out of the negotiated price, which is a critical element of this proposal.

Experience suggests that the HHS Secretary can successfully negotiate prices

The experience of governmental agencies such as the Department of Veterans Affairs and the Department of Defense provides a solid example in support of the HHS Secretary successfully negotiating drug prices. These agencies have negotiated drug prices on behalf of their beneficiaries for years and have obtained the lowest prices in America today.[18] It is estimated, for example, that the VA pays 44% less than Medicare for a same basket of drugs.[19]

There is strong public support for allowing the HHS Secretary to negotiate drug prices

The Kaiser Family Foundation performs a periodic survey of the American public to examine the public's opinions, knowledge, and experiences on

[17] Insurer bargaining and negotiated drug prices in Medicare Part D. Lakdawalla D., Yin W. NBER Working Paper 15330. http://www.nber.org/papers/w15330
[18] GAO-13-358. Prescription Drugs:Comparison of DOD and VA Direct Purchase Prices. https://www.gao.gov/products/GAO-13-358
[19] Venker B, Stephenson KB, Gellad WF. Assessment of Spending in Medicare Part D If Medication Prices from the Department of Veterans Affairs Were Used. JAMA Intern Med. 2019;179(3):431-433.

various issues related to the U.S. health care system.[20] In February 2019, the Kaiser Family Foundation survey found that 86% of the general public and 82% of Americans aged 65 and older supported allowing the federal government to negotiate with drug companies to get a lower price for people on Medicare.

Having the HHS Secretary negotiate drug prices would benefit employers

Currently, many Medicare prescription drug plans are managed by the same PBMs who manage the drug benefit for private plans, including for self-insured employers.[21] This means that when PBMs can't negotiate effectively for Medicare plans, they can't negotiate effectively for private plans, and vice versa.

Employers need help getting good prices for high-cost drugs

US companies, especially very large employers, like to think that they are getting the best possible deals from their PBMs. However, this is not always the case. We were asked by ERIC, the Committee that represents large

[20] KFF Health Tracking Poll – February 2019: Prescription Drugs. https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/

[21] Insurer bargaining and negotiated drug prices in Medicare Part D. Lakdawalla D., Yin W. NBER Working Paper 15330. http://www.nber.org/papers/w15330

nationwide employers who are also plan sponsors, to examine the prices that 10 of the largest US corporations were paying for biologics and biosimilars. The first thing that we found was that the PBMs did not always give these companies the information they needed to determine if they were getting a good deal. When we finally got the data, we found that two companies of the same size and using the same PBM were paying about 10% different prices for a same high-cost biologic drug.[22]

Employers and workers are spending unnecessarily high amounts on branded drugs. Increased price transparency can help reduce that

PBMs have a financial incentive to keep high-cost, high-rebate drugs in employers' drug formularies. This is because, for branded drugs, PBMs can make a profit by retaining some portion of the rebates plus any fees that they obtain from drug manufacturers, and drugs that are more highly priced can generally offer greater rebates. Therefore, drugs that have high prices and high rebates may be favored in the formulary in detriment of lower-cost alternatives. In the Medicare program, for example, we found that 70% of part D prescription drug plans had placed at least one branded drug more favorably than its corresponding generic in the formulary.[23] This increases cost unnecessarily for both plans and beneficiaries. Unfortunately, employers

[22] These are initial results from an ongoing research project and have not been published.

[23] Socal MP, Bai G, Anderson GF. Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics Are Available. JAMA Intern Med. 2019 Jun 1;179(6):832-833.

do not always have the full information to identify that these distortions are present in their drug formulary. [24]

Reducing wasteful spending from high-price high-rebate drugs could save employers up to 24% of their overall pharmacy spending

An analysis of 15 large US companies by the Pacific Business Group on Health, a purchaser coalition representing 60 public and private organizations across the U.S that collectively purchase healthcare for 10 million Americans,[25] has shown that reducing the use of high-cost, low-value drugs could save 3% to 24% of a company's *overall* pharmacy spending. [26] Having a transparent price for branded drugs available for all employers would increase transparency and would help employers identify where they are spending too much with certain drugs, better equipping employers to identify and ultimately remove wasteful spending from their drug benefit.

[24] Bai G, Socal MP & Anderson GF. Policy Options To Help Self-Insured Employers Improve PBM Contracting Efficiency. Health Affairs Blog. May 29, 2019. https://www.healthaffairs.org/do/10.1377/hblog20190529.43197/full/

[25] http://www.pbgh.org/about/members

[26] Vela, L. Reducing Wasteful Spending in Employers' Pharmacy Benefit Plans. https://www.commonwealthfund.org/publications/issue-briefs/2019/aug/reducing-wasteful-spending-employers-pharmacy-benefit-plans

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Having the option of accessing the HHS-negotiated price would benefit employers in two ways: lower drug prices and increased transparency

Having the option of agency-negotiated price would, first, offer lower prices to employers and to workers who obtain coverage through employer-sponsored health insurance. PBMs would still be allowed to negotiate down prices, bringing additional price reductions into the system. The experience in the Japanese system, where the government negotiates a maximum price and payers obtain further discounts from their own subsequent negotiations, shows that drugs' actual selling prices will be lower than the maximum price in the government fee schedule because of competition among distributors.[27] In addition, HR 3 would benefit employers by providing them with a transparent maximum price. Having a transparent pricing benchmark will show employers if they are getting a better deal by opting in or opting out, improving their decision-making.

For patients, greater price transparency may reduce cost-sharing

Currently, when beneficiaries must pay a percentage of the drug cost, the patient's cost-sharing amount is calculated based on the drug's list price (i.e., the price before rebates and discounts are applied). The drug's net price after

[27] Ikegani N, Anderson GF. In Japan, All-Payer Rate Setting Under Tight Government Control Has Proved To Be An Effective Approach To Containing Costs.

rebates and discounts is usually not known at the time that the patient is obtaining their drug and therefore it cannot be used. HR 3 will allow for HHS-negotiated prices to be available at the time that patients are obtaining their drug, allowing these prices to be used in cost sharing calculations. HHS-negotiated prices are likely to be much lower than the list price, which would likely translate to lower cost-sharing amounts for patients.

Having a penalty is an important element to enable the negotiation

The US pays more than other countries especially for drugs that have been on the market for many years. When drugs already have an established market, and there are patients who depend on them, PBMs are less likely to be able to say "no" and remove the drug from the formulary. Therefore, some drugs may exhibit egregious price-hiking behaviors such as Daraprim's overnight 5000% price increase back in 2015 without concerns for losing market share.[28] It is important to have a clear penalty that can prevent these behaviors and ensure that drug manufacturers come to the table to negotiate.

Having an inflationary rebate is an important mechanism to prevent price hikes for drugs that are not eligible or not selected for negotiation

[28] https://khn.org/news/for-shame-pharma-bro-shkreli-is-in-prison-but-daraprims-price-is-still-high/

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Drugs that are not eligible or that are not selected for negotiation in a given time period may still exhibit price increases that can be detrimental for payers and beneficiaries. HR3 establishes an inflationary rebate that provides an important mechanism to prevent such price increases for branded and generic drugs alike.

In order to protect and reward innovation, new drugs are granted patents that provide a period of time in which the drug has a monopoly i.e., no other competitor may enter the market. Drug manufacturers set the drug's launch price to allow them to recoup their research and development investments during the drug's monopoly period. Price changes that occur after a drug has launched are unlikely to be related to the need to recoup R&D investment.

Other developed countries have mechanisms in place to prevent this type of behavior. In the US, many of today's high-cost drugs originally entered the market at lower prices and have only become expensive over time.

Allowing the HHS Secretary to negotiate drug prices is unlikely to discourage drug innovation

The concern that negotiating prices would discourage innovation comes from the perception that, if pharmaceutical manufacturers were to have lower

revenue, they would not have sufficient funds to invest in research and development for new drugs. However, there are some facts that speak against this perception.

First, pharmaceutical manufacturers are spending more on drug marketing than on drug research and development.[29] Having a strong drug development pipeline is crucial in order to attract investors and remain competitive in the market. Even if manufacturer revenues were to decrease under the new policy, manufacturers would be unlikely to choose to cut spending on drug development when they could first implement cuts to the marketing budgets.

Second, the costs of research and development for each drug are debatable. Median estimates vary from about $2 billion to a about $650 million per drug.[30] At the same time, estimates suggest that, after four years in the market, a drug will have generated over 9 times higher revenue than its own research and development costs.[30]

[29] Swanson A. Big pharmaceutical companies are spending far more on marketing than research. https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/

[30] Prasad V., Mailankodi S. Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval. JAMA Intern Med. 2017;177(11):1569-1575. ttps://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2653012

Lastly, the federal government, though its agencies such as the National Institutes for Health (NIH), currently funds a significant portion of the research and development costs for pharmaceuticals, especially at the initial phases of drug development, when failure rates are high. If the savings obtained from price negotiations were reinvested, the fraction represented by governmental funding could be significantly increased.

Drug costs are unlikely to shift to other countries if the Secretary uses an international benchmark in the US

Most developed countries have mechanisms in place to negotiate or regulate drug prices.[31] For example, the UK has a system of value-based pricing based on health technology assessment. In this system, a drug's benefits are compared to the other drugs that are available in the market for the same condition. The drug's price is then determined according to the value that the drug adds in comparison to its therapeutic alternatives. Such mechanisms are unlikely to be influenced by the US decision to include the country's price in the international benchmark. In addition, most countries already reference other countries' drug prices when negotiating or setting drug prices domestically. A potential unintended consequence of this practice, however, is that drug manufacturers could choose to not launch in a certain product in a

[31] Maniadakis N, Kourlaba G, Shen J, Holtorf A. Comprehensive taxonomy and worldwide trends in pharmaceutical policies in relation to country income status. BMC Health Serv Res. 2017; 17: 371.

given country if they know the country will be used as a reference in order to maintain the average price high. This is mostly a concern when including countries with less developed pharmaceutical markets in the international price. If only major pharmaceutical markets are included in the international price, manufacturers are highly unlikely to choose not to launch their product in that country.

FINAL REMARKS

High drug prices strain American employers, workers, and retirees. Because most Americans obtain health insurance through their employers, lowering US health care costs not only helps bring down premiums and out-of-pocket payments; lower health care costs also contribute to making American workers and corporations more competitive in the global market.

Thank you so much. I look forward to answering any questions that you may have.

Chairwoman WILSON. Thank you, Dr. Socal. And we will now recognize Mr. Holt.

TESTIMONY OF CHRISTOPHER HOLT, DIRECTOR OF HEALTH CARE POLICY AMERICAN ACTION FORUM

Mr. HOLT. Thank you, Chairwoman Wilson, thank you Ranking Member Walberg, Members of the Committee. I very much appreciate the opportunity to speak with you about this issue of complex drug prices. The legislation before you, H.R. 3 aims to bring down drug costs across the U.S. Healthcare system without harming innovation or creating barriers to access for patients. These goals are laudable. I do not believe however, that the policies in H.R. 3 can achieve the lower drug costs sought without negatively impacting the development of future cures, as well as patient access to existing medications. In the face of rising demand and increasing prices for drugs, the way to reduce prices without harming innovation and access is to increase supply and heighten competition.

Unfortunately, the policies proposed in H.R. 3 are likely to have the opposite effect. Title I of H.R. 3 proposes to create a process whereby the Secretary of Health and Human Services will negotiate directly with drug manufacturers over the price of specific pharmaceuticals and then make that price available to all third-party payers in the United States.

This in and of itself is an extraordinary market intervention by the Federal government. The proposal of direct government negotiation is predicated on the notion that the prices that the Federal government currently pays for medications are completely at the whim of manufacturers and that market forces or negotiation have no impact. In reality, however, prices for the drugs and the Medicare part D program right now are already determined through a vigorous negotiation process that involves plans, sponsors, PBMs and manufacturers. In the Medicare part B program, which covers physician administered drugs, we do not have the same benefit from the competitive nature and structure of part D but even here, market forces do play a role.

While the formula for determining what Medicare pays for part B drugs can and I think should be reformed, it does include most if not all privately negotiated rebates and price concessions in the group market. In other words, private competition and negotiation are driving down the government's price in part B as well.

Still, there are increasing calls for the Secretary to negotiate drug prices directly. The process that H.R. 3 would establish, however, cannot accurately be described as a negotiation. Instead, this bill would import foreign governments price controls through an average international market price based on the average volume weighted sales of the price of the drug in six foreign markets. This price, which U.S. policy makers would have no role in determining beyond selecting the countries to be referenced would serve as a target price in the negotiations and would be used to set both the maximum price that could be charged and a de facto floor as well.

The negotiation would be limited to a range of not more than 120 percent of the average international market price and in effect, not less than 99 percent as the Secretary would be required to accept any offer below the average international market price.

Within that limited range, the manufacturer would have no leverage in the negotiation process. The secretary would have carte blanche to require any proprietary data, details of the company's business practices with civil monetary penalties for non-compliance.

Most important, the manufacturer would be required to reach an agreement and if they do not, would face a tax on the gross receipts of their drug of up to 95 percent.

There is no requirement on the secretary to reach an agreement. Offering the choice between a lower price or an excessive tax cannot be described as a negotiation. Rather, it is government dictated price controls; but because of the centrality of the average international market price to the process, the resulting price will not consider the full therapeutic needs of U.S. patients or their views on value.

Policymakers in the U.S. will ultimately have little control over the prices of drugs or the determination of value. The bill includes these heavy-handed provisions because the government has very limited leverage in a true negotiation. As detailed in my written testimony, the Congressional budget office has consistently found that the Secretary could not obtain lower prices in part D through negotiation without eliminating planned choice for beneficiaries or impeding their access. The process outlined appears likely to eventually encompass nearly all branded drugs and biologics sold in the U.S. and will certainly restrict the flow of capital to pharmaceutical companies leading to a decreased capacity for future research and development.

I appreciate this opportunity and I look forward to your questions.

[The statement of Mr. Holt follows:]

Testimony on:

"The Lower Drug Costs Now Act (H.R 3)"

Christopher Holt

Director of Health Care Policy, American Action Forum*

U.S. House of Representatives, Committee on Education & Labor

Subcommittee on Health, Employment, Labor, and Pensions

September 26, 2019

*The views expressed here are my own and not those of the American Action Forum. I am indebted to my colleagues Douglas Holtz-Eakin, Tara O'Neill Hayes, and Jonathan Keisling for their assistance.

Chairwoman Wilson, Ranking Member Walberg, and members of the committee, thank you for the opportunity to testify before you today regarding The Lower Drug Costs Now Act (H.R. 3) and drug costs broadly. I hope to make three basic points.

1) Government negotiation of drug prices, as outlined in H.R. 3, is not in any real sense a negotiation. It amounts to federal price setting and would be a notable deviation from how the federal government has traditionally engaged with markets and private companies.

2) Proposals to tie drug prices in the United States to those of other countries are price setting by another name. Importing prices from other countries determined by their own government intervention in the market is in effect importing those countries' price-setting decisions—and potentially those countries' access issues as well.

3) In the face of rising demand, the only way to reduce prices without harming innovation or access to treatments is to increase supply and heighten competition. There are actions policymakers can take, and in some cases are taking, to incentivize lower prices and more competition. Policymakers should be cautious in this undertaking, however, as many proposals could do more harm than good.

Let me discuss each of these in turn.

Government Negotiation of Drug Prices

Title I of H.R. 3 would require the Secretary of Health and Human Services (HHS) to enter into a binding negotiation process with the manufacturers of at least 25 branded drugs each year—based on various criteria that I will discuss below—regarding the maximum price Medicare or any third party payer in the United States can be charged for that drug. The premise is regularly repeated: Drugs, particularly those provided through the Medicare Program including the Prescription Drug Program (Part D), are not subject to any competitive pressures; rather, prices are dictated by manufactures who can demand whatever they desire. But this premise is not an accurate depiction of the reality.

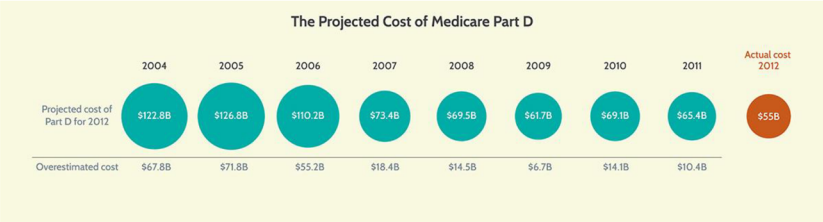
Competition and Negotiation in Part D Under Current Law

Direct negotiation by the Secretary of HHS is indeed expressly forbidden in the Part D statute, a fact that certainly contributes to some confusion over this issue. Yet the program nevertheless sees aggressive negotiation over the prices of medications between Part D plan sponsors and drug manufacturers. This competitive process is the key factor in the program's success to date. Today, Part D beneficiaries have access to 27 different plans, on average, enabling individuals to choose a plan that is tailored to their needs.[1] Because there are a number of plan options for beneficiaries, individual plans have the ability to use preferential tiering strategies to negotiate discounts for specific drugs. If a beneficiary requires or desires a specific medication that is not on the preferred formulary (or covered

at all) for one plan, they can choose to sign up for a different plan that provides the medication at a more desirable price.

If the government, however, were to seek to negotiate the prices of specific drugs, the system would break down. Plans have leverage to drive discounts because they can restrict or deny access to specific medications or offer the medication in ways that make it more desirable to their beneficiaries. For the federal government to undertake this kind of negotiation, there would need to be a single federal formulary. In other words, the Secretary would have to be willing to say no to many treatments on behalf of all beneficiaries in order to drive discounts system-wide. Beneficiaries' choices would drop from 27 plans to 1. Further, beneficiaries would no longer be able to shop for the plan that is best for them; rather, they would have to simply hope the government was able to negotiate a good deal for the drug(s) they need. Policymakers and the American public have long been reticent to make that trade off. The Congressional Budget Office (CBO) has repeatedly held that in absence of a willingness to deny coverage for specific medications, the Secretary would not have the leverage necessary to drive any savings to the Part D program.[2] In short, given these constraints, direct negotiation of drug prices by the secretary would not work.

In contrast, the design of Part D has worked incredibly well. As demonstrated in the following infographic, total program expenditures came in far lower than initial CBO projections. Part D's 10-year cost (starting in 2006) was projected in 2004 to be $957.3 billion, after the Medicare Modernization Act was passed but before the program started. By 2011, the combination of five years of actual data and five years of projections totaled $499.4 billion, for a cost under-run of $457.9 billion, or about 48 percent. The last CBO forecast for 2012 Part D spending made prior to implementation was in 2005, and the projected 2012 spending in that year was $126.8 billion. After the bids came in for 2006, the 2012 forecast was reduced to $110.2 billion. In all but one of the next six years, the forecast for 2012 was reduced further. The actual amount was $55.0 billion – about 57 percent lower than the original pre-implementation forecast.[3]



It is not uncommon for critics of the program to cite the large number of name-brand drugs that came off patent during the early years of the program—the so-called patent cliff—and the ensuing flood of generic medications that entered the market as the reason the initial estimate was so far off the mark. CBO was not caught flat-footed by this development, however, as American Action Forum (AAF) President, and then-CBO Director, Douglas

Holtz-Eakin has recounted many times. CBO carefully studied the coming deluge of generic treatments and accounted for that development in their scoring of the program. What they failed to anticipate was how effectively the competitive nature of Part D's negotiations would drive generic uptake.

None of this is to suggest that Part D is not in need of reforms. As AAF experts have previously written, Medicare Part D reinsurance expenditures have grown rapidly for the federal government in recent years. This growth has been driven by an increase in both the number of beneficiaries reaching catastrophic coverage and the share of costs that each of them incurs in the catastrophic phase. This rapid growth has caused reinsurance expenditures to increase from less than one-third of the federal government's subsidy of the Part D program in 2007 to more than two-thirds of the subsidy in 2016. Increasing drug prices are one driver of this increase, but policies and perverse financial incentives affecting the benefit design and insurers' formulary decisions are also to blame. One way to realign incentives is a restructuring of the program's benefit design.

In 2018 AAF proposed to increase insurer liability in the catastrophic phase to roughly 70 percent while simultaneously reducing the government's liability to 20 percent. Then move the drug manufacturer rebate program from the coverage gap to the catastrophic phase to cover the remaining costs. These changes will significantly increase the incentive for both insurers and drug manufacturers to control costs. Further, AAF proposed providing beneficiaries with true financial protection by imposing an out-of-pocket cap. Plan sponsors and beneficiaries would also benefit from a simplified benefit structure, since the coverage gap would be eliminated and beneficiary co-insurance will be held steady at 25 percent above the deductible until reaching the catastrophic threshold. Such reforms should encourage behavioral changes that reduce overall program costs for all stakeholders.[4] Variations of this proposal have been included in both the Senate Finance Committee's drug pricing package and H.R. 3, though significant differences exist between the specifics of the three versions.

Critique of Government Negotiation as Proposed in H.R. 3

H.R. 3 seeks to bypass the problems with government negotiation detailed above by empowering the Secretary to negotiate on behalf of all third-party payers for a Maximum Fair Price (MFP), below which Part D Plan sponsors and other payers in the group and individual markets could presumably still negotiate better rates. In order to give the Secretary leverage in these negotiations, without creating a national formulary, the legislation proposes to enact draconian penalties—including a tax of up to 95 percent of the annual gross sales of a product when a manufacturer refuses to enter into negotiation with the Secretary. Under the proposal, the Secretary would choose a minimum of 25 drugs annually, from a list of 250 drugs that are among the 125 highest cost drugs in Part D or Part B and either lack competition as defined in the legislation or are insulin products. As a starting point for the negotiation, the Secretary would establish a ceiling price of 120 percent of the volume-weighted average price of the drug in Australia, Canada, France, Germany, Japan, and the United Kingdom, or the Average International Market (AIM) price. Once the negotiations conclude and the new MFP is established, the manufacturer would be

required to offer that price to all payers, including private insurers in the group and individual market. In other words, the federal government would set the price nationwide for all payers. Manufacturers would be prohibited from increasing their price above the rate of inflation. Additionally, payers could seek additional price concessions—which could be particularly important in the commercial market where some plans may well have negotiated lower rates for specific drugs than the ultimate MFP—though it is unclear what incentives manufacturers would have to go below the MFP. Finally, if a manufacturer were to charge more than the MFP they would face civil penalties of 10 times the difference in the price charged versus the MFP.

Three things seem worth noting. First, the rhetoric of a voluntary-bilateral process seems facetious when any manufacturer who declines to participate in the voluntary process is subject to the aforementioned 95 percent tax on gross receipts. Additionally, the process of reaching an agreement on an MFP cannot truly be said to be a negotiation when the manufacturer is required to reach an agreement with the Secretary or else be deemed not to have negotiated in good faith—and once again face the tax penalty. Using rhetoric like "voluntary" or "negotiation" is not uncommon in policy debates, but proponents of these policies should be forthright about what it is they are advocating for. The process outlined in this legislation appears to be neither voluntary nor a negotiation.

Second, the definition of a product lacking competition is incomplete. Under H.R. 3, a drug is said to lack competition if it is a brand-name drug and does not have a generic or biosimilar competitor. While that phrasing may sound reasonable, it paints an incomplete picture of competition in the drug market. Take the example of Sovaldi, Gilead's Hepatitis-C cure that was originally launched at $84,000 for a full course of treatment. Sovaldi was a first ever cure for Hepatitis-C; previous treatments sought to slow the disease's progression, but they didn't cure it and they were expensive. Sovaldi was widely recognized as a cost-effective treatment, improving quality of life for patients and lowering overall costs to the health care system. But the upfront cost still caused understandable outrage, and without competition and with enough demand, it remains true that however reasonable Gilead's price may have been, there was little downward pressure on Gilead's pricing decisions. Nevertheless, Sovaldi is not an example of market failure. Rather, within two years, competitors Merck and AbbVie had also introduced comparable Hepatitis-C treatments. And by February 2015, Gilead had cut Sovaldi's list price by 46 percent in the face of these competing products. Under H.R. 3, however, Sovaldi would be considered to lack competition because those other drugs are not generic copies. Rather, they are other brand-name drugs that are similar in their curative effects. Thus, even though Sovaldi faces competition from similar products, treating the same condition, for the same population, resulting in demonstrable price concessions, H.R. 3 seems to consider this situation a market failure.

Third, the scope of the proposal is broader than it might first appear. While the Secretary is required to negotiate for 25 drugs annually, they can choose to negotiate for as many of the 250 eligible drugs as they are capable of. Considering that the Food and Drug Administration (FDA) approves an average of 33 novel drugs a year,[5] it seems likely that eventually every single new drug would end up included in this negotiation process. That

is, every drug would have an absolute maximum price, set by statute, of 120 percent of the AIM price, and all drugs would be capped at the rate of inflation. Ultimately, there would be a government mandated price for every drug, regardless of the population's therapeutic needs or the underlying bio-pharma economics.

Ultimately, at a very basic level, under H.R. 3, the government would set the parameters for the negotiation. The government would determine whether a manufacturer had complied with those parameters. And the government would level substantial penalties on manufacturers who do not comply with its price concession demands. The more one drills down, the clearer it becomes that the process envisioned cannot be reasonably called a negotiation. The power differential between the two parties is too dramatic.

The Average International Market Price

Returning to what is effectively H.R. 3's price ceiling, the AIM price, a deeper dive seems worthwhile. There is no doubt that other countries pay less for medications than does the United States. There are myriad reasons for this fact, but it remains a frustrating reality for policymakers, the public, and most likely drug manufacturers themselves. Further, there are, unfortunately, few easy solutions to this problem that are without negative implications for U.S. patients.

H.R. 3 proposes to determine the AIM price for targeted drugs based on a volume-weighted average price of the drugs in Australia, Canada, France, Germany, Japan, and the United Kingdom. Manufacturers selected for the negotiation process by the Secretary would then be limited in what they could charge for the drug in question to no more than 120 percent of the AIM price. In effect, the proposal imports foreign price controls as a baseline for setting U.S. drug prices. While it is difficult at this juncture to evaluate the full impact of this specific proposal, the Trump Administration has proposed something similar, the International Price Index (IPI) which would cap the price of some Part B drugs at 126 percent of an index of 14 countries, including the countries selected for the AIM price. It is worth looking at some of the implications of IPI to better understand the potential ramifications the AIM price.

Impacts on Innovation

According to analysis by AAF's Tara O'Neill Hayes in comments to the Centers for Medicare and Medicaid Services (CMS) on the IPI proposal, if the demo were applied to all Part B drugs, expenditures for which now equal nearly $30 billion, revenues would be reduced approximately $9 billion per year.[6] We have seen historically that reduced revenues do have significant impacts on future investment and development decisions. Pharmaceutical development is an inherently risky proposition, and substantial return on investment is necessary to attract investor capital. To make the point, in 1986, research and development spending by pharmaceutical firms in Europe exceeded that of the U.S. by roughly 24 percent.[7] As European countries began restricting prices, investment by pharmaceutical companies began to decline in those countries, while investment in drug development in the U.S. expanded. Considering that the cost of successfully bringing a drug to market has

been estimated at approximately $2.87 billion,[8] the $9 billion in lost revenue per year potentially attributable to the IPI proposal would be equivalent to the cost of three new medicines each year. In the case of the AIM price, the figure would be set at 120 percent of the index, rather than 126 percent in the IPI proposal, and the capped price would be applied to all U.S. payers rather than limited to Medicare Part B, which accounts for only 10 percent of all drug expenditures in the United States.[9] If the effect on drug development of the AIM price is similar to the impact of the IPI, expanding those effects to 100 percent of the U.S. market would be the equivalent of 30 fewer drugs a year, which is as previously noted nearly the average number of new drugs approved by the FDA annually.

Access to Treatment

As further detailed in Haye's comments to CMS, in the United States, 89 percent of all 290 new medicines and 96 percent of the 82 new cancer medicines launched between 2011 and 2018 were available within three months. In the 14 countries that CMS has identified for inclusion in the IPI proposal, even after adjusting for population, only 51.5 percent of all new medicines and 59.7 percent of new cancer drugs are available in these 14 countries within 17.4 months. Of the 54 new medicines launched during this same period covered under Medicare Part B, only 28, on average, are available in all 14 countries, and it took an average of 18 months for access to be granted after their initial launch.[10] Other countries that seek to limit drug spending through restrictive government price controls have made the determination that lower spending is more important than access to the range of innovative new drugs. Having the government decide that Americans should not have access to new, innovative treatments in a timely manner because the value of those treatments is not worth the cost to tax payers, or in this case private payers as well, has long been a bridge too far for both American patients and policymakers. Changing that calculus would be a sea change. Markets provide an effective means for determining value to consumers, one that policymakers should be reticent to eliminate.

Lowering Drug Spending

In the face of rising demand, the only way to reduce prices without harming innovation or access to treatments is to increase supply and heighten competition. H.R. 3 does nothing to increase the supply of drugs or the level of competition in the market. Effectively, H.R. 3 gives the federal government the power to fix the price of specific medications at a dollar figure determined by federal bureaucrats. This price fixing will invariably have implications for both innovation and access to treatment. It is often argued that manufacturers will continue to invest in R&D because, after all, bringing new treatments to market is their business. It is necessary to remember, however, that manufacturers depend on investment capital. Federal policies that dramatically curtail return on investment will have a detrimental effect on manufacturer's ability to attract the capital necessary to continue bringing new treatments to market. Instead policymakers should look to expand supply and competition.

The FDA has helped in this undertaking by approving a record number of generic drugs and biosimilars.[11] But other barriers to unlocking robust market competition remain.

Barriers to Entry

Manufacturers of innovator drugs rightly and understandably want to protect their market share as long as possible. As discussed, bringing a drug to market is a risky and expensive endeavor, and investors need the promise of a formidable profit to be incentivized to make that investment. And there can be no generic without first having the expensive innovator drug. The needs of the investors to receive a return, however, must be balanced with the needs of the consumers and taxpayers to afford those drugs in order for the market system to remain sustainable. There are obvious incentives for brand-name manufacturers to extend the length of their market exclusivity through various means. Congress can scrutinize the opportunity to create entry barriers, such as brand-name manufacturers allegedly abusing the REMS system and, if appropriate, legislate to help even more generics come to market quickly.[12] (One such example is the CREATES Act.)

Legal Enforcement of Competition Policy

Another challenge is the case of single-source generics. Often, once a generic drug has been on the market long enough, it acquires enough of the market share that the brand-name manufacturer stops producing its version of the drug. In many cases, the price reaches a low enough point that other generic competitors also exit the market, leaving a sole manufacturer. In some high-profile cases, we see what amounts to abuse of monopoly power—that sole manufacturer taking advantage of its position and dramatically increasing its price once there is no more competition and consumers have no choice but to purchase the now high-priced drug. Congress could look at incentives for second manufacturers and accelerating approval of competitor products when such incidences arise.

Conclusion

It is also important to recognize that a shift to tighter regulation of pharmaceutical pricing would involve tradeoffs. Other countries that employ such approaches do not have timely access to the breadth of pharmacological breakthroughs that U.S. patients enjoy. If the federal government were to take a more directed approach to managing drug spend, such as those proposed by H.R. 3, it would almost certainly lead to two types of access issues. The first is simply a question of whether manufacturers would continue to produce and sell targeted products at the government-established price. In other countries that dictate prices, manufacturers have answered this question negatively, leading to reduced access to treatments when compared with the United States. Second, policies aimed specifically at drugs with particularly high prices threaten to upend incentives for the most innovative new medical treatments, which often by their very nature are more expensive to develop and produce, and increasingly serve smaller patient populations. Federal policymakers have historically been reticent to actively limit public program beneficiaries' access to the medications they and their doctors determine to be best. H.R. 3 would potentially limit access for all U.S. patients.

[1] https://www.kff.org/medicare/press-release/people-on-medicare-will-be-able-to-choose-among-24-medicare-advantage-plans-and-27-medicare-part-d-drug-plans-on-average-during-the-open-enrollment-period-for-2019-new-analyses-find/
[2] https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/03-03-wyden.pdf
[3] https://www.americanactionforum.org/research/competition-and-the-medicare-part-d-program/#_ftn7
[4] https://www.americanactionforum.org/research/redesigning-medicare-part-d-realign-incentives-1/
[5] https://www.fda.gov/media/120357/download
[6] https://www.americanactionforum.org/comments-for-record/comments-to-cms-on-proposed-international-pricing-index-for-medicare-part-b-drugs/
[7] https://www.nber.org/papers/w12676
[8] https://csdd.tufts.edu/csddnews/2018/3/9/march-2016-tufts-csdd-rd-cost-study
[9] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html
[10] "New Medicines Availability in IPI Countries vs United States," PhRMA analysis of IQVIA Analytics Link and FDA, EMA, and PMDA data. December 18, 2018.
[11] https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm625627.htm
[12] https://www.biopharmadive.com/news/congress-creates-act-generic-branded-samples/543147/

WILSON. Thank you. We will now recognize Dr. Garthwaite.

TESTIMONY OF CRAIG GARTHWAITE, ASSOCIATE PROFESSOR OF STRATEGY NORTHWESTERN UNIVERSITY KELLOGG SCHOOL OF MANAGEMENT

Mr. GARTHWAITE. Thank you, Chairwoman Wilson and Ranking Member Walberg and Members of the Committee for inviting me to testify today about H.R. 3, the Lower Drug Cost Now Act. While this bill has a number of features, in my testimony today, I will primarily address the proposed pharmaceutical price controls in the legislation. While supporters of legislation hope to characterize it as introducing Medicare drug price negotiations, that is not accurate.

Instead, the bill gives the HHS Secretary unprecedented power to set market prices for the entire healthcare economy. Under the bill, the prices for the most expensive drugs that lack competition would be limited to 1.2 times the price in a set of six developed markets.

Firms that don't comply will be fined up to 95 percent of the drug's revenue. Economics is a simple term for this proposal. It is a price control. This is particularly true in the case where the mandated price will then be passed along to the commercial market, which already has a robust system of negotiations.

While I understand that calling these price controls a negotiation might be more politically palatable, that doesn't make it accurate. Now those in favor of price controls argue they're necessary because the higher prices decrease access to potentially lifesaving products. They often characterize those high prices as serving no other purpose than satisfying the greed and unending pharmaceutical profits.

The reality is far more complicated than this simple caricature. High prices are part of a necessary tradeoff to provide the incentives for firms to invest the capital required to develop lifesaving drugs in the first place. At its heart, drug development involves a difficult tradeoff of reduced access today for increased innovation tomorrow.

I don't say this lightly. I understand that high prices can decrease access to potentially lifesaving medications but frankly, there are no easy answers here.

The economic evidence is clear, if we institute price controls of the nature discussed in this bill, we will see fewer investments in the development of new drugs for conditions that don't currently have treatments.

Such decreases in innovation create their own access problems. While It is clear that patients today paying high prices can suffer decreased access for medication, and this is not an optimal outcome, those patients have a significant benefit that shouldn't be overlooked. They, through their PBMs have the luxury of negotiating the price of their drug.

If you are sick with a condition today for which there are no treatments, a drug is not available at any price. This is the access problem that is so often missed in these discussions. Those who claim innovation won't be affected by price controls, simply misunderstand or deliberately ignore the economic evidence. In a mod-

ern market, a large share of biotech products result from venture capital firms, making substantial and risky investments to commercialize basic science into products that improve people's lives. The incentive for those investments come from the high prices and profits earned by today's successful firms. The venture capital firms at the heart of this process are not beholden to the pharmaceutical industry. They can invest in any sector of the economy. If you lower returns, capital will follow out of this sector into other more profitable sector, therefore it doesn't matter how much pharmaceutical firms spend on marketing, and it doesn't matter if someone believes a pharmaceutical company earns too much money and therefore can withstand the lost profits.

While people like to mention these facts, the claim that innovation won't be affected, the basic economics and a number of empirical studies demonstrate that firms invest in products based on the expected return. The question then becomes how much do we value the innovation that would disappear because of these price controls?

After all, an optimal innovation policy is one where the benefits of innovation outweigh the costs of reduced access today. It is possible we are currently getting this balance wrong. It might be that we provided too strong of an incentive in favor of new products at the cost of people not being able to access products today.

We must remember that everything about the existing parameters of our tradeoff is ultimately a policy decision. There is nothing magical about a 20-year patent life. The very fact that it is constant, across both products and markets suggests that It is not the result of some finely-tuned calibration that weighs these costs and benefits. That said, while there is nothing magical about this parameter in our current policy, it is clear that moving away from this existing policy will decrease investments and innovation and the important thing to realize is that might be okay. The extra innovation we are getting may not be worth it, but that is the debate that Congress should be having. Instead, legislation such as H.R. 3 and the Trump administration's international pricing index effectively outsource this debate to foreign governments. This is not a profile encouraged by our policymakers. Why should access to new innovation for Americans be determined by policy decisions in London, Paris and Berlin? Simply because It is too hard for us to have the conversation about what products we want to say no to today in order to have a true price negotiation? In contrast to other developed economies who may have lower prices for the same drug, the United States relies far more heavily on markets because we are a large and diverse economy and market forces are better for allocating goods and services than central planning but we must recognize that markets can fail and when they fail, there is a role for the government to step in. There are many features of H.R. 3 that do that.

[The statement of Mr. Garthwaite follows:]

TESTIMONY OF CRAIG L. GARTHWAITE, Ph.D.

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Before the
House Committee on Education and Labor
Subcommittee on Health, Employment, Labor, and Pensions

On

"Making Health Care More Affordable:
Lowering Drug Prices and Increasing Transparency."

September 26, 2019

In contrast to most other developed countries, the United States relies more heavily on private markets to finance and provide healthcare services. While this is a source of consternation for some, this use of economic markets is not a policy accident and instead reflects a belief that there are many advantages to market based healthcare. A large and diverse country such as the United States has a wide variety of preferences and meaningful differences in the willingness to pay for quality. In this setting, the central planning inherent to regulated prices is unlikely to maximize welfare, and an economic market is the superior method of allocating goods and services. This is even more true once we consider the variety of economic actors necessary for the development of innovative new healthcare products and services. It is hard to imagine what omniscient actor could more efficiently balance these forces. Therefore, despite many contentions to the contrary, a market-based system remains the best mechanism for providing the appropriate incentives for long term welfare maximization.

However, relying on the market for the provision of such a vital set of goods and services requires both recognizing that healthcare markets, like any other market, can fail and that all markets require vigilant protection of the structures and institutions necessary to promote robust and vigorous competition. In addition, given the unique nature of healthcare there are times where society choose to finance access for a variety of vulnerable groups that otherwise would be unable to afford such goods and services. Ignoring these facts could result in healthcare markets that decrease welfare compared to a more regulated option.

Concerns about the appropriate role for markets in healthcare are perhaps most frequently discussed in the world of pharmaceuticals. At least one reason for this heightened attention is that the pharmaceutical sector requires some amount of government intervention to reach a welfare maximizing outcome. This is because the very heart of the innovative process for new drugs represents a market failure that must be addressed. The failure results from that fact that the scientific advancements generated by firms in the development of innovative pharmaceutical products are essentially a public good, i.e. the knowledge is effectively non-rival and non-excludable.[1] Absent government protection, rational firms realize they will be unlikely to capture the value generated by the large investments necessary to bring a product to market. This results in an economic phenomenon known as "hold up" whereby firms are unwilling to make value creating investments in the first place.

[1] The degree to which this is fully a public good depends on how much information can be gleaned from the actual product, the regulatory filings, and the published research. For example, small molecule products can be more easily reverse engineered and therefore absent intellectual property protections are relatively easier to copy. Biologic products, however, have a more complex production process and therefore copying the technology is easier than making the product *de novo* but harder than for a small molecule product.

To address this initial market failure, governments offer various forms of intellectual property protection. Through either patents or other forms of market exclusivity, governments arm firms with time limited periods of enhanced market power that allow them to capture the value creating by innovative products. During this time period, the high prices curtail some access to valuable medicines. However, this reduced access today is deliberately traded off for the development of new products in the future. These new products provide access to patients for whom there would otherwise be no treatment.

Effectively, policies governing the development of pharmaceutical products involve trading off the static inefficiency of reduced access to products today in order to create the dynamic efficiency of increased development of new products in the future. To the extent that the value created by the new products exceeds the deadweight losses created by the high prices (and resulting decreased quantity), the periods of market exclusivity are welfare enhancing. This could be true even if the prices are quite high.

This tradeoff is a source of much of the controversy for prescription drugs because the reduced access today involves some number of readily identifiable individuals who are unable to access existing and potentially life-saving medications because of price.[2] Unsurprisingly, this particular form of a lack of access garners large amounts of press and political attention. However, it is important to remember a perhaps far greater access problem for patients suffering from conditions for which no treatment options exist at all.[3] For these individuals, there is no price at which they can purchase a treatment, and patients with these conditions will only gain access in the future by the dynamic efficiency created by intellectual property protection. As we consider the optimality of policies governing the pharmaceutical market, it is critical to balance the oft-discussed need for access to existing products with the less-discussed lack of access from the absence of effective treatments.

In addition, it's important to note that the existing forms of intellectual property protection do not preclude all price competition. While patented products are protected from an exact replica being brought to market, they do face competition from therapeutic substitutes that treat the same condition with a different product. These substitutes do not decrease prices to the same extent as an exact generic replica but they do introduce meaningful competition. In addition, given pharmaceutical products often have fairly heterogeneous treatment effects – these competing products can increase the set of available treatments for patients.

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[2] Garthwaite, Craig, and Benedic Ippolito. 2019. "Drug pricing conversations must take the cost of innovation into consideration." STAT. January 11.

[3] This is particularly true because the impact of high prices on quantity is far more complicated in a world of widely available health insurance. Those who are insured may not suffer as much decreased access as they would in a market without third party payment. However, those for whom drugs do not exist certainly will not access a treatment at any price.

As a result, the innovative firm cannot charge any price it desires but must consider both customer willingness to pay and the potential competition from therapeutic substitutes. In the private market, drug price negotiations between payers (via their pharmacy benefit managers) and pharmaceutical manufacturers are fierce with therapeutic substitutes being pitted against each other to gain access to patients. Products that provide truly unique treatments have fewer potential substitutes and can successfully command higher prices. Those offering limited advances over current products face stiffer competition for customers and must offer lower prices to gain market share.

A key feature of the trade off at the center of innovation policy is that the periods of market exclusivity are meant to be time limited. Society does not intend to grant permanent monopolies to firms that bring even very innovative products to market. Therefore, strict regulatory vigilance is required to ensure that after market exclusivity has expired, products face swift and robust competition from generic or biosimilar competitors. Such post-exclusivity competition both decreases prices and in the case of biosimilars can drive meaningful competition to decrease production costs and increase efficiency in this nascent industry.

While the Lower Drug Costs Now Act that is being discussed in today's hearings has a variety of features, a core of the proposed legislation would supplant this competitive market for drug pricing with a series of government administered prices that are based, in part, on the prices charged in a select group of foreign markets. Despite the fact that the supporters of the legislation describe the bill as promoting drug price "negotiation," there is little about this legislation that represent true negotiation. Instead, the bill intended for the prices of a subset of true to be limited to a small fraction above the prices determined by the leaders of a set of foreign markets. Firms that don't comply would initially face a penalty equal to 65 percent of the drug's gross sales. Each quarter without complying to the price from HHS, the fee would increase by 10 percentage points up to a cap of 95 percent of gross sales. From an economic standpoint, this is a price control not a negotiation.

Perhaps most concerning is the breadth of these so-called negotiated prices. Unlike previous calls for Medicare to take a more active purchasing role, this legislation would extend those prices to the broader private market. This would greatly increase the impact of the proposed negotiated prices. Beyond this greater impact, it also suggests that the purported negotiations function more as an attempt at government administered prices. After all, prices in the private market are already heavily negotiated by experienced private firms. What these firms lack is the threat of an outside option that amounts to effectively taxing away all of the drug's revenue. For this reason, the legislation should be expected to have more of an effect on prices than existing negotiations in the private market.

The existing empirical evidence demonstrates that price concessions of this level would almost certainly decrease investments in innovation. [4] It is important to note that the mere fact that innovation will decrease is not a reason to abandon any reconsideration the parameters of the access and innovation tradeoff described above. It is useful to realize that everything about this tradeoff is fundamentally a policy decision. There is nothing magical or sacrosanct about our current 20 years of patent life, 5 years of market exclusivity, orphan drug policies or other innovation policy parameters that have been established to attempt to promote innovation. One need look no further than the fact that patent lengths are the same across products types (both within the pharmaceutical category but also across the economy) to note that these policies do not seem to be the result of a finely tuned economic model that weighs the economic benefits provided by specific types of products.

While the existing parameters may not reflect a perfectly though out calculus, they do determine the existing level of investments in innovation in market. Therefore, changing these parameters will decrease investment in innovation and therefore should reflect a willingness to decrease the flow of new products to market in exchange for lower prices. Policies which do not seriously consider the potential negative impacts on innovation from changing these innovation policy parameters are likely to have unintended consequences.

Optimal policy making requires that policymakers decide on the preferred degree of intellectual property protection required to encourage the desired level and type of innovation. After setting these parameters, it is incumbent on regulators to monitor and enforce these systems. This includes providing the necessary structures for strong competition between therapeutic substitutes during periods of exclusivity and the development of robust generic competition beginning immediately at the end of the exclusivity period. Our goal is not to provide unlimited benefits to firms, but instead to provide appropriate market-based incentives that encourage firms to develop innovative products that increase welfare. Ultimately, firms will optimally respond to any incentives government creates – and therefore a well-functioning healthcare market requires policies that embrace economic reality rather than hope for a preferred outcome.

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[4] Acemoglu, Daron, and Joshua Linn. 2004. "Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry." The Quarterly Journal of Economics 119 (3): 1049-1090.
Finkelstein, Amy. 2004. "Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry." The Quarterly Journal of Economics 119 (2): 527-564.
Blume-Kohout, Margaret E., and Neeraj Sood. 2013. "Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development." Journal of Public Economics 97: 327-336.
Dranove, David, Craig Garthwaite, and Manuel Hermosilla. 2014. "Pharmaceutical Profits and the Social Value of Innovation." NBER Working Paper No. 20212. June.
Dubois, Pierre, Olivier de Mouzon, Fiona Scott-Morton, and Paul Seabright. 2015. "Market Size and Pharmaceutical Innovation." The RAND Journal of Economics 46 (4): 844-871.

This also includes being careful about policies which change the rules of the proverbial "game" mid-stream. The development of pharmaceuticals is a long and risky process where firms make investments that they only expect to payoff over a potentially decades long time horizon. Encouraging firms to make these types of investments requires that they have some certainty that the rules of the game will not be changed midstream. While that doesn't mean that the U.S. cannot change pricing regimes, it does mean that policies such as retroactive revenue confiscation because of past price increases or the seizing of intellectual property has the potential to break the implicit contracts that underlie firms' willingness to do business with the U.S. government. This is not a partisan issue. To the same degree that I publicly opposed Republican efforts to defect from making promised risk corridor payments under the ACA, I would strongly caution against any efforts that undermine the faith private firms currently place in the predictability of our innovation policy.[5]

I. The Tradeoff Between Access and Innovation in the Modern Pharmaceutical Market

It is not surprising that attention about high healthcare prices has focused on the pharmaceutical sector. Patented prescription drugs are sold for many multiples of the marginal cost of production and, as a result, firms *appear* to be profiteering at the expense of patients. Complaints that high prices are simply about corporate greed ignore that they are the result of deliberate government policies intended to provide the necessary incentives for the development of innovative products. By granting intellectual property protection, the government allows innovative firms to earn large profits without the threat of competition resulting from the immediate entry of a firm making an identical product. Economic research suggests this profit incentive matters and consistently documents that pharmaceutical R&D responds to potential market size. Pretending this is not the case ignores reality and will only lead to inefficient value-destroying policies.

While the optimality of trading off some amount of access today in order to gain access tomorrow is clear, the parameters of the length and breadth of this tradeoff are policy decisions for which there is no definitive economic answer. These policy parameters reflect the relative value society places on lost access today and potential welfare gains from innovation in the future.

Understanding the nature of the trade-off and determining the appropriate policy parameters in the contemporary market requires understanding a bit more about the modern pharmaceutical development process. New products come to market through the partnership of a variety of actors in the value chain. This includes basic science done for understanding the nature of disease, early stage pre-clinical research to develop a proof of concept, and then an arduous process of navigating the regulatory process to prove that a product is ultimately safe and efficacious. Each stage of this process represents meaningful risk and firms will

[5] C. Garthwaite and N. Bagley, "The Republicans' Uncertainty Strategy," *New York Times*, June 29, 2017.

only undertake each successive step in the development process if the expected net returns are sufficiently attractive compared to the next best use of the invested funds.

I.A. Basic Science Research and the National Institutes of Health

Certainly, the development process begins with basic science research – a meaningful portion of which is financed by the National Institutes of Health (NIH) as well as other government entities and non-profit organizations. This means many expensive products on the market rely to some degree on basic science that received government funding. For example, one study found that all of the 210 products approved from 2010-2016 relied to some degree on research funded by an NIH grant.[6] This fact has led many activists and policymakers to contend that the NIH is "responsible" for bringing these products to market and therefore should be required to demand price concessions as part of their patenting activity.[7] Some have gone as far as to say that the NIH should exercise its "march-in rights" and seize the patents of products which are deemed to have prices that are too high.[8] While they might lend themselves to attractive slogans and sound bites, such policies will be far more complicated than is often discussed.

Understanding the limits of proposals to strengthen the role of the NIH in pricing requires thinking more carefully about the government's role in drug development in the first place. At a broad level, advances in basic science that improve the understanding of how diseases work or the mechanisms of action driving the efficacy of potential products are relatively hard to successfully protect with our existing intellectual property protections. As a result, it is hard for firms to appropriate the value of investments in basic science. In effect, despite various intellectual property protection regimes, investments in basic science retain many of the public good related market failures discussed above. Firms that do no reasonably believe they can profit from investments will not make them, and as a result there is a fear that basic science research will be under-provided. As an economic concept, the NIH is ideally meant to solve this public goods problem by stepping into the market and funding the basic science that otherwise would not occur.

That said, without significant additional investments in drug development, this government funded basic science research does not result in treatments that address unmet needs in the market and increase economic welfare. In current market, these additional investments are provided by private firms that do additional research and development to commercialize the NIH funded basic science. In reality, the goal of the NIH

[6] E. Galkina Cleary, J. Beierlein, N. Surjit Khanuja, L. McNamee, F. D. Ledley, "Contribution of NIH funding to new drug approvals 2010–2016," *Procedures of the National Academy of Sciences,* March 2018, 115(10).
[7] L. Zhou, "The new bipartisan Senate bill aimed at making Big Pharma lower drug prices, explained," *VOX*, July 31, 2019.
[8] M. Mezher, "Lawmakers Urge HHS to Exercise 'March-in' Rights to Fight Higher Drug Costs," *RAPS.org, January 11, 2016.*

should be to attract as many firms as possible to leverage its investments in basic science. This would provide the most "bang for the buck" from our government dollars. Currently, this is accomplished by placing relatively few constraints on partnerships between the NIH and private firms.

This was not always the case. Prior to 1995, the NIH included a "fair pricing clause" in its partnerships with the private sector. This clause required firms to provide reasonable evidence demonstrating their pricing decisions were in the public interest goals of the NIH.[9] However, in 1995, this clause was removed. In describing this decision, the Director of the NIH said that the institute agreed "with the consensus of the advisory panels that enforcement of a pricing clause would divert NIH from its primary research mission and conflict with its statutory mission to transfer promising technologies to the private sector for commercialization."[10] Exhibit 1 shows that number of cooperative research and development agreements (CRADAs) between the NIH and private firms. In the years immediately following this decision, the number of these partnerships increased markedly – likely because of greater certainty about potential returns from these partnerships.[11]

I.B. The Decentralization of Early Stage Drug Development

Proponents of the Lower Drug Costs Now Act point to the fact that the savings from the greater price regulation dictated by the bill can be redirected towards the NIH to offset the expected decline in innovation. However, this belief ignores the current role of the NIH – which is to evaluate and fund basic science and not drug development and commercialization. While there are a small number of examples of the NIH taking part in more advanced stages of drug development, these are certainly the exception rather than the rule – as would be expected given the purpose of the NIH is to solve the public goods problem for basic science research. To move into a primary drug development role, the NIH would need to transform into something that more closely resembles the private market. It is not simply a question of providing more funding for the NIH's current system, but transforming in many ways the purpose and activities of the current NIH.

While it is possible the NIH could complete this transformation, this would mean it is no longer primarily solving the public goods problem of basic science and instead would attempt to determine which potential

[9] Specifically, this clause read: "Because of [NIH's] responsibilities and the public investment in research that contributes to a product licensed under a CRADA, DHHS [Department of Health and Human Services] has a concern that there be a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public. Accordingly, exclusive commercialization licenses granted for the NIH intellectual property rights may require that this relationship be supported by reasonable evidence." Quoted in "Federal R&D, Drug Discovery, and Pricing: Insights from the NIH-University-Industry Relationship," *Congressional Research Service,* 2012.

[10] "Federal R&D, Drug Discovery, and Pricing: Insights from the NIH-University-Industry Relationship," *Congressional Research Service,* 2012.

[11] In interviews prior to the policy change, pharmaceutical manufacturers pointed to uncertainty about pricing as a concern in potential partnerships with the NIH.

opportunities to commercialize this science should come to market. This effectively involves introducing more central planning to the development of new products. Such a shift would run counter to the strategic decisions of the major players in the private market which are *decreasing* the degree to which pharmaceutical firms dictate the path of research through internal R&D programs. Instead, the world of biotech drug development involves large numbers of small startups that are increasingly funded by venture capital firms. The most promising and successful of these firms are generally acquired by the larger market participants that then guide the product through the FDA approval process and handle the post approval sales and marketing strategies.

The fact that so much early stage innovation is done by private firms have led many to claim that regulators are free to decrease prices without harming innovation. After all, since the firms currently selling the product didn't do the early stage R&D, those early innovative activities are not driven by the eventual profits of these more established firms. This couldn't be further from the truth. The ultimate goal of the venture capital investors in these early firms is for a profitable "exit" for their funds in the form of an acquisition. The financial terms of this eventual acquisition are dictated by the potential revenues of the product in the market and thus would be affected by regulated prices that decrease average returns.

In this way, the access and innovation tradeoff is perhaps even greater in the modern world of venture capital backed early stage drug development. This funding is inherently mercenary in nature and in search of the highest returns. If potential returns from biotech investments fall, these funds will simply flow from the pharmaceutical sector to the next best option. In this way, policies which decrease the potential profits will lower investments in early stage investments and the resulting increase in profits. While we might think that the NIH could step into the role of venture capital and provide funding to early stage biotech firms, there is little evidence they would be effective at this role. At a minimum, we must acknowledge that it is a vastly different enterprise than they are currently engaged in and therefore requires more than simply additional funding for their current activities.

Again, we may find it optimal to limit the flow of innovation in exchange for greater access to the smaller number of products. However, this must be a reasoned calculation and not one based on the false belief that the efforts of even a greater funded NIH or the better angels of a scientist's nature will somehow fill the void vacated by the venture capitalists. This reasoned choice must consider the overall value created by innovation over the long term compared to the relatively short period of exclusivity where access is diminished because of high prices but is certainly not reduced to zero.

II. Cross Country Pricing Differences and Reference Pricing Systems

Even a cursory look around the globe reveals that other developed countries that are broadly similar to the United States have chosen different policies with respect to the access to existing pharmaceuticals. Through a combination of direct price controls, active negotiation, and other regimes these countries have successfully negotiated far lower prices that the U.S. market.

This has led many to state that the U.S. could also institute similar policies without suffering decreased access to innovation. After all, the residents of countries such as Denmark and Germany use the same drugs as U.S. citizens at a lower price. At the extreme, such beliefs stand at the center of the various reference pricing schemes that have been proposed by both the Department of Health and Human Services and in the Lower Drug Costs Now Act.

These policies rest on a belief that it is fundamentally unfair that the profits earned from U.S. patients provide the incentives for global innovation efforts that these lower price countries get to enjoy. While I share the belief of a certain level of inequity from the current system, it's unclear reference pricing will correct this situation. Instead, we may be left with the U.S. paying lower prices and everyone having less innovation.

We must first recognize that there is no sense in which the current prices in other developed countries represent the "correct" price simply because it is a lower price. There is absolutely nothing to suggest that the other developed countries most often included in the various reference pricing systems have in anyway determined their prices based on calculation of the innovation tradeoffs. Instead, they have made these decisions with the explicit knowledge that much of the global innovation will be funded by the United States regardless of their actions. In this way these smaller markets free ride of the innovation incentives in other markets.[12]

This leads to the open question of what the ultimate price would be in these other developed economies after the implementation of a U.S. reference pricing system. For some indication of this eventual price, we can look to the literature on most favored nation policies such as the Medicaid "best price" rule. While Medicaid is obviously a different setting, it shares several economic features with the international reference pricing rules.[13] This theoretical and empirical literature suggests that the prices in the countries in the reference price basket will be higher than the current international price but likely lower than what the U.S. is currently paying. There are two reasons for this.

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[12] D. Lakdawalla, "Economics of the Pharmaceutical Industry," *Journal of Economic Literature*, June 2018, 56(2): 397-449.
[13] M. Duggan and F. Scott Morton, "The Distortionary Effects of Government Procurement: Evidence from Medicaid Prescription Drug Purchasing," *Quarterly Journal Economics*, Feb 2006, 121(1): 1–30.

First, pharmaceutical manufacturers will now be less likely to give as large of a discount to these countries. Note that this is not because these firms were previously giving a discount to these countries, i.e. these firms are not leaving money on the proverbial table. Manufacturers negotiate as hard as they can with foreign markets to determine how high they can raise their prices before the decreased revenue (from a lower quantity sold) outweighs the higher revenue from the higher margin. After a reference pricing system is in place, this calculation changes. Firms are willing to suffer the decreased sales resulting from demanding higher prices in order to avoid giving such a large discount to the United States.

Second, it is possible in a world where U.S. prices will be suppressed by regulation other countries will increase their prices to account for the lost innovation. Under an ideal setting, this would result in U.S. prices falling and international prices rising to the point that the total returns to innovation remain the same but are more evenly financed across OECD countries. However, it is unclear whether the political systems of those countries would allow for such a shift in the distribution of funding sources. Thus it is possible we will end up in a world where innovation investments are far below what would be optimal for the preferences of U.S. citizens.

Furthermore, it is unclear that even without political constraints, these countries would make the same decisions as the U.S. if our policymakers attempted to actually grapple with the amount of innovation it was willing to sacrifice in order to increase access to existing medications. Effectively, a decision to create reference pricing for U.S. prices is outsourcing our innovation policy decisions to the governments of other developed countries. While this is certainly expedient, there is nothing to suggest that the decisions of these countries would represent the optimal policy outcomes for U.S. citizens.

While it is true the tradeoff is ultimately a policy choice, it would seem that this choice should reflect the preferences of the market participants in our country and not those of foreign markets? There is little evidence to suggest a reference pricing system would reflect the preferences of these U.S. customers.

III. The role of government in U.S. healthcare

For the reasons discussed above, determining the parameters of the access and innovation tradeoff is difficult. This is made even more complicated by the heavy role of government in the procurement of healthcare for vulnerable populations such as the indigent, elderly, and disabled. Given the fact that healthcare is a unique product for which society places particular value on an individual's ability to access services regardless of their ability to pay, the U.S. has developed a series of social insurance and transfer programs to help vulnerable populations access care. Over time these programs have grown, and public

spending now accounts for just over half of all healthcare spending in the United States – a fact that makes healthcare markets distinct from the rest of the economy.

Given the economically meaningful role of the public sector in the healthcare market, the ability to maintain a competitive market inherently relies, at least in part, on government policies and regulations. Ultimately, healthcare is our nation's most meaningful public-private partnership. This has become even more apparent as the United States increasingly relies on private markets and firms for the provision of publicly funded social insurance benefits. This includes the Medicare Advantage program, Medicaid Managed Care, and even the much-derided Affordable Care Act – which I've previously noted is perhaps the most conservative market based approach to the provision of health insurance for such a large number of low-income individuals.[14] Private firms are being used to provide these services because, at their core, they have the strong incentive to respond to consumer demand in a quest to maximize profits. These incentives allocate resources in ways that increase welfare. It is unlikely that a government entity could achieve a similar result, and therefore optimal healthcare policy harnesses market forces while maintaining no illusions about the motivations of the firms it employs to efficiently provide goods and services.

However, successfully managing these public-private partnerships requires establishing rules that enhance rather than inhibit competition. To this end, the Lower Drug Costs Now Act contains a number of positive modifications to the Medicare Part D program that should be lauded. These are outside of the focus of this hearing, so I will not discuss them in detail. I will note that many of these are in the same spirit as those proposed by Senate proposals – and I hope that this will be an area for bipartisan progress on addressing market based reforms for drug pricing.

IV. Government Efforts on Drug Pricing Can Be Based in Market Principles

I want to be clear that belief that increasing access today will decrease innovation does not preclude any role for government in pharmaceutical pricing. First, as noted above the government is already heavily involved in the market because it establishes the rules by which intellectual property is protected and finances large portions of the healthcare market. Second, simply because the U.S. hopes to use regulated markets to establish prices doesn't mean that the such a market based system is immune to market failures. In such specific cases, regulation maybe create more welfare than a market plagued by failure.

[14] Garthwaite, Craig. 2017. "Why replacing Obamacare is so hard: It's fundamentally conservative." The Washington Post. July 10.

Given these factors, there are clearly potential places for the government to intervene. The question quickly becomes: which types of products do you choose to target? The proposed legislation at the center of this hearing intends to target products which face little competition. On the one hand, the attraction to targeting these products is understandable. After all, these types of products are generally higher priced than those facing either therapeutic or generic competition. On the other hand, these high prices don't clearly reflect some market failure that should be addressed by instead of reflect products the create *unique value.*

Determining which products should be targeted is so important because prices are not simply static policy objects that can be manipulated with little dynamic consequences. Instead, prices send signals to the market about where capital should eventually be allocated. By placing greater pricing pressure on products which address unmet need, we face the danger of shifting resources away from those products and towards those where there may be more competition but also where the U.S. prices will, to a greater degree, be more determined market forces.

Instead of focusing attention on artificially lowering these prices for products with patent protection that generate unique value, optimal policy should focus on two goals: (1) addressing high prices that result not from a deliberate policy tradeoff to reward high value products but instead from a market failure; and (2) fostering competitive pressure among existing products.

Below I document several potential policies that would better address distortions from high prices in the United States.

IV.A. A Lack of Competition for Generic Products Treating Small Patient Populations

Markets for generic small molecule products are intended to have fierce price competition facilitated by the automatic substitution of prescriptions towards less-expensive generic products. In a well-functioning generic market, firms compete primarily on price and therefore profits are determined by a firm's ability to manufacture products at the lowest marginal cost. This fierce price competition means that successful entrants must be able to produce enough to reach the minimum efficient scale (MES) of their production process. Absent sufficient quantity, entrants realize they will find themselves at a perpetual cost disadvantage to incumbent firms and therefore will rationally decline to enter the market. For sufficiently small markets, there is only enough demand for a single manufacturer to reach MES – and the incumbent firm is a natural monopolist that maintains meaningful pricing power.

In recent years, several firms have recognized the pricing power available to ANDA holders for generic products with sufficiently small potential markets. This was perhaps best personified by the pricing strategies

of Turing Pharmaceuticals, but aspects of this strategy have been implemented by other firms and thoroughly documented in several media outlets.[15] The ability for these firms to charge monopoly prices for generic products is not the result of the above-discussed tradeoff between access today and innovation tomorrow – society has long since paid for the innovation from any of these products. Instead, the high prices represent firms taking advantage of a market failure created by the small patient population. While large pharmaceutical firms were historically either unwilling to exploit this pricing power or unaware of this financial strategy, the practice of firms charging high prices without fear of entry in small generic markets is now widespread throughout the industry (albeit the strategy is typically employed by smaller firms with fewer invested assets in the industry). If Congress hopes that for-profit firms will simply avoid this pricing strategy going forward, they will be sorely mistaken. Instead, solutions to market failures for small-market generics will need to come either from firms being harmed by this practice or through government action.

For some of these products, private firms are stepping forward with market-based solutions. Specifically, a consortium of hospitals led by Intermountain Healthcare has created CivicaRx – a joint venture designed to address the high prices charged for many generics that are administered in a hospital setting.[16] For products administered in the hospital, providers are unable to pass the increased costs along to patients or payers and have therefore decided to vertically integrate and manufacture the products themselves.

While vertical integration in this setting is an efficient response by hospitals in response to a market failure in their supplier market, CivicaRx will likely not find it valuable to undertake the manufacturing of products that are sold directly to patients through retail or specialty pharmacies. Those products do not impact the financial health of the hospitals involved in the joint venture. Therefore, solutions for these other products must come from new government policies that either reduce the number of natural monopoly markets or use economic tools to more directly intervene in the natural monopoly markets that remain.

If high fixed entry costs make it difficult for multiple firms to profitably produce small-market generics, one potential policy solution is to lower these fixed costs. This would decrease the quantity required for a new entrant to reach MES and compete with the incumbent manufacturer. In recent years, the FDA has been focused on programs to accomplish this goal. For example, there have been efforts to streamline and

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[15] Hopkins, Jared S., and Andrew Martin. 2018. "These New Pharma Bros Are Wreaking Havoc on Prescription Drug Prices." Bloomberg. April 6.
Pollack, Andrew. 2015. "Drug Goes From $13.50 a Tablet to $750, Overnight." The New York Times. September 20.
Rockoff, Jonathan D., and Ed Silverman. 2015. "Pharmaceutical Companies Buy Rivals' Drugs, Then Jack Up the Prices." The Wall Street Journal. April 26.
[16] Abelson, Reed, and Katie Thomas. 2018. "Fed Up With Drug Companies, Hospitals Decide to Start Their Own." The New York Times. January 18.

harmonize the generic application process across developed countries.[17] There have also been attempts to increase the speed and efficiency of the ANDA process, which would decrease barriers to entry and potentially increase the number of markets that could support multiple firms.[18]

I would encourage the FDA to continue to evaluate the approval process to look for additional efficiencies that would decrease entry costs. However, even the most efficient process for entering a generic market will require some expenditures to demonstrate the safety and bioequivalence of the product – and this will always represent a meaningful fixed-cost investment. Therefore, another potential solution to promote entry is to attempt to increase the size of some generic markets. While this can't be accomplished within any geographic boundary (i.e., we are unlikely to uncover more patients with these types of conditions), I would encourage Congress and regulators to consider a broader system of importation across developed countries with similar safety and regulatory systems (i.e., the countries the FDA is currently empowered to turn to in the case of drug shortages). Aggregating demand across these markets would increase total quantity and the number of products that could successfully be produced by multiple manufacturers. Some have argued the FDA could implement this strategy today by considering generic products with large price hikes to be a situation of shortage.[19] However, it is likely that Congressional investigation and debate are needed before we implement such an important change to the sourcing of generic medications.

Even after efforts to decrease costs and increase market sizes, there likely will remain some markets that still cannot support multiple firms. In this case, further regulations are likely necessary to reach an efficient outcome. Senator Elizabeth Warren has previously proposed that the government step in to manufacture generic drugs when products have small market sizes and large drug price increases.[20] I understand and appreciate the motivation for Senator Warren's proposal and think that it is a potentially viable policy option for addressing this particular market failure, i.e., the lack of competition in markets for generic products without sufficient size to support multiple firms.

However, I fear that a government entity will likely fail at being an efficient producer of these products – after all, this is not an enterprise in which they specialize. As a result, the marginal costs of a government producer would likely be higher than for a private firm with experience in drug production. Before the

[17] Gottlieb, Scott. 2018. "Advancing Toward the Goal of Global Approval for Generic Drugs: FDA Proposes Critical First Steps to Harmonize the Global Scientific and Technical Standards for Generic Drugs." FDA. October 18.
[18] Elvidge, Suzanne. 2018. "FDA sets another record in 2018 for generic drug approvals." BioPharma Dive. October 12.
[19] Greene, Jeremy A., Gerard Anderson, and Joshua M. Sharfstein. 2016. "Role of the FDA in Affordability of Off-Patent Pharmaceuticals." JAMA 315 (5): 461-462. doi:10.1001/jama.2015.18720.
[20] Warren, Elizabeth. 2018. "It's time to let the government manufacture generic drugs." The Washington Post. December 17.

government undertakes such a new and complicated economic activity, I would propose a private-sector solution in which Congress empowers the FDA to provide a new form of market exclusivity for generic products with market sizes that do not support multiple competitors.

The exact specifics of such an exclusivity would need to be worked out, but a first step would be for Congress to ask the FTC to examine how many potential patients are necessary for a market to support multiple generic firms. While most generic prescriptions are likely for molecules that can support multiple competitors, there are potentially a large number of molecules with small patient populations that can't support multiple manufacturers. For example, there has been an increase in the number of exits by ANDA holders in recent years, with many firms citing a lack of profitability. The median generic market currently has only two manufacturers, and approximately 40% have a single manufacturer – which likely is the result of limited market potential for these molecules.[21] That said, the current number of firms participating in the market in equilibrium does not provide sufficient information to understand whether the market could ultimately support multiple firms. After all, it is the threat of entry and not actual entry that disciplines profits. Inferring the number of firms that a particular generic market could support based on the number of current firms could be particularly problematic given the ongoing allegation of collusion in this market.[22] Therefore, it is important for economists at the FTC to determine the exact market size and structure that would indicate that the market for the generic product is a natural monopoly where the incumbent firms possesses significant pricing power. Ideally this investigation would incorporate the potential market-expanding policies of decreasing entry costs and potentially increasing the market size to include some limited foreign markets.

After establishing the market characteristics likely to lead to natural monopolies, I would propose the FDA be required to undertake a request for proposal (RFP) process for those markets. Under this RFP process, any private firm could apply for the rights to be the exclusive manufacturer of a natural monopoly generic medicine at a certain fixed percentage above manufacturing costs. As part of this RFP process, firms would compete on the amount of margin they would require to serve the market. The winning firm would possess the exclusive rights to sell the drug at this regulated price for a time period sufficient to recover the fixed costs of entry. At that time, the FDA would have the option of re-auctioning off the market exclusivity. In order to ensure the efficient operation of this process, it may also be necessary for the FDA to set a maximum percentage that they will accept before they will turn to a non-profit or government supplier for the product. This will limit any ability of firms to collude to divide up the markets they choose to enter.

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[21] Berndt, Ernst R., Rena M. Conti, and Stephen J. Murphy. 2017. "The Landscape of US Generic Prescription Drug Markets, 2004-2016." NBER Working Paper No. 23640.
[22] Silverman, Ed. 2019. "Here's how prosecutors say generic drug makers schemed to fix prices." STAT. February 19.

I would encourage Congress to immediately investigate solutions in the area of small-market generics, as this problem will only grow in importance. Recent scientific advances have allowed for an increasing personalization of medicine. Along with co-authors, I have documented the rising share of clinical trials involving a patient-specific biomarker to determine either efficacy or safety.[23] As can be seen in Exhibit 2, in recent years there has been a marked increase in trials for these types of products. Almost by definition, personalized medicine will involve products with limited patient populations, and for many of these products we should be worried about whether robust generic competition will ever emerge.[24] Therefore, while the problem of small-market generics is not a dominant feature of today's market, it will only grow in importance. It will likely be far easier to address the problem now than it will be when the number of powerful interests manufacturing such products increases.

IV.B. Policies to Promote Robust Competition Between Branded Therapeutic Substitutes

While innovative firms maintain time-limited exclusivity to manufacture their patented products, competition should still emerge from therapeutic substitutes that can provide meaningful pricing pressure that transfers surplus to consumers and/or increases output. Prescription drug price competition in pharmaceuticals results from intense negotiations between manufacturers and pharmacy benefit managers (PBMs). These negotiations take the following form (which is graphically summarized in Exhibit 3).

First, the actual payer (i.e., a self-funded employer or fully funded insurer) enters into a contract with a PBM. Under the terms of this contract, the PBM manages the payer's pharmacy claims, a process that includes activities such as administering the prescription drug benefits, designing formularies to negotiate price discounts, implementing utilization management, and creating retail pharmacy networks. The compensation received by PBMs in these contracts is complicated and detailed, but at a high level it involves a per-member administrative fee and a portion of negotiated discounts that the PBM can retain.

While PBMs undertake a large number of functions, perhaps the most meaningful economic activity is negotiating discounts or "rebates" from pharmaceutical manufacturers. This negotiation process begins with manufacturers setting a list price, which is the price initially paid by the payer. PBMs and manufacturers then negotiate economically meaningful rebates in order to arrive at a net price. The negotiating power of the manufacturer is determined by the unique value created by its product, and so manufacturers whose products have a large number of potential therapeutic substitutes have less negotiating power. The negotiating power

[23] Chandra, Amitabh, Craig Garthwaite, and Ariel Dora Stern. 2018. "Characterizing the Drug Development Pipeline for Precision Medicines." NBER Working Paper No. 24026.

[24] The problem of competition for precision medicine will be further complicated in situations where the patented product is a biologic product.

of PBMs results from the number of customers they represent and their willingness and/or ability to move those customers across products after receiving a large discount. The more customers a PBM can credibly shift, the greater the discount they can negotiate. In order to shift share, PBMs use a combination of consumer cost sharing and utilization management techniques such as prior authorization and step therapy.

To the chagrin of many, rebates negotiated between manufacturers and PBMs are closely guarded secrets. However, for many reasons maintaining this confidentiality improves market efficiency by increasing the size of the rebate and expanding output. Perhaps the most important reason is that manufacturers are less likely to give large discounts if they believe other consumers will observe the size of this rebate and use it as a starting point for subsequent negotiations. A rational manufacturer would anticipate such an outcome and ultimately offer smaller rebates to the entire market. For this reason, economic research suggests that widely known negotiated prices will raise prices rather than increase competition.[25,26] In addition, the public posting of prices can facilitate tacit collusion among firms. When negotiated discounts are publicly observable, firms have more certainty that other competitors in the market are not offering lower prices in order to steal share. In a setting with limited potential entry, this knowledge can serve as the basis for tacit collusion. Previous research in other settings has discussed and documented how public knowledge about price discounts therefore can facilitate such tacit collusion – a separate channel through which ending the confidentiality of rebates would lead to higher prices.[27]

The final step of the negotiation process is that PBMs transfer some amount of the rebate back to the payer, which initially purchased the drug at its list price. The amount of the rebate that is transferred is dictated by the contract between the payer and the PBM.. Both large and small employers are increasingly likely to have contracts under which they are supposed to receive the entirety of the rebate. However, a meaningful share of both large and small employers are contractually entitled to only a portion of the rebate negotiated by the PBM.

IV.C. Improving Information about Flow of Funds Between Manufacturers and PBMs

Rebates have gained an undeserved bad reputation, resulting from a lack of understanding of their important role in controlling pharmaceutical prices. This has culminated in a recent Department of Health and Human

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[25] Albæk, Svend, Peter Møllgaard, and Per B. Overgaard. 1997. "Government-Assisted Oligopoly Coordination? A Concrete Case." The Journal of Industrial Economics. Vol. 45, No. 4, pp. 429-443. December.
[26] Byrne, David and Nicolas Roos. 2015. "Learning to Coordinate: A Study in Retail Gasoline." American Economic Review 109(2): 591-619.
[27] Cutler, David, and Leemore Dafny. 2011. "Designing Transparency Systems for Medical Care Prices." New England Journal of Medicine 364 (10): 894-895. doi:10.1056/NEJMp1100540.
Cooper, Thomas E. 1986. "Most-Favored-Customer Pricing and Tacit Collusion." The RAND Journal of Economics 17 (3): 377-388.

Services proposal to end the safe harbor protections for rebates under the Medicare program – a regulatory change that would effectively end the use of rebates for publicly insured consumers (and potentially for the entire market).[28]

The proposed rule appears to be motivated by a belief that rebates offered as a discount off of the list price are partially responsible for rising drug prices. However, this belief is misguided. There is nothing about rebates that inherently causes higher pharmaceutical spending. Ultimately, there are two primary concerns about rebates highlighted as rationales for the proposed safe harbor regulation. First, many cost-sharing provisions of prescription drug insurance contracts expose patients to the list rather than the net price of the drug. For example, patients who pay percentage-based coinsurance or who have a deductible that applies to pharmaceutical spending purchase drugs based on the list rather than the net price. The share of the population in such situations has grown markedly and now comprises approximately half the market.

The purpose of consumer cost sharing (copayments, coinsurance, and deductibles) for pharmaceuticals is to address moral hazard, i.e., either the excess consumption of products or consumers purchasing an expensive version of a product when a lower-priced alternative is available. Cost-sharing provisions are based on list prices in an attempt to maintain the confidentiality of negotiated discounts. If patients in the deductible period paid the negotiated price for the medication or if percentage-based coinsurance was based on the negotiated rather than list price, then it would be trivial for rival firms to gather information on the menu of discounts available in the market. As discussed above, maintaining confidentiality of these rebates likely increases price competition and leads to lower net prices – which overall is good for consumers. That said, forcing consumers to pay artificially high cost sharing is likely inefficient, as it unwinds the insurance contract by forcing sicker individuals to pay greater costs and can potentially decrease adherence to prescription protocols.

It is clear we should find policy solutions to pass along more of the negotiated discounts to consumers. However, it is critical that any policy solution saves the proverbial baby while throwing out the bathwater by maintaining the ability of PBMs to effectively negotiate larger rebates with manufacturers. Therefore, I propose that PBMs be required to base cost-sharing payments on a number that more closely approximates the net price of the product. This number could be the average net price across PBMs for that product, the average net price for the therapeutic class, or the minimum price paid in the market, i.e., the Medicaid best price. Assuming that PBMs have sufficient ability to modify their formularies, any of these options should still expose the patient to enough of the cost of the product to address moral hazard concerns while not

[28] Office of Inspector General and Department of Health and Human Services. 2019. 84 FR 2340. February 6.

exposing consumers to artificially high prices that unwind the generosity and efficiency of the insurance contract.

Note that some have complained that policies that pass along rebates to consumers at the point of sale would lead to higher premiums. While it is true that this would be the case, it is not clear this is necessarily a problem. These higher premiums would reflect, in part, a more complete insurance product. It is not immediately clear consumers are fully aware of the financial exposure they have to expensive medications, and therefore we should not think that increasing the completeness of insurance in this setting is clearly a negative outcome.

A second concern about the current system of confidential rebates and other payments between manufacturers and PBMs is that it creates a potential incentive for a PBM to give preference to a higher-list-price drug that offers greater rebates and other fees. Effectively, the concern is that the PBM will not be a good agent for its principal, i.e., the final payer. I argue that to the extent this is a concern, it is actually not about the structure of the rebate contract and instead reflects a more fundamental question about the amount of competition in the market for PBM services. If that is the case, policies to address this practice should focus on the market structure rather than the contractual form.

In a competitive market, the structure of the PBM contract would not matter. PBMs would compete for a payer's business by offering a set of services of specific cost and quality, and fully informed insurers would pick the preferred combination of these characteristics. If we believe PBMs are using rebates to capture a larger share of surplus in this market, this reflects a lack of competition for these services rather than an inherent problem with this contractual form.

Whether or not the PBM market is competitive is currently unclear. On the one hand, there are reasons why we might be concerned about competition in this market. A series of mergers over the last decade have left three firms with nearly 80 percent market share – a structure that might make one concerned about the degree of competition. Some of these concerns were expressed by FTC Commissioner Brill in a dissenting opinion regarding the merger of Express Scripts and Medco in 2012.[29] However, simple measures of market concentration are not proof of a lack of competition. With three large competitors, it is possible there is sufficient competition, and the actual level of competition in this market is fundamentally an empirical question.

[29] Brill, Julie. 2012. "Dissenting Statement Of Commissioner Julie Brill Concerning The Proposed Acquisition Of Medco Health Solutions Inc. (Medco) By Express Scripts, Inc. (Esi)." FTC File No. 111-0210. April 2.

The concern about PBMs being attracted to higher-rebate drugs can be best demonstrated by a simple example. Consider a drug that currently has a list price of $100. The manufacturer proposes to the PBM a 20% list price increase – resulting in a new list price of $120, which is initially payed by the payer (i.e., employer or fully funded insurer). The manufacturer also proposes to increase the rebate paid to the PBM by $15, resulting in a net price increase of only 5%. However, the PBM is only required by its contract to transfer 50% of rebates to the payer, meaning it keeps $7.50 of the rebate and the payer gets $7.50. Therefore, the payer spends $12.50 more, with $5 going to the manufacturer and $7.50 for the PBM.

Ultimately, the unanswered question is whether the $7.50 collected by the PBM represents too much surplus or instead is the appropriate payment for its negotiating activities. In a well-functioning competitive market, we would expect that if the $7.50 the PBM captures from the example above represents too much of the surplus, the PBM would ultimately face competition from another PBM offering a better contract to the payer. Such a contract would propose to decrease the total spending to the payer. However, this requires a market with multiple PBMs actively competing for contracts, a situation that may not exist in the current market. Competition is even less likely to emerge if the firms in the market realize there are large barriers to entry and the incumbent firms would be better off not actively engaging in price wars to gain share.

Strong competition is even less likely to emerge if payers are unaware of the full scope of surplus created by their prescriptions. Many large firms hire sophisticated benefit consultants and increasingly demand fully transparent contracts that provide them full information on all "rebate" dollars. In theory, this provides information about the surplus created by their prescriptions. That said, there are reasons to be concerned that despite these efforts payers may still be unaware of all of the funds flowing between the PBM and the manufacturer. In addition to rebates, PBMs also receive various administrative fees and other payments from manufacturers. Ultimately, the PBM determines which of these payments are rebates (and therefore covered by the price transparency and rebate sharing requirements), and what is instead a fee (that does not need to be disclosed or shared).[30] These fees are not trivial – for some contracts they can account for 25-30% of the money moving between the manufacturer and the PBM.[31] If we consider the simple example above, the situation for the payer could be even worse if, instead of offering a rebate of $15, the manufacturer offers an administrative fee to the PBM. In that case, the payer would bear the full cost (i.e., $20) of the list price increase, and the PBM and manufacturer would split the surplus. Ultimately, manufacturers are agnostic

[30] Eickelberg, Henry C. 2015. "The Prescription Drug Supply Chain 'Black Box': How it Works and Why You Should Care." American Health Policy Institute. December.
[31] Dross, David. 2017. "Will Point-of-Sale Rebates Disrupt the PBM Business?" Mercer. July 31.

between describing payments to the PBM as "fees" or "rebates" – they simply care about the total amount of money they collect and distribute as a result of these negotiations.

To further complicate matters, sophisticated payers hoping to gather more information about the flow of funds between the PBM and manufacturers that results from their prescriptions often face meaningful restrictions on the ability to audit their PBM-payer contracts.[32] These can include the exclusion of particular auditors that are deemed to hold views that are hostile to PBMs, requirements that audits be held at the headquarters of the PBM, unwillingness to provide contracts with manufacturers, restricted access to claims data, and strict limitations on the number of years that can be audited.[33] While many of these restrictions can be cast as attempts to maintain rebate confidentiality, they also increase the amount of asymmetric information between PBMs and payers about the amount of available surplus.

Recently the Department of Health and Human Services proposed to address this problem by eliminating the safe harbor for rebates in the Medicare program. While this policy has been abandoned, other efforts underway have the same goal of ending confidential rebates based on the price of the drug and shift the market to a series of up-front price discounts and flat fees negotiated between PBMs and manufacturers.[34] This would effectively end the confidentiality of negotiated prices while also not decreasing the amount of surplus captured by PBMs – after all, a PBM with market power can calculate a flat fee as easily as the current percentage based-rebate system.

It is perhaps not surprising that policies from both parties are coalescing on attempting to end rebates. Frustrated by rising drug prices, people are looking for a scapegoat and a system of shrouded prices by large firms fits a convenient narrative. That said, it would be extremely unwise to limit the ability of PBMs to negotiate large discounts. Instead of ending the current system of confidential rebates, I've proposed (along with Fiona Scott Morton) that we move to a system where all payments currently paid between the manufacturer and the PBM flow first to the payer before being split between the payer and the PBM.[35] PBMs and payers would be free to negotiate any split of the rebates, fees, and other funds that are paid by the manufacturer – but such a negotiation would now occur between two parties with equal information about the amount of money at stake. There are variety of ways to implement the move to such a system. One

[32] Weinberg, Neil, and Robert Langreth. 2017. "Inside the 'Scorpion Room' Where Drug Price Secrets Are Guarded." Bloomberg. May 4.
[33] Advisory Council on Employee Welfare and Pension Benefit Plans. 2014. "PBM Compensation and Fee Disclosure." Report to the United States Secretary of Labor.
[34] U.S. Department of Health and Human Services. 2019. "Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients." January 31.
[35] Garthwaite, Craig, and Fiona Scott Morton. 2017. "Perverse Market Incentives Encourage High Prescription Drug Prices." ProMarket Blog. November 1.

possible solution would be for regulators to end the safe harbor for payments between manufacturers and PBMs and instead create a separate safe harbor for payments between manufacturers and payers. I'd note that if the current PBM market is competitive, this proposed policy solution should have little effect on the distribution of surplus.

IV.D. Biosimilar Adoption and Rebates

While rebates serve a vital function in drug price negotiations, there are also situations where the structure of the rebate contract can create a barrier to entry for new competing products. For example, rebate contracts sometimes reference rival products, particularly with respect to a rival's placement on the formulary. Depending on the economic context, such rival-referencing contracts could be either anti-competitive or pro-competitive. For example, a manufacturer may offer larger rebates if its product is the only one in a therapeutic area on the preferred tiers of the formulary. If there are many potential products that are competitors for the entire market, such a contract could be efficient. In fact, these types of contracts are at the heart of the PBM strategy. In describing his strategy, the Chief Medical Officer of Express Scripts said, "So we went to the companies, and we told them, we're going to be pitting you all against each other. Who is going to give use the best price? If you give us the best price, we will move the market share to you. We will move it effectively. We'll exclude the other products."[36] Since 2012, there has been marked growth in the use of these exclusion lists. Likely related to this fact, since 2012 there has also been a large increase in the amount of rebates in the system.

In situations where manufacturers are competing for access to the PBM's entire patient population, these types of contracts can be pro-competitive, leading to large discounts and increased welfare. However, for some types of products, large portions of the market are not truly contestable, i.e., the PBM will not be able to effectively move a fraction of the patients to the low-price product. For example, patients who are currently using a biologic product are unlikely to be willing to switch to a competing biosimilar at almost any price. In addition, PBMs might find that payers would not be happy with strategies that forced their patients to move across biologic products in this manner.

In a situation where a new entrant cannot effectively compete for a large fraction of patients, a rebate contract for the incumbent product that is contingent on the absence of the rival entrant on the formulary can serve as an almost impenetrable barrier to entry. This situation is sometimes referred to as a rebate "wall" or "trap." Effectively, the new entrant finds that it cannot offer the PBM a large enough rebate on its

[36] Wehrwein, Peter. 2015. "A Conversation with Steve Miller, MD: Come in and Talk With Us, Pharma." Managed Care. April 5.

products (which represent a relatively small share of sales) to overcome the lost rebate dollars from the incumbent (which represents a majority of the market). In such a situation, the new entrant would find it quite hard to ever gain meaningful market share. Perhaps more concerning, realizing the existence of these rival-referencing contracts, potential biosimilar firms may never choose to attempt to create products in the first place. Concerns about the use of rebates in this manner have been raised by many individuals, including FDA Chairman Scott Gottleib and the CEO of Novartis Vas Narasimhan.[37,38] They are also the subject of antitrust litigation between reference products and biosimilar firms, which is winding its way through the court system and should provide additional guidance about the legality of these practices.[39,40]

Given the potential for the rebates contingent on rival products to block potential entrants, regulators should consider more careful oversight and monitoring of rebate contracts that reference rivals. In situations where a large portion of the market is not contestable by the new entrant – for example, in the case of the first biosimilar entering against a reference product – it may be advisable for regulators to create additional restrictions on the ability of rebate contracts to reference the position of rival products on the formulary.

IV. Conclusion

Pharmaceutical pricing in the U.S. has attracted the attention of a bipartisan set of policymakers. As I discuss above, this is understandable given that the business model involves charging large prices well above the marginal costs of production. Of course, the large fixed costs of drug discovery and development are less obvious to consumers.

These concerns have prompted calls for greater drug price regulation, such as the various features of the proposed Lower Drug Costs Now Act. Price controls of the degree proposed in the legislation would have meaningful consequences on future innovation and therefore must be debated in an intellectually honest manner that grapples with these tradeoffs.

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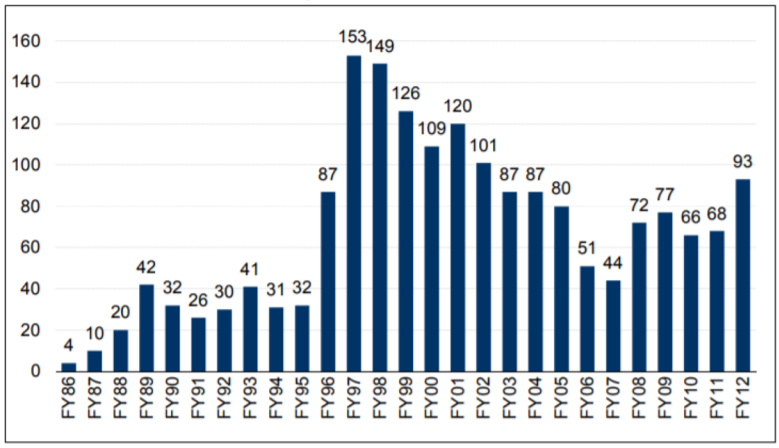
[37] Liu, Yanchun. 2018. "FDA chief says pharmas use rebates to block biosimilar competition." MarketWatch. July 19.
[38] Narasimhan, Vas. 2018. "Novartis CEO: How To Create Cheaper Alternatives To The Most Expensive Drugs." Forbes. April 12.
[39] Biosimilars Council. 2018. "Brief Of The Biosimilars Council As Amicus Curiae In Opposition To Defendants' Motion To Dismiss." Civil Action No. 2:17-cv-04180-JCJ. United States District Court For The Eastern District Of Pennsylvania, January 26. Accessed March 4, 2019. https://www.accessiblemeds.org/sites/default/files/2018-01/AAM-Amicus-Brief-Pfizer-vs-J%26J-1-26-18.pdf.
[40] United States District Court for the Eastern District of Pennsylvania. 2017. "Complaint, Case 2:17-cv-04180-JCJ." September 20. Accessed March 4, 2019. https://www.courtlistener.com/recap/gov.uscourts.paed.534730.1.0.pdf.

Exhibit 1

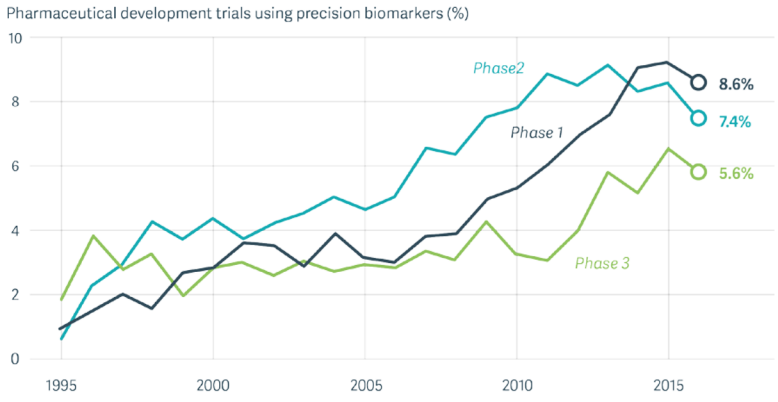
NIH Cooperative Research and Development Agreements (CRADAs), by year



Source: National Institutes of Health, Office of Technology Transfer http://www.ott..nih.gov/about_nih/statistics.html.

Exhibit 2

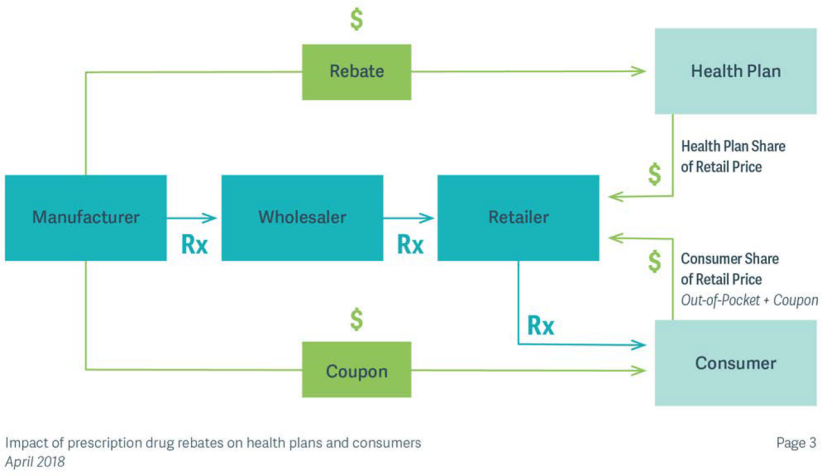
Precision Medicine Development Trials, 1995-2016



Source: A. Chandra, C. Garthwaite, and A.D. Stern, NBER Working Paper No. 24026 and forthcoming in E. Berndt, D. Goldman, and J. Rowe, eds., *Economic Dimensions of Personalized and Precision Medicine*, University of Chicago Press

Exhibit 3

Simplified Flow of Products (Rx) and Payments ($) in the Prescription Drug Supply Chain



Source: https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf

Chairwoman WILSON. Thank you. Thank you, Mr. Garthwaite. I will now recognize Mr. Mitchell.

TESTIMONY OF DAVID MITCHELL, FOUNDER, PATIENTS FOR AFFORDABLE DRUGS

Mr. MITCHELL. Chairwoman Wilson, Ranking Member Walberg, Members of the Committee, I am honored to be here. I am David Mitchell, I am founder of Patients for Affordable Drugs. More importantly, I have an incurable blood cancer and prescription drugs are keeping me alive. Every two weeks I spend half a day at a clinic getting infused drugs, which unfortunately are slowly failing, so last week, my doctors added an oral chemo drug. I am now taking four drugs. Now that my drugs carry an annual list price of $875,000, I have relapsed twice. Eventually I am going to run out of options so the importance of innovation is not theoretical for me; it is literally life and death. But my experience as a patient taught me one irrefutable fact and that is drugs don't work if people can't afford them.

To address out of control prices, however, we really must come to grips with some larger facts. Despite what drug companies tell us, and the general point that was made just now by Professor Garthwaite, sky high prices are not all about innovation. Multiple studies show there is no correlation between the cost of R&D and the price that is assigned to a drug.

Taxpayers front a huge portion of the bill for the basic science that leads to new drugs. Every single drug approved by the FDA from 2010 to 2016 was based on funding from taxpayers, science brought forward through the NIH. Meanwhile, independent analyses show that 9 of 10 drug companies spend more on advertising and marketing than on R&D. Why do drug companies charge so much? Because they can. Yes, drug companies should make a profit when they develop innovative drugs, but our current system is broken. And it is costing us all and our family finances, our health outcomes and lives.

H.R. 3 would ensure drug companies charge a fair price to patients while protecting access to lifesaving drugs and innovation.

I want to run through some highlights of H.R. 3 that I believe enjoy bipartisan support. First, it brings our prices more in line with what other wealthy nations pay using an international price index, very much like the Trump administration proposal. Second, it stops drug companies from increasing prices faster than the rate of inflation, just like the bipartisan Grassley-Wyden bill. Finally, it caps seniors' out of pocket costs for prescription drugs at $2,000 a year. Grassley-Wyden has a slightly higher cap.

Now I want to mention three other provisions important to patients. H.R. 3 ensures that Americans with public and private insurance have access to lower price drugs.

As an employer myself for 30 years, it is important that this bill gives 150 million Americans and their employers access to lower drug prices. Second, savings can go to new drug research and innovation at NIH.

Finally, it protects access to all drugs unlike in the private sector, H.R. 3 does not rely on a formulary and drugs are covered by Medicare just as they are today.

Now we all know the bill is under attack. Here is what people are saying. I heard some of it today. It is socialism. Well, competition and negotiation are cornerstones of capitalism. The truth is taxpayers negotiate on everything from aircraft carriers to printer paper. The only reason we don't negotiate for drugs today is because pharma inserted the prohibition into law in 2003, otherwise we'd be negotiating. It'll kill innovation; Dr. Garthwaite just made that point. Well, nobody cares more about innovation than me. As a patient, however, I find this to be a scare tactic and I find it offensive. HHS Secretary Azar refutes it best. He says: "It is a tired talking point. The idea that if one penny disappears from pharma profit margins, American innovation is going to grind to a halt."

And finally, it is going to lead to rationing. Well, my Lord, we already have drug rationing in this country. People are skipping doses, cutting pills in half, choosing between food and paying for their drugs. People are dying because they can't afford their insulin. H.R. 3 will stop rationing by lowering drug prices. Now right now, there's a fundamental question drug companies want us to ask about drug prices: what are we willing to pay to save a life? And I can tell you, that is easy. When It is your child's ability to breathe, when It is your cancer, the answer is anything, but that is the wrong question.

We should be asking what is the right amount of money the drug companies should make on these drugs? With hundreds of clinical trials underway right now for new gene therapies that are currently priced at a half a million dollars or more, we cannot pay just any price the drug companies demand. Neither American families, nor our system can afford that. I feel incredibly grateful to be here today speaking on behalf of patients. I do believe the moment is at hand to address this problem, and with bipartisan support, we will. Thank you.

[The statement of Mr. Mitchell follows:]

PATIENTS FOR AFFORDABLE DRUGS™

Statement of David E. Mitchell
Founder, Patients For Affordable Drugs

before the

U.S. House of Representatives Subcommittee on Health, Employment, Labor and Pensions of the

House Committee on Education and Labor
for a hearing on

Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency

September 26, 2019

Chairwoman Wilson, Ranking Member Walberg, Members of the Committee. I am honored to be here today.

Section I. Background and Introduction

My name is David Mitchell. I am the Founder of Patients For Affordable Drugs. We are a bipartisan organization focused on policies to lower prescription drug prices. We don't accept funding from any organizations that profit from the development or distribution of prescription drugs.

In the two years since we launched, we have collected over 20,000 stories of patients struggling to pay high drug prices. And we have built a community of more than 150,000 patients and allies that mobilize in support of policies to lower drug prices.

More importantly for today, I have an incurable blood cancer, and prescription drugs are keeping me alive.

My story starts almost nine years ago. I woke up with excruciating back pain, which I chalked up to activities and, of course, my age. On this particular morning, however, it was worse than ever before. Standing in my bedroom alone, I suddenly collapsed on the floor and couldn't move.

After visits to the ER and various doctors, I found out why I couldn't move — a crushed T-11 vertebra.

Cancer had literally broken my back.

Multiple myeloma attacks my bones. It broke my ribs and ate holes in my pelvis, arm bones, and skull. Doctors repaired my spine, and the fact that I can stand is a miracle of modern medicine.

Unfortunately, I will never be a cancer survivor. Multiple myeloma is incurable. But with expensive medication, I can keep it at bay for some period of time. Unless we invent a durable cure, I will be in continuous treatment until I die.

So every two weeks, I spend several hours at a local clinic getting an infusion of drugs that currently cost around $650,000 per year. That doesn't include my non-infused drugs. Once those are factored in, the total list price for my treatment right now is more than $875,000 per year.

I am very grateful for these drugs; they are keeping me alive. I have already relapsed twice. So the importance of innovation is not theoretical for me — it is literally life and death.

But my experience with cancer has taught me one irrefutable fact: Drugs don't work if people can't afford them.

Section II. The Cost of Drugs

From 2011-2016, prescription drug spending in the U.S. grew by 28%, which was more than 2.5 times inflation during that period.[1] Forty-two percent of cancer patients deplete their entire net worth within the first two years of treatment — in part due to high drug prices.[2] And drug spending growth is projected to accelerate by 31% by 2023.[3]

Telling Congress that drugs are too expensive feels a little absurd. This is the one issue just about everyone agrees on.

In fact, a recent poll from the Kaiser Family Foundation found that 70% of Americans say lowering prescription drug prices should be Congress' top health care priority. Respondents ranked it ahead of addressing surprise billing and ensuring protections for people with pre-existing conditions.[4] People are hurting.

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[1] Analysis of Centers for Medicare & Medicaid Services, Office of the Actuary prescription drug spending data, Table 11 and BLS data on CPI-U 2011-2016.

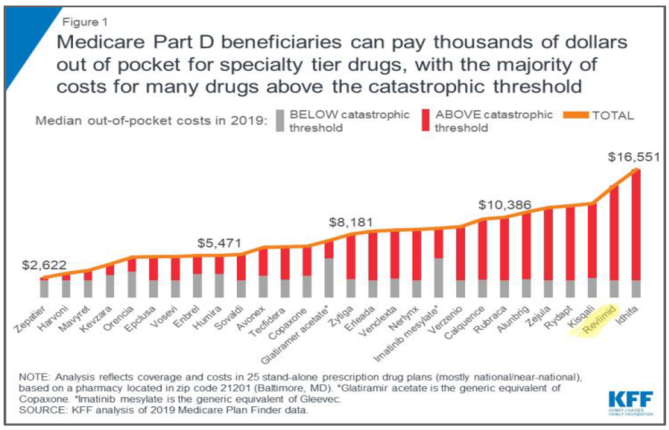
[2] Death or Debt? National Estimates of Financial Toxicity in Persons with Newly-Diagnosed Cancer. Gilligan, Adrienne M. et al. The American Journal of Medicine , Volume 131 , Issue 10 , 1187 - 1199.e5

[3] Analysis of Centers for Medicare & Medicaid Services, Office of the Actuary prescription drug spending data, Table 11.

[4] https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-september-2019/

This makes my story far from unique.

When I first got sick, doctors put me on a drug called Revlimid. I was on an employer plan then, and my out-of-pocket costs were $3,250 per year for that one drug. I could afford my prescription. But for Medicare patients on Revlimid, the median out-of-pocket cost is $14,461 per year — that's over half their annual income.[5,6]



A week ago, I started taking a second generation version of Revlimid. It has gone up in price by 65% over the past six years. Here is how it worked for me under Medicare Part D: My out-of-pocket cost for the first four-week supply was $2,758. My coinsurance every four weeks will be $850. That means my total annual out-of-pocket cost will be more than $13,000 per year — just for one drug.

Revlimid is an old drug — it was approved by the FDA in 2005 — and the principal reason it is so expensive is because its maker, Celgene, has gamed the system and refused to sell samples to generic companies trying to bring a competitor to market.[7, 8] It is why we need to pass the CREATES Act.

But Celgene is not the only drug manufacturer gaming our system and abusing patients. Take insulin manufacturers. Three companies control the global insulin market. They have raised

[5] https://www.kff.org/report-section/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019-tables/
[6] https://www.kff.org/report-section/medicare-beneficiaries-out-of-pocket-health-care-spending-as-a-share-of-income-now-and-projections-for-the-future-report/
[7] https://www.centerwatch.com/drug-information/fda-approved-drugs/drug/889/revlimid-lenalidomide
[8] https://www.bloomberg.com/news/articles/2018-05-17/u-s-names-drugmakers-gaming-safety-system-to-shield-profits

prices in lockstep — more than 300% over a recent ten year period.[9] Insulin is like water for people with diabetes.

Nicole Smith-Holt lost her 26-year-old son Alec to diabetic ketoacidosis, three days shy of his payday, because he couldn't afford his $1,300-a-month insulin and supplies.[10] Despite incredible activism from the diabetes community, prices have not fallen. In 2019 alone, reported deaths from insulin rationing have included: Jesimya David Scherer-Radcliff, 21;[11] Kayla Davis, 29;[12] Josh Wilkerson, 27;[13] Meaghan Carter, 47;[14] and Jada Louis, 24.[15] One in four U.S. patients with type 1 diabetes, like Alec, are forced to ration insulin.[16]

Drug prices are bankrupting us. And as people are rationing drugs and skipping them altogether, high prices can literally kill us.

Section III. It's Not About Innovation

The good news is, we can fix this. Despite what drug companies tell us, sky-high drug prices are not about innovation.

Pharma's argument seems to make sense on its face: research and development are expensive.

This claim mangles the facts.

There is no direct correlation between R&D costs and the price of a drug. As policy expert Avik Roy wrote: "Proponents of high U.S. drug prices argue that high prices are necessary to support pharmaceutical innovation. But, with a modicum of scrutiny, the fatal flaws in this argument become immediately apparent."[17]

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[9] https://diabetescaucus-degette.house.gov/sites/diabetescaucus.house.gov/files/Congressional%20Diabetes%20Caucus%20Insulin%20Inquiry%20White paper%20FINAL%20VERSION.pdf

[10] https://khn.org/news/insulins-high-cost-leads-to-deadly-rationing/

[11] https://www.kare11.com/article/news/family-says-21-year-old-son-died-rationing-insulin/89-d451a01b-9170-4341-9010-155cb87edccc

[12] https://www.t1international.com/blog/2019/08/29/rationing-while-waiting-refill-took-kaylas-life/

[13] https://www.washingtonpost.com/local/he-lost-his-insurance-and-turned-to-cheaper-form-of-insulin-it-was-a-fatal-decision/2019/08/02/106ee79a-b24d-11e9-8f6c-7828e68cb15f_story.html

[14] https://www.theguardian.com/society/2019/sep/23/diabetes-americans-soaring-insulin-prices?CMP=share_btn_tw

[15] https://myglu.org/articles/jada-louis-died-because-she-had-to-choose-between-paying-for-rent-or-insulin

[16] https://www.inquirer.com/health/consumer/insulin-ration-diabetes-drug-costs-20190625.html

[17] https://freopp.org/a-market-based-plan-for-affordable-prescription-drugs-931e31024e08

Dr. Peter Bach of Memorial Sloan Kettering Cancer Center and his colleagues also examined this issue in depth. Their findings "counter the claim that the higher prices paid by U.S. patients and taxpayers are necessary to fund research and development."[18]

Right now, drug companies make enormous profits — roughly two to three times the average of the S&P 500 — and spend most of it on expenses outside of R&D.[19] Nine out of 10 big pharmaceutical companies spend more on marketing, sales, and overhead than on research.[20]

From 2013 to 2017, the five largest U.S.-based drug companies spent less than one-fifth of revenue on research and development on average.[21] The same companies — Johnson & Johnson, Pfizer, Merck, AbbVie, and Amgen — spent about 70% more on sales, marketing, and administrative expenses than R&D in this same timeframe.[22]

We must fuel innovation. And yet, I can also tell you that the risk companies cite is not the reality. That money invested in research isn't coming from companies alone; it's coming from the American people.

U.S. taxpayers foot a huge and critical portion of the bill to develop new drugs. Based on a survey of PhRMA's own member companies, one out of every three dollars spent on drug research comes from American taxpayers.[23,24]

Under our current system, taxpayers are forced to pay three times for breakthrough treatments. First as taxpayers investing in research at the NIH, second as patients at the pharmacy counter, and a third time through tax dollars that support America's largest health insurance programs — Medicare and Medicaid.

The National Academies of Sciences, Engineering, and Medicine recently hosted a workshop where experts discussed multiple ways to ensure our investment in NIH balances critical innovation with essential access and affordability. Some of the approaches discussed include:

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[18] https://www.healthaffairs.org/do/10.1377/hblog20170307.059036/full/

[19] https://www.gao.gov/products/GAO-18-40

[20] https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.dc7e820c4172

[21] Analysis of SEC Filings. Top 5 US-based companies by market cap as of November, 2018 (JNJ, PFE, MRK, ABBV, AMGN).

[22] Analysis of SEC Filings. Top 5 US-based companies by market cap as of November, 2018 (JNJ, PFE, MRK, ABBV, AMGN).

[23] https://www.sciencemag.org/news/2018/09/nih-gets-2-billion-boost-final-2019-spending-bill

[24] https://www.phrma.org/advocacy/research-development

- NIH could reinstate its reasonable pricing provision in Cooperative Research and Development Agreements (CRADA) and Exclusive Licensing Agreements. This provision was removed by the NIH in 1995.[25]
- Congress could create an outside entity to support NIH and ensure price is addressed when technology is transferred from the NIH to the private sector.

A specific legislative proposal to address these issues is the bipartisan WePAID Act introduced in the Senate by Senators Chris Van Hollen (D-MD) and Rick Scott (R-FL). The bill would ensure that drug companies set a reasonable price and limit annual price increases in cases where taxpayers contributed to the development of a new drug.

Yes, drug companies should make money when they create innovative drugs. But we are way out of balance, and it's costing us all — in bankruptcies, health outcomes, and lives.

The fact is, there is one key reason drug companies charge such high prices: Because they can.

Section IV. Immediate Legislative Solutions

Fortunately, there are three steps our nation could take today to rebalance the actual risk of innovation with a fair price for patients: reform patent law, end the days of monopoly pricing power without taxpayer negotiations, and force transparency from drug middlemen.

Let's start with patent law.

When a company brings an innovative drug to market, it should receive a fair return for risk and investment. But drug manufacturers are abusing America's patent and exclusivity system to prevent free-market competition and block affordable generic and biosimilar drugs from coming to market.

Between 2005 and 2015, at least 74% of the new drug patents issued were for drugs already on the market.[26]

Of the roughly 100 best-selling drugs, nearly 80% obtained an additional patent to extend their monopoly period.[27]

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[25] https://www.nytimes.com/1995/04/12/us/us-gives-up-right-to-control-drug-prices.html
[26] https://www.bloomberg.com/news/articles/2017-11-01/most-new-drug-patents-are-for-old-remedies-research-shows
[27] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3061567

These tactics have led to longer exclusivity than our laws intended. The median length of post-approval market exclusivity for small-molecule drugs is not five years or even the seven years allowed for orphan drugs. It is 12.5 years.[28]

Members of this committee are supportive of numerous bipartisan bills to address patent abuses and anti-competitive industry practices. I thank Committee members for their work. We have lent our support to numerous bipartisan bills making their way through the House and Senate to address gaming of the patent system like: pay-for-delay deals, product hopping, REMS abuses, patent thickets, and sham citizen petitions. We remain hopeful that these bills will be enacted into law this congress.

Next, we need Medicare price negotiations.

Over the past five years, AbbVie, the company that makes the top selling drug in the world, Humira, has more than doubled the price here in the United States. But in Europe, Abbvie sells the exact same drug for 80% less.[29] On average, Americans pay twice as much for prescription drugs as other nations.[30]

Why does the rest of the world get affordable drugs while Americans pay outrageous prices? One big reason is that other countries negotiate directly with drug companies. We should, too.

Given the prices we pay, it is clear that not allowing Medicare to negotiate directly and relying on pharmacy benefit managers to negotiate is not working. We know that not only from the experiences of other nations, but also from the Veterans Administration (VA). The VA negotiates and Medicare Part D could have saved $14.4 billion in 2016 alone by negotiating as the VA did.[31]

Medicare negotiations can take several approaches; the VA's is just one. H.R. 3 — the *Lower Drug Costs Now Act* — takes another comprehensive approach. Here is what makes the bill effective:

1. **It ends the ban on Medicare negotiating directly with drug companies to lower prescription drug prices** and empowers HHS to negotiate prices for the 250 most costly drugs each year.

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[28] FN-*Wang B, Liu J, Kesselheim AS. Variations in time of market exclusivity among top-selling prescription drugs in the United States. JAMA Internal Medicine 2015;175(4):635-637.*

[29] https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html

[30] https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/

[31] https://www.statnews.com/pharmalot/2019/01/14/medicare-drug-prices-veterans-affairs/

We support the non-compliance penalty of up to 95% of gross sales of a drug if the manufacturer refuses to negotiate. We believe it is a superior penalty to others that have been offered. As patients, we prefer this approach to a formulary. We also prefer the penalty to competitive licensing given documented concerns with access and effectiveness as compared to the penalty.[32]

Additionally, I believe the bill's focus on the most costly drugs makes sense for the same reason Willie Sutton said he robbed banks: "That's where the money is." In Medicare Part D, the top 250 drugs account for 8.6% of drugs but 78% of spending. Medicare does not need to negotiate for thousands of drugs in Part D that have competition and low prices.

Finally, it employs an international price index to set a maximum fair price for any negotiated drug. This mechanism is similar to a proposal offered by the Trump Administration and would ensure Americans are finally protected from paying two to three times what other wealthy nations pay for drugs.

2. **It ensures that Americans — regardless of insurance type — have access to lower-priced drugs**. A drug corporation would be required to offer the negotiated price to Medicare and *non-Medicare* insurance plans — including people who buy insurance through their employer, Healthcare.gov, etc. If a drug company overcharges Medicare or fails to offer the fair price to people, it will be subject to a penalty of 10 times the difference between the price charged and the maximum fair price for the drug.

   Prior to retirement, I owned and help manage a small business. We wanted to offer the best benefits we could afford and we did. But rising health costs — and drug costs in particular — were always a challenge.

   Consider specifically the impact when an employee gets a costly disease. *The New York Times* recently brought this issue into sharp focus. A family covered by the Boilermakers' Union health insurance required an expensive drug for a rare bone disease. At one point, for every hour the union's members worked, 35 cents of his/her pay went to the drug company to pay for the family's prescriptions. High priced prescription drugs are driving up insurance premiums.[33]Extending lower drug prices to private plans will help millions of working people and businesses.[34]

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[32] https://www.healthaffairs.org/do/10.1377/hblog20190724.85223/full/
[33] https://www.fiercehealthcare.com/payer/report-prescription-drug-costs-driving-up-insurance-premiums
[34] https://www.nytimes.com/2019/08/25/health/drug-prices-rare-diseases.html

3. **It stops drug companies from increasing prices on Part B and Part D drugs faster than the rate of inflation**, and imposes penalties on drug companies if prices rise above inflation. This provision has the added appeal of being a key feature of bipartisan Senate Finance package.

4. **It caps seniors' out-of-pocket costs for prescription drugs at $2,000 per year**. Currently, out-of-pocket costs for seniors on Medicare can be over $15,000 per year. Just one of my Part D drugs costs me more than $13,000 out-of-pocket annually. Deadly disease and chronic health conditions are not a moral failing, and we should not penalize people, especially older Americans, who are fighting to manage diseases that require high priced drugs.

5. **It directs savings to new drug research and innovation**. Taxpayers already finance much of the early, high risk science that leads to new drugs through the NIH. This plan will ensure that a share of the savings from lower drug prices will go to innovation and new drug development.

Next, I'd like to spend a moment focusing on the arguments against allowing Medicare to negotiate.

1. **It's socialism.** Competition and negotiation for lower prices are cornerstones of capitalism. Taxpayers negotiate on everything from aircraft carriers to printer paper. The only reason we don't negotiate in Medicare is because drug corporations inserted the prohibition into law in 2003.

   Negotiating with drug companies who have monopolies on prescription drugs is not anti-competitive, it restores balance to our broken system. When Congress enacted Medicare in 1965, opponents of the program used a similar talking point of "socialism." Today, Medicare is one of the most important and popular advancements in our history.

   As for the countries that H.R. 3 uses for reference pricing — Australia, Canada, France, Germany, Japan and the UK are all democracies. But more importantly, each has a longer life expectancy at birth and at age 65. They have better health outcomes and each spends far less on prescription drugs per capita than we do.[35,36] Their prices are much lower.[37]

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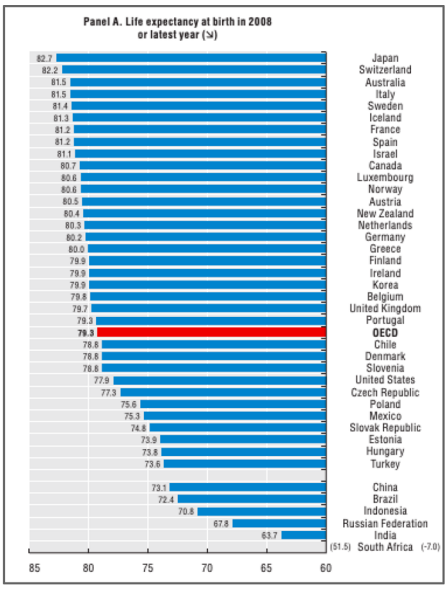
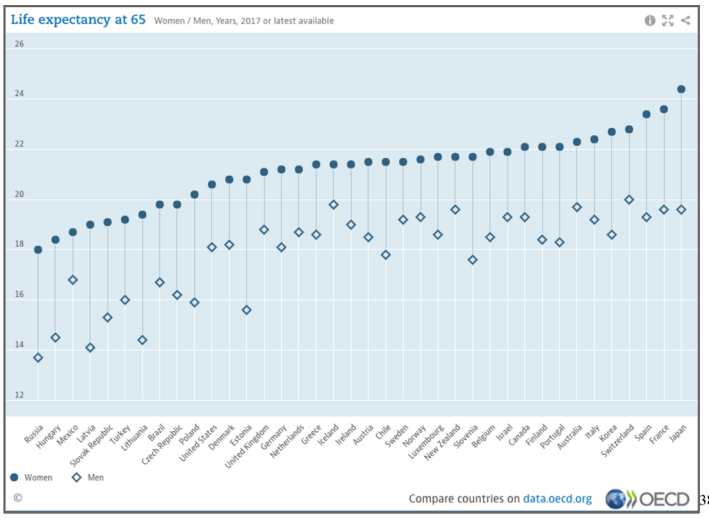
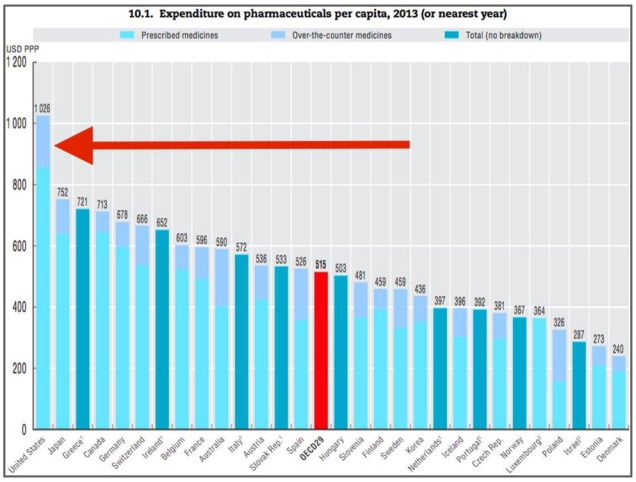
[35] https://www.oecd.org/berlin/47570143.pdf
[36] https://data.oecd.org/healthstat/life-expectancy-at-65.htm
[37] https://www.businessinsider.com/pharmaceutical-spending-by-country-2015-11


Panel A. Life expectancy at birth in 2008
or latest year (a)
82.7 Japan
82.2 Switzerland
81.5 Australia
81.5 Italy
81.4 Sweden
81.3 Iceland
81.2 France
81.2 Spain
81.1 Israel
80.7 Canada
80.6 Luxembourg
80.6 Norway
80.5 Austria
80.4 New Zealand
80.3 Netherlands
80.2 Germany
80.0 Greece
79.9 Finland
79.9 Ireland
79.9 Korea
79.8 Belgium
79.7 United Kingdom
79.3 Portugal
79.3 OECD
78.8 Chile
78.8 Denmark
78.8 Slovenia
77.9 United States
77.3 Czech Republic
75.6 Poland
75.3 Mexico
74.8 Slovak Republic
73.9 Estonia
73.8 Hungary
73.6 Turkey
73.1 China
72.4 Brazil
70.8 Indonesia
67.8 Russian Federation
63.7 India
(51.5) South Africa (-7.0)
85
80
75
70
65
60



[38]



[39]

[38] https://www.data.oecd.org/healthstat/life-expectancy-at-65.html
[39] https://www.businessinsider.com/pharmaceutical-spending-by-country-2015-11

2. **It will kill innovation.** As has previously been covered, there is enough spending in the system to reduce drug prices and not impact R&D. Drug companies collect almost half of all health care profits despite generating less than 20% of industry revenue.[40]

   Some industry reports assert that it costs $2.6 billion to bring a new drug to market. But those reports are based on a study paid for by drug corporations using data the drug companies refuse to disclose. Independent analyses put the cost of a new cancer drug at closer to one quarter of that amount.[41]

   Furthermore, taxpayers already pay for much of the basic science leading to new drugs. Every single drug approved by the FDA from 2010-2016 was based on science funded by taxpayers through the NIH.[42]

3. **It will lead to rationing.** We already have drug rationing in this country. People are skipping doses, cutting pills in half, choosing between food and paying for their drugs every day. People are dying because they can't afford their insulin. H.R. 3 stops rationing and ensures affordable drugs.

4. **It will impose access restrictions.** There is nothing in the bill that restricts access to drugs. Unlike in the private sector, H.R. 3 does not create a formulary, and all drugs will continue to be covered by Medicare at all times, as they are today.

5. **It's a tax on drugs.** H.R. 3 imposes a penalty on a drug corporation that refuses to negotiate with American taxpayers. Drug corporations negotiate with every other country in the world. If they won't negotiate with us, they will pay a penalty. But it's easy for drug corporations to avoid the penalty — by negotiating. And it's important to remember that drug companies acknowledge that they earn a profit in the other countries where they charge much lower prices.

H.R. 3 is long overdue. It undoes an act of corruption that Big Pharma perpetrated in 2003 to block Medicare negotiation, and it levels the playing field for patients and consumers. It has significant bipartisan elements including international reference pricing, an inflation cap on price increases, and limits on out-of-pocket costs for people on Medicare.

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[40] https://www.axios.com/health-care-pharma-hospitals-q2-2019-7c20729d-ab9b-460b-9ea8-b08902491eec.html?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top

[41] https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2653012

[42] https://www.pnas.org/content/115/10/2329

And let's be clear, 90% of Democrats, 87% of Independents, and 80% of Republicans support allowing the government to negotiate with drug companies.[43]

Finally, we need more transparency around Pharmacy Benefit Managers (PBMs). They are the middlemen between insurance companies and manufacturers. These groups cut secret rebate deals that determine how much insured patients pay — but there's no transparency in this process.

As a patient, I cannot know if the preferred drug on a formulary is the most effective drug, the least expensive among equally effective options, or the drug for which the PBM received the biggest rebate. That is unacceptable.

Moreover, rebates are sometimes used to stymie competition. Professor Robin Feldman explains "the system contains odd and perverse incentives, with the result that higher-priced drugs can receive more favorable health-plan coverage, channeling patients toward more expensive drugs."[44] Lower-priced alternatives may be unable to gain traction in the market because of a huge, legal kickback given for use of the more expensive brand — costing patients, consumers, and taxpayers.

Secret rebates are bad policy and bad medicine. They don't put patients first. They put profits first. We need transparency.

Section V. Conclusion

Right now, Big Pharma wants us to ask this question: What are we willing to pay to save a life?

And that's easy. When it's your child's lungs on the line, when it's your wife's diabetes, your husband's cancer, the answer is "anything." Yes, we will empty our 401ks; yes, we will take out another mortgage on our home; yes, we will give every precious thing we have, every cent, for one more year. One more day.

The chance to walk my daughter down the aisle? The chance to meet my grandkids — to watch them grow up? There is no amount I wouldn't give for that.

But that's the wrong question. We should be asking: *What is the right amount of money that drug companies should make on these drugs?*

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[43] https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/

[44] https://www.washingtonpost.com/outlook/2018/11/26/why-prescription-drug-prices-have-skyrocketed/?utm_term=.f9e74687f9af

With hundreds of clinical trials underway for new gene therapies that are currently priced from a half-million to more than two million dollars, we cannot agree to any price a drug company wants to charge. Neither American families nor our health care system can afford that.

Through our organization, I met a woman named Ruth Rinehart. Ruth has primary immune deficiency, and her treatments cost around $52,000 per year. After working as a nurse for 30 years, she retired; and when her husband lost his job, they could no longer afford her treatments. They were forced to file for bankruptcy and eventually lost their home. Today, Ruth and her husband are in debt, living paycheck to paycheck, and she's back at work.

I feel incredibly grateful to spend my retirement fighting so that people like Ruth can one day enjoy theirs.

Because no one should have to choose between their health and their home.

All of you hold the power to fix this broken system. My request to you: Deliver for the American people. It's time to enact reforms. It's time to stop these blatant abuses that keep drug prices high. Keep a focus on patients. And keep working together to address this urgent issue.

Cancer broke my back, but it stiffened my spine. I believe this is a problem that we can solve. That we must solve. And with bipartisan support, we will solve. Thank you for your time.

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Chairwoman WILSON. Thank you, Mr. Mitchell. Under Committee Rule 8(a), we will now question witnesses under the five-minute rule. I will now yield myself five minutes.

I want to thank all of you for your testimonies, thank you so much. Mr. Mitchell, you mentioned that you started a new oral chemotherapy drug last week. Can you repeat the list price for that drug and tell us what your out-of-pocket expenses are? Because we have five Members of Congress that I know of that take oral chemotherapy today.

Mr. MITCHELL. So, this is the drug I started taking last Wednesday night. It is called Pomalist. It is 21 capsules. It carries a list price of $17,200. I have to take it this way every four weeks. The first fill was $2,758. My out of pocket, under part D, and I will be paying $850 dollars every four weeks out of pocket for this drug.

Chairwoman WILSON. Ms. Talente, in your testimony, you share the stories of several of the patients whom you worked with at the National MS Society. You point out that the patients always struggle with the fear that they are contributing to overall health care in their workplace, health plans, and they don't want to be perceived as that person who is responsible for making everyone else pay. This is very troubling to me. Can you talk a bit more about the stigma that MS patients face and how does it present barriers to employment, to access, and to care?

Ms. TALENTE. That is probably more than we have time for today, but I will touch on some of it. Health care cost is certainly a big part of that. So, the MS disease modifying treatments are about 75 percent of the cost of treating someone with MS.

And as I highlighted, the median price of those brand treatments is more than $88,000 today, and so that is definitely a drain on employers' health care cost and health care burdens, and I have talked with people with MS who are the employee. I have talked with people with MS whose spouses are the employee and many of them are guilt-ridden about the cost that they are bringing to bear on their employer and their coworkers, and many of them are afraid and when people do lose their job for whatever reason, many of them, rightly or wrongly, attribute that loss of employment to being that health care burden.

Chairwoman WILSON. Thank you. Many on the other side of the aisle and in the insurance industry often say that patients need to have more skin in the game to keep costs under control. To me this seems like an excuse for plans to raise deductibles and increase cost-sharing for patients. And we are talking about medications, this notion of skin in the game can have troubling consequences for patients.

Mr. Isasi, what effect does requiring patients to pay more out-of-pocket have on their ability to access care, including prescription drugs?

Mr. ISASI. Well what we know right now is a third of Americans who are trying to access prescription drugs to stay healthy or to get healthy are not taking that medication as directed because they can't afford it. And some of those people, the majority of them are actually cutting their pills in half, or skipping doses, some are just not taking them at all. We hear stories all the time about patients who end up becoming seriously ill or dying because they can't take

the prescription so as we heard earlier, these very high costs don't actually allow people access to the innovation that the pharmaceutical company is promising. It is actually rationing.

Chairwoman WILSON. Okay. Now we expect this bill to have—to greatly reduce cost for patients and tax payers and I believe it is important that we use savings to improve crucial health programs for American people, so I am going to ask the witnesses. Perhaps Mr. Isasi and Ms. Talente. Are there any programs such as the NIH or Medicare in which you believe Congress should invest these savings? We will start with you, Mr. Isasi.

Mr. ISASI. Absolutely, I think that what we know for sure is right now it is seniors and Medicare beneficiaries across the country have spoken—they are desperately in need of an oral health care benefit. In Medicare there is none. They are desperately in need of a hearing benefit in Medicare. There is none. They are desperately in need of a vision benefit. There is none. So there is a lot of need right now to make the Medicare benefit comprehensive so that we are giving folks who are receiving it the best chance at living their best self-actualized life and in addition, we also know that all of these innovations that the drug industry is profiting from, almost all of them—all of the ones that are currently being approved in the last five years started with NIH research, so let's invest in the place where the innovation actually occurs which is our public and private institutions that receive NIH funding.

Chairwoman WILSON. Thank you. Ms. Talente, you have a couple of seconds.

Ms. TALENTE. We know that for every MS treatment on the market today, you can tie back some critical understanding of the biological function of the mechanism of action of the understanding of MS back to research that was done at the National Institutes of Health so investments there, at NIH is probably one of the best ways to spur the future innovation and bring cures in the future.

Chairwoman WILSON. Thank you so much. I remind my colleagues that pursuant to committee practice, materials for submission for the hearing record must be submitted to the committee clerk within 14 days and now we will have questions from Mr. Walberg, Ranking Member.

Mr. WALBERG. Thank you, Madam Chairwoman and thanks to the panel for being here. Mr. Holt, when Medicare's prescription drug program was implemented, it included a non-interference clause that prohibited the Secretary of HHS from intervening in negotiations between private firms or private plans.

Has this model been successful in driving down costs and increasing competition with Medicare beneficiaries and second, would the direct negotiation provision in H.R. 3 destabilize these efforts?

Mr. HOLT. Yeah, so when part D was first developed, the idea was to get as many plans competing as possible but there was concern that the negotiation wouldn't work so there was a Federal fallback plan that would have had a premium of, I think, 35 dollars at the time. Today it would be at about 44 dollars. In reality, the negotiations between the manufacturers and the plans and PBMs have led to a situation where the premium, I think next year is expected to be about 30 dollars on average per beneficiary, so we've definitely seen that the negotiation in part D has been very effec-

tive. That is not to say that there aren't reforms that could be made to part D and I think this bill at least starts to address some of that but yeah, we've seen very effective negotiation in part D.

Mr. WALBERG. Would we see destabilization of these efforts by direct negotiation as proposed in H.R. 3?

Mr. HOLT. Yeah, and particularly early on where some drugs would be having their price set by the Secretary and the others would still be part of this negotiation would be really difficult to predict how that would affect the overall benefit.

Mr. WALBERG. Mr. Holt, when talking about the high cost of prescription drugs, Sivaldi, the cure for Hepatitis C is the poster child. Although the drug cost 84,000 dollars for a full course of treatment at the time of its launch, within two years, competitors introduced rival treatments and the price came down by 46 percent, which I hasten to say is still too high for many people. In your opinion, was this an example of market failure?

Mr. HOLT. No, I mean this is an example of how markets should work. Competitors come in and we see concessions as a result.

Mr. WALBERG. Would it be considered a market failure under H.R. 3?

Mr. HOLT. Under H.R. 3, Sivaldi would be considered to be a drug that does not have competition.

Mr. WALBERG. Thank you. Mr. Garthwaite, Dr. Garthwaite, you explained in your written testimony that development of pharmaceuticals is a long and risky process and that firms rely on some degree of regulatory and market predictability when deciding to invest. How would H.R. 3 undermine the predictability and the willingness of firms to take chances for the sake of innovation?

Mr. GARTHWAITE. On the predictability side, you'd be a bit at the whim of the Secretary of HHS as to whether you're going to be one of the drugs that is picked to have your price negotiated.

In addition, we would be targeting our negotiation on those drugs that generate the most unique value in the market, those that don't have competition and therefore are the only choice. Now that might seem positive to some people but I would note that is the very nature of drugs that we would want to see people invest in so we would be sending a signal to the private market that drugs that meet unmet demand, that provide truly new treatment options are going to have their price severely capped and while Mr. Mitchell mentioned the Secretary Azar's comment about one penny of profit, that is not what we are talking about here. We are not talking about marginal changes to profitability and I am sorry that Mr. Mitchell thinks it is a tired talking point but the trouble with the truth is it doesn't change.

The truth is if you decrease the return to innovation, you will get less innovation and I am happy to have a debate about whether we want less innovation. I am not happy to sit here and say that won't be the response. It is personal to me as well. I have lost very close family members to cancer because they didn't have the drugs that you have the ability to pay for. That is an access problem that we have to take very seriously.

There are a lot of conditions for which we don't have access today because there is no drug and we have to keep those people in the

debate as well because sadly they can't be sitting at the table testifying because they are no longer here.

Mr. WALBERG. Thank you. Let's go to some case history, Dr. Garthwaite in countries that have enacted price control similar to the ones included in H.R. 3. Do their patients have the same access to new therapies as patients in the United States, and second, do patients in those countries face increased wait times, drug shortages or denial of coverage for lifesaving drugs?

Mr. GARTHWAITE. This varies a bit by countries. We often talk about the idea of European healthcare or developed country healthcare. There is no one system that we want to talk about or that we can point to and say they are all the same.

In the UK, for example, where NICE is the committee that negotiates this. Yeah, patients have reduced access to drugs. Patients with cystic fibrosis don't get access to Vertex' products there and that is a choice that they've made. In Germany, they pay higher prices, they get more access, but they don't get access to some drugs that we get here because they deem that they are not worth the money that is being paid and that is all fine. There is no secret to how Europeans get lower prices. They are not better negotiators than us. They'll just walk away. They are willing to walk away from drugs. We don't want to do that here. We don't want to face the hard choice in that H.R. 3 so what do we say? You're going to give us the price we want, or we are going to take all of your money as a drug company. That is not a negotiation.

Chairwoman WILSON. Thank you.

Mr. WALBERG. Thank you, I yield back.

Chairwoman WILSON. Mr. Norcross of New Jersey.

Mr. NORCROSS. Thank you, Madam Chairwoman for having this hearing and it certainly is long overdue to have some real conversations that lead to both the continuation of innovation but at a reasonable price. I can tell you the folks in my district, nothing twerks them up more as to find out their great country spent somewhere close to $40 billion a year in NIH funding which means we had skin in the game. That money does not magically appear from somewhere. It is those taxpayers we represent and yet the stories that I hear from a young man who goes for his insulin and what he pays a year and if they can go right across the border into Canada, 1/10th the price.

So, Ms. Talente, I'd like to ask you a couple of questions. When we talk about negotiations going beyond where we have historically been to where this bill puts us, we spent $40 billion on NIH and it is not all for one particular area. There's a lot of research there and you say they bring this great intervention. Do you see that America gets a discount on some of the pricing from those innovative drugs that come from NIH? Are we getting that special break?

Ms. TALENTE. No, not that I have seen.

Mr. NORCROSS. So, we pay for it and under many cases we pay substantially more than other countries?

Ms. TALENTE. Yes, that is true.

Mr. NORCROSS. This is the thank you we get for putting that research. I really appreciate that. But can you walk me through the negotiations that Medicare has? Can you directly say because we pay this much more for our pharmaceuticals in this country,

that we are getting more breakthroughs across the board but particularly in MS?

Ms. TALENTE. Generally, what we see is that the breakthroughs in innovation hop in and then those products go through the drug approval process in other countries as well, so they are not just coming to the U.S., they are going to other countries around the world.

Mr. NORCROSS. You find it somewhat distressing that we make the greatest investment and pay the greatest prices?

Ms. TALENTE. I find it disturbing that people are going without their medication because they can't afford it.

Mr. NORCROSS. Thank you. I want to talk about some of the issues with the PBMs. Having spent the better part of my private career dealing with health plans, pharma plans, the PBMs that came into existence some time ago were the greatest thing since sliced bread. They were out there fighting for us, but now they are part of the problem. So when we see negotiations, we the end users, even though we buy a large plan, don't see the direct negotiations that take place. In other words they are being done behind closed doors.

So, Dr. Socal, how can we ensure those PBMs are pricing, those price savings are passed on to the end consumers?

Dr. SOCAL. There are two ways that we could do it. We could try to capture every single change in the negotiation process and make that known, which I don't think is feasible and I don't think it helps to the negotiation process or we can have a benchmark and we can show this is the benchmark that other countries are paying and you as an insurance plan, you have something that you can compare your price to. So you don't really know all the working mechanisms that are happening behind the curtain but you have a very clear benchmark that you can take a look at to know if you are getting a good deal or not.

Mr. NORCROSS. The rebates, that is part of the area that we don't see anymore, and you might get the savings but you might not. What do you think the most effective way, other than to open up that process, and to some degree I agree with you that it is very difficult to follow everything, that is why they are doing so well. The confusion that the average person doesn't have the time to go but rebates see to be a real issue that they are not making to the end user.

Dr. SOCAL. And I would add it is not only the fact that there is a rebate, it is the fact that the rebate is intertwined with the revenue source for the PBM. So, if PBMs were to pass on fully all rebates, all fees, everything to the payers, that possibly would generate less distortions to the market. But PBMs' revenue depends by in large on rebates and that generates a series of distortions and oftentimes higher prices for the payers as well.

Mr. NORCROSS. I am out of time. Thank you, I yield back.

Chairwoman WILSON. Thank you, Mr. Norcross. Dr. Foxx?

Mrs. FOXX. Thank you, Madam Chairwoman. I want to thank our witnesses for being here today. Mr. Holt, what current regulatory guardrails exist in the pharmaceutical industry to give incentives to companies to undertake financial risk associated with

developing new drugs? Would H.R. 3 impact the current patent system and exclusivity periods that attract investment?

Mr. HOLT. I don't know that H.R. 3 would directly impact the patent system. I think clearly H.R. 3 has serious implications for capital to continue coming to drug development.

Mrs. FOXX. Mr. Holt, H.R. 3 would allow the Secretary of HHS to negotiate the prices for up to 250 drugs per year. In your opinion, does HHS have the necessary access to data and regulatory review capacity to undertake this process and what are the consequences of granting HHS this information?

Mr. HOLT. So currently no. the legislation does grant HHS really unlimited power to demand any and all information from manufacturers in order to in theory facilitate the negotiation although it is not clear to me that HHS needs any of that information since the Secretary can basically just wait out the manufacturer during the discussion; but I have real concerns about the proprietary data being handed over to the government.

Mrs. FOXX. Thank you. Dr. Garthwaite, you note in your testimony the important role of the National Institutes of Health and other government entities in funding scientific research that contributes to product development. You explain further, however, that NIH is focused on basic scientific research and not the start to finish pipeline of pharmaceutical trials and production. What role does private investment play in bringing innovations to the market and how would H.R. 3 undermine this process?

Mr. GARTHWAITE. So private market basically commercializes the basic science that the NIH does and so it helps to think a bit why we have the NIH in the first place. The NIH solves what economists call is a public goods problems. So you generate a bunch of basic science, anyone can use it. You can't protect it, and because you can't protect it, you can't appropriate the value. No private firm is going to ever do that research because they can't get their money back, so that is where the very valuable role of the NIH comes in. In fact, as tax payers, we should be happy that the NIH is being used in all drugs because we are getting the most bang for our buck on the share of the 30 billion dollars that goes to drug development.

So if you want to use savings from this bill to then get new drugs to market, you are going to have to really change the function of the NIH in some way to really start to focus more on commercialization, which is not something they've done before, and it is not clear it is going to be something that they are very good at.

I would note that this is in many ways a centralization of the research process with NIH, but they are going to act like they are their own little venture capital company. At the same that the private market is choosing to decentralize research to a large number of small biotech companies and so you would really have to change the nature of what the NIH is to get that to work and it is going to be sort of a competition between taking away the incentive for the private market to invest commercialization dollars, how much innovation will you lose there compared to how much you think you could get by having the NIH serve this new and untested role. That is the—you have to think about that. I don't know if we have a good answer as to which of those would dominate.

Mrs. FOXX. Thank you. Dr. Garthwaite, proponents of H.R. 3 argue that implementing an "international price index" would force foreign countries to pay their fair share of the pharmaceutical research and development cost that are largely borne by the United States. Would this proposal result in other countries paying more for research and development or everyone paying for less research and development?

Mr. GARTHWAITE. The answer is kind of both, I guess. Foreign countries are going to pay a little bit more. We are going to pay a lot less, a net will meet somewhere in the middle from that so we will get a little bit more money out of the foreign countries and I share Mr. Norcross' frustration. I would like it if the other countries paid more of this than we currently do. That would be the first best, right? Every country sort of pays its fair share. Unfortunately, what's probably going to happen is they'll pay a little bit more, we will pay a lot less and we will get less innovation and that is unfortunately where we are going to be.

Mrs. FOXX. Well we've always been the leaders in many, many, many things and to me this is a small price to pay for the access that our citizens have to the drugs that are developed. Thank you very much. I yield back.

Chairwoman WILSON. Now, Mr. Morelle, New York.

Mr. MORELLE. Thank you, Madam Chair for holding this important hearing today. I will start out by saying I am a capitalist. I believe in investment and innovation, new products, new development cycle. I think it has benefitted Americans tremendously over the years but I am struck by the issue of innovation in pharmaceuticals because I have met with pharmaceutical companies, I know the talking points, but I find it interesting and I will just use an example which is probably not entirely analogous but if you think about what's happened in the development of personal computing over the last 30 or 40 years, there's been massive innovation, massive investment, and yet the price of these devices has continued to drop despite the fact that there is more and more investment in innovation. I think back to my old social studies books about Henry Ford who priced the Model Ts when they were coming off the assembly line so that individual workers could afford them so he would help build a market.

The difference in pharmaceuticals, I understand is you didn't have to buy a car if you didn't want to. You could find other ways to exist. Mr. Mitchell and people like him don't really have an option of not buying the car in the analogy. They have to buy the drug because it is lifesaving, so I struggle to understand exactly why the innovation cycle works in just about every other industry, but it doesn't seem to work very well in the pharmaceutical industry.

Particularly in the advent of supercomputers, mapping of the genome and more and more information available to pharmaceutical companies but let me—so I will just use that as sort of a sense of where I come from on this and I am happy to talk to others and by the way, Dr. Garthwaite, I thought you said at one point, and I don't have time unfortunately but I'd like to get into it with you, perhaps offline. You mentioned something about the advertising costs and salaries don't affect return on investment for investors

but actually all costs go into it unless I misunderstood—did I misunderstand you? Okay, I apologize. I only have three more minutes but I will look at the testimony, but I do apologize if I mischaracterized that so thank you for clearing it up.

I did want to talk about insulin. In my district, insulin prices have skyrocketed as I assume it is everywhere else but in Rochester alone, where I represent, the 50 most popular diabetes medications cost the Medicare program and beneficiaries approximately $24.7 million in 2016 dollars. The monthly cost of a widely used insulin would be 74 percent lower Australian prices, 70 percent lower UK prices and 52 percent lower Canadian prices. We talked about cost setting in those countries as a reason for that, but it is important to know.

Studies show manufacturers could charge as little as $7 to $11 per month for insulin and still make a profit. The average monthly—I'm sorry yearly price—annual price of insulin nationwide is $450 which is a considerable multiple of that number so Dr. Socal, if you might, in your testimony you talked about the role competition plays in controlling health care costs and when there is no competition, prices tend to rise and I would just be curious about what barriers there are. Insulin, in particular does not have—first of all it has been on the market for a long time so could you talk to me about how—is there innovation? Is that what is driving the price of insulin because it doesn't seem for something that is been around so long that is the issue.

Dr. SOCAL. Well it is a combination of multiple factors but I would first start by highlighting yes, it is an older drug, it has incurred changes and innovation over time, especially in the sense of new application mechanisms, new tweaks to the length of the effect, faster effect, longer effect and things like that but most importantly, the prices for insulin, it is a quite good example of what I mentioned before.

PBMs cannot say no to insulin. You cannot say no. It is a drug that you really need, and you need right now. It is similar to a situation where you have a very serious infection and you need an antibiotic. You cannot wait a week or a month to get your antibiotic. It is the same way with insulin, but people with diabetes, they need the same urgency of access every single day, every single time.

Mr. MORELLE. And is the innovation that you talked about, is that what is driving the price of insulin?

Dr. SOCAL. No, that is not driving the price of insulin. It is really distorting a little bit the competition between the insulins that do exist in the market so before when it was brought up, the fact that well there are some therapeutic classes where you do see branded drugs available in the market and they compete against each other, yes but we have to think about the clinical aspects of that and I am a physician, I am very familiar with what patients feel and they feel I am used to my insulin, to my application mechanisms. If I was going to change, it is not going to control my disease as effectively so those clinical aspects also play a lot in terms of being able to say no and negotiate effectively for that.

Mr. MORELLE. Thank you so much. Thank you, Madam Chair.

Chairwoman WILSON. Thank you. Thank you so much. Dr. Roe?

Dr. ROE. Thank you, Madam Chair for having this and I hope we will continue to have these hearings. I am going to go on a little history tour.

I graduated from medical school this December 49 years ago and I graduated from medical school there was one cephalous borne antibiotic and now there are—I call them self-acknowledging. There are so many of them. There were five anti-hypertensive. Three of them made you sicker than the hypertension did, and we didn't use them much. Now there are 50 at least.

My first pediatric rotation in medical school was at St. Jude's children's hospital. I can still remember seeing some of those kids. 20 percent of them lived, 20. Now It is 83 percent I believe is the last number I saw from St. Jude's and Mr. Mitchell, you are getting the benefit of some incredible research that is been going on and I hope it continues to go on. I have struggled with this for 40 years, seeing patients as a private practice doctor and a teacher in medical school. The innovation that we have, these new medications and then patients being able to afford them. If you can't take it, as Mr. Mitchell said, it doesn't do you any good and Mr. Morelle, I could not agree with you more, insulin was discovered in 1921 by Benning and Best in Toronto, Canada. There is no reason for it to be 10 times as high in Canada as it is here in this country and you look at these countries that—that this international pricing is going to be and of the 270 new global medicines lost in the United States since 2011 to 2018, 100 percent of them are available in the United States. 41 percent of them are available in Australia, so one of the ways you do is no question, the CBO is correct. You limit—when you limit how much somebody would pay, you are going to limit what's available for people to take and that is the dilemma I have and I think Ms. Talente, I think one of the things that we can do and Mr. Mitchell, there is no question that there are diseases out there and new innovations that are going to come along that are going to be expensive and I think we have to take those patients that are in these very high risk situations and put them in a high risk pool where their costs are no greater than anybody else and we are going to continue to find cures. I will run through very quickly. Dr. Lemial Diggs was my hematology professor in medical school. He lived his entire life trying to cure sickle cell disease for African Americans. His entire life.

I can remember sitting by bedsides of pregnant women and taking out the sickle blood and transfusing normal hemoglobin into that woman for 35 weeks so she could get through her pregnancy and we could deliver her baby safely. Now, at NIH, some of the basic science research. It looks like we are going to be able to take an intenuated HIV virus, put the right genetic code and cure sickle cell disease. That is remarkable, but it is not going to be inexpensive and we as a society have to decide are we going to have the innovation and we're going to help the people that have MS—numbers of patients, a million patients in the United States have MS and these treatments are incredibly expensive, so what we have to do is I want the innovation but I don't want, as a doctor, 41 percent of the new drugs that I have access to and especially, I have said this all along. I don't care if your case is one in a million. If it occurs in you, it is 100 percent. Just like Mr. Mitchell's is 100 per-

cent for him, in that patient, so I am going to ask Dr. Garthwaite just a couple of questions.

In 2018, the FDA approved 58 novel drugs. In 2017, the pharmaceutical industry spent 97 billion on research, development and so forth and a typical R&D, we know It is somewhere between 800 million and 2.7 billion to bring molecule to market so that I can write a prescription for it. Do you think that the elimination, effectively the elimination of the private industry and R&D by 2023 under this bill will adversely impact patients 10 years from now and do you think the NIH will be able to offset that loss through their budget, even though It is only a third of private spending?

Mr. GARTHWAITE. So I have doubts on whether the NIH will be able to offset it, even if we gave them a lot more money. As I said, it is not just about giving the NIH more money, It is about them doing an entirely different set of activities than they currently do and we know that private firms partner with the NIH based on their ability to get returns. We know that in 1995, we used to say that the NIH would have a fair pricing clause attached to their partnership with private firms. We took that away. We said there are no more pricing constraints on the partnerships, the number of these partnerships skyrocketed in the years after that, so we need to have a respect for the fact that the private market are the people who commercialize drugs. We could try to make the NIH that entity, but it would be vastly different than they currently do.

Dr. ROE. That is not what's going on in Switzerland or other places—or France. They have a robust market. The private companies do that research there and It is not done by the government of France or the government of Switzerland.

Mr. GARTHWAITE. But they do it to sell it to the United States. Global firms do research and sell to us.

Dr. ROE. Well I do want to continue. Madam Chair, I really do appreciate this hearing and I hope we continue this discussion.

Chairwoman WILSON. We will.

Dr. ROE. We don't have enough time.

Chairwoman WILSON. Thank you, Dr. Roe. Mr. Courtney of Connecticut.

Mr. COURTNEY. Thank you, madam chairwoman and thank you for hosting this hearing. Last November, this country experienced a historic moment. It was the largest voter turnout in a midterm election since 1914. We elected a new majority with a plurality of 10 million votes which shattered all records in history of this country and if you looked at the exit poling, health care cost was the number one concern of voters and more particularly the cost of prescription drugs so holding this hearing on this bill is in my opinion keeping faith with the loud strong message that came out less than a year ago through our democracy.

Yesterday, we got more validation about this issue. Kaiser Family Foundation released its annual health benefits survey of employer-sponsored health insurance. The study found that the average premium for family plans has increased 22 percent since 2014 which has been a very low inflation environment and last year to this year, it was a 5 percent increase, again, far surpassing the rate of inflation. According to the Americas Health Insurance

Plans, 23 percent of private health insurance premiums go towards prescription drugs. The largest share of healthcare costs, larger than doctor services, office visits and hospital stays. In addition, we have seen the trend toward high deductible coverage as a way, a desperate way of trying to moderate the increase of a premiums so again, there's an additional layer of cost which patients and workers have been experiencing.

So Dr. Socal, when we talk about the brave new world of high-deductible health insurance, lowering the list price of drugs, which as you pointed out in your testimony is really where the rebates are worked off, but they are not shared with workers so could you kind of talk a little bit more about the way that all transpires.

Dr. SOCAL. Absolutely. First of all, let me just mention that from an employer perspective, you want to offer the best benefit you can to your workers so an employer, if possible, they would choose to offer the best plan they can and the offering of these high-deductible health plans, more and more—the more frequent offering for those plans, it already reflects how companies are struggling to pay for their bills and they are sharing these agreements with patients. The real problem is that once you are enrolled in a high-deductible health plan, automatically, there is some sort of parallel mechanism to save money like a savings account, for example.

Patients believe they are going to be protected like an insurance agreement, however the price that they are going to be faced with is going to be the list price so you cannot save your way to pay for the list prices that the insurers are negotiating down.

Mr. COURTNEY. That was on page 7 of your testimony, which again, basically says list prices before rebates determine America's cost-sharing amounts so again, the patient and the worker again is really sort of excluded from all the—

Dr. SOCAL. Absolutely, they are always faced during the initial deductible, even for somebody who is fully insured, doing the cost-share and cost-sharing—percentage cost sharing is more frequent for the highest cost drugs, so patients are always paying over the list price, never over the negotiated price.

Mr. COURTNEY. Thank you. And Mr. Isasi, again, AHIP, which, you know, maybe hasn't always been aligned with your organization in the past but I mean do you see any—do you disagree at all with their analysis that prescription drugs now are sort of consuming the highest percentage of premium dollars?

Mr. ISASI. Prescription drugs are 25 percent of premium dollars at this point. They have gone up exponentially which means if any of us aren't on prescription drugs, we are still paying for them.

Mr. COURTNEY. So again, if we are looking at a strategy both public sector and private in terms of just how we moderate and hopefully reduce premiums. I mean that sort of trend just sort of screams out for Congress to act, is that right?

Mr. ISASI. That is exactly right and just on this innovation question that keeps coming up. A couple of points: Sovaldi, which was raised before. Gilead bought the drug from the researcher at the VA and then their analyst said enter the market at this price and we will make a ton of money and then they quadrupled it. And then the patients in the VA couldn't afford to get the drug. That

is innovation. MS, we have talked a lot about MS. In the last five years, the drug went from $60,000 to $90,000. In five years, same drug, that is not innovation. That is not about innovation. In fact, what we know right now is 75 percent of the drugs that are coming to market are coming to market because they are especially drugs that can get the Medicare beneficiaries in a catastrophic coverage where they only pay 5 percent. The government pays 80 percent, the plan pays 15 percent. Think about what it would mean if we had iPhones where 80 percent of the cost was government subsidized, 15 percent was paid by the iPhone retailer and then 5 percent was paid by us. That is what we are living with right now. That is not innovation; that is why we don't have low cost drugs.

Mr. COURTNEY. And that is why we need to move on H.R. 3—

Mr. ISASI. Absolutely.

Chairwoman WILSON. Thank you. Mr. Johnson from South Dakota.

Mr. JOHNSON. Thank you, Madam Chair, I appreciate it. So Mr. Garthwaite, I understood your comments. They made sense to me that venture capitalists and for that matter other capital contributors, they could invest in any industry and so that doesn't offend me that the pharmaceutical companies would need to have a certain return on investment that need to earn that return on investment to attract that capital.

It seems like from the data we have looked at and from the testimony we've heard today, the pharmaceutical companies are not earning anywhere close to that necessary return on investment and the European markets, so where do the pharmaceutical companies make up that shortfall and the target return on investment?

Mr. GARTHWAITE. The United States.

Mr. JOHNSON. I mean obviously that is the answer. I mean I do find myself more and more affiliating myself with the comments of the President that in that environment it looks like Europeans are really taking advantage of us. That may not be their intention but that is certainly the effect.

Dr. Foxx, I thought had some good questions about and also kind of where do we go from here.

Your response that yeah maybe we would come down a bunch and they might come up a little bit but that means that yes, we are paying less but we are getting a lot less innovation. I get that is logical; it seems fatalistic, it seems like we are putting ourselves and the rest of the world in a box. Is there any other way? Is there any way to better balance this European versus American contribution to the return on investment?

Mr. GARTHWAITE. I think if you are looking for optimism, you shouldn't have invited an economist here to testify. That is not really what we do. I mean listen, It is unfair. What's happening is that the Europeans are free riding off of American dollars and I think that is bad. I think the only thing worse is that no one is providing this innovative money. I mean sometimes if we want to get so caught up in the idea of fairness, we are going to cut our nose to spite our face.

We are going to stick it to the Europeans, right? They are going to have to spend more and we are going to win in that sense, but what are we going to win? We are going to win lower prices, okay?

And fewer drugs in the future. This is all dictated by returns and while I understand Mr. Isasi's example that Gilead didn't make the drug itself, a company named Pharmasset made Sivaldi. Why did they do it? So they could sell it to Gilead. In the end, the venture capitalists are looking for an attractive exit from their innovation and Pharmasset. They sold it and then Gilead priced it and took it to market and that is what people are looking for in this. The return is what dictates this.

Mr. JOHNSON. So I do understand the value of paying more for a drug so that a country, like America, can get a preferred access to that drug but I found myself being struck by Ms. Talente's comment, her testimony that in most years, most of the increase in drugs, the price that Americans pay for drugs come from year over year increases of drugs that are already on the market rather than new market entrance. Does that comport with the knowledge you have got about what drives pharmaceutical inflation?

Mr. GARTHWAITE. Unfortunately, I am well aware of the health—the article she is citing. It is a tragically flawed article. It uses bad data. It doesn't understand how drugs are priced. It uses non-rebate data, and older drugs have bigger rebates, so by construction, if you don't take rebates into account, it will look like the price increases are coming from older drugs, not newer drugs, and so I mean I don't know what else to say other than the article is wrong.

Mr. JOHNSON. So what suggestions, Mr. Garthwaite, if H.R. 3 is not the right approach, because I do find myself believing wholeheartedly that the system—that this balance that you very articulately and logically laid out for us—I believe in that balance. Cost and innovation, there's a tension between those two.

I do get the sense that maybe we haven't balanced that properly so if H.R. 3 isn't the right solution, give us some thoughts about where we should go from here.

Mr. GARTHWAITE. Absolutely. First, let's do things that make the market work. Some of the reasons it doesn't work is because of decisions that Congress has made. We have the catastrophic program that Mr. Isasi is talking about where the government pays 80 percent of the cost of high-priced drugs. That is ludicrous. That doesn't provide insurers the strong incentive to negotiate, so let's flip that, let's put 80 percent on the back of the insurer. All of a sudden, they are going to get a lot more interested in negotiating the high price of the drug.

We have protected classes that say you have to cover every drug in the category. You don't have to come to Kellog and take our wonderful negotiations classes to know that if they have to pay your price, you can just sit there and wait. We have generics that have very small markets and therefore can't attract multiple competitors. There, we've already paid for the innovation. We might want to think about regulation for those products, things like the Daraprim product that Martin Shkreli raised the price on that sort of got everyone upset. Maybe that is where we need regulation. It is not that I am opposed to regulation in any setting, I want to be clear. We want regulations when markets failed but a high price is not a market failure if that price is generating the incentive for the innovation we want and so targeting the places where the mar-

ket isn't working, provide insurers with the incentive to negotiate and vigilantly monitor the competition. Don't allow people to gain patents, don't allow people to exclude their competitors. Have robust anti-trust authority for people who are breaking the rules and then if all that happens and we are still at this position, then let's talk about a failed market but we haven't even given the chance for the market to work yet.

Mr. JOHNSON. Thank you very much. Madam Chair.

Chairwoman WILSON. Thank you. Ms. Shalala of Florida.

Ms. SHALALA. Thank you very much. I am interested—obviously you have described the cost-shifting that is going on from the Europeans to us. It is been going on for a long time and it is not so easy to get at that and during the time that I was the HHS Secretary, I begged for an opportunity to negotiate because I was opposed to the importation, which I thought was unsafe and I still believe it is unsafe. But explain to me and all of you can comment on this, how the Europeans can negotiate directly, have a more limited list of drugs and get better outcomes than we get in whatever you want to describe the market for because I don't see analysis that tells me that large numbers of Europeans are dying from certain diseases because their health administrators are negotiating are tough negotiators on the price of drugs.

Mr. GARTHWAITE. So I mean what we can do is we can do what the Europeans do and start saying no to some drugs on our own. So we talked about insulin. Why is one reason insulin is expensive? Yes, it is an old drug but it has evolved a lot over time and there are two categories you might want to think about. We have human and analog insulin, analog insulin being a newer insulin. Caramore, which is a Medicare Advantage provider in California, they put a bunch of their type II diabetics, a large fraction on them on human insulin, the older kind and then they monitored for any adverse events. They had no increase in hypoglycemic events and they had a big decrease in savings.

Ms. SHALALA. So basically what you're saying to us is that where there are more than one drug that will treat the patient, we have not seen different outcomes necessarily for most patients but we are not prepared to do that?

Mr. GARTHWAITE. The gentleman left, Mr. Morelle but in tech what happens is we take slightly worse products that have meaningfully lower costs. In the U.S., healthcare we are unwilling to do that. Right?

We want—we will never take a slightly worse product, even if It is thousands of dollars less. We will, however, take a slightly better product and pay thousands of dollars more and until we are willing to say we won't do that, that you have got to give us the return for our money, we are not going to get any savings.

Ms. SHALALA. Madam Chair, this is a very important point because what we are describing is—we have not focused on outcomes. I am interested in outcomes. I am interested in whether we can make Americans healthier, and if we can use a negotiated process to do that, are there any circumstances or will any of you—would you propose any different ways of organizing the negotiation other than using an international price index?

For example, the VA negotiates now, the prices are online. You can actually see the contracts online. I mean we do have American government officials that now have experience in negotiating prices, whether it is on Medicaid or whether it is VA or whether it is for Tricare, we have had a lot of experience.

Mr. ISASI. Well I was going to say absolutely and we know that, for example, what Mr. Garthwaite is talking about in so much of his testimony is this hypothetical world in which if only we could do this and if only we could do that but the truth is we live in a world where there is a Medicare benefit, cash off of coverage that pharmaceutical companies are pricing to that coverage, there has been a 96 percent increase in price only in that coverage. They are playing a game with us, but he is in this hypothetical world. To your point, in particular with launch prices, we should be able to understand what is the real value of this drug? Does it really provide a benefit? How does it compare to what is on the market currently? We are not doing that as a country. You are describing that occurring in other countries, Mr. Garthwaite is as well.

We are not doing that as a country so we just put it on the market, they market it to doctors, doctors bring it to their patients and now we are spending $6,000 for something that should probably cost 5 cents.

Ms. SHALALA. The head of Eli Lilly came in to see me before they dropped their price for insulin and they actually had the nerve to say to me he could have dropped the price lower. I mean—

Mr. ISASI. They tripled—insulin tripled between 2003 and 2012 and it went up 10 times faster than all the drugs since then. Ten times faster, meanwhile they are suing other competitors to make sure they can't come to market with a biologic similar.

Ms. SHALALA. Mr. Holt, just one small point. I am an academic and normally when we testify or publish articles, we identify if our organization takes money from—in your case from pharma. I didn't see that acknowledgement on your testimony. I would hope that you would disclose whether your organization does take any money from pharma or has in the past taken money from pharma. I yield back.

Chairwoman WILSON. Mr. Holt?

Mr. HOLT. Our organization is a 501C3 and we don't disclose our donors. I am not allowed contractually to do that, and I also don't have anywhere near the knowledge of our donor situation to do so.

Ms. SHALALA. It is actually online, the IRS reports.

Mr. HOLT. Not ours. Maybe people who give money to us but ours are not.

Chairwoman WILSON. Thank you. Mr. Allen of Georgia.

Mr. ALLEN. Thank you, Madam Chairwoman and thank you for this expert testimony today. Obviously, I think every district in the country, when we go home, healthcare is number one. No question about it.

What I have been able to observe is nobody in healthcare is happy. Patients, Mr. Mitchell, are not happy, providers aren't happy, and the government has thrown trillions of dollars at this. The cost is skyrocketing and yes, we've got—we are developing great drugs. We are—I think, again, in a free market environment.

There is no question that free markets drive innovation. The government doesn't innovate anything. Yes, we can do studies, we can pay people to do studies but still to be able to raise the capital to invest, to be able to come up with these things that save lives is critical to this whole process so here is the question. And again, we do believe that this thing needs to be fair throughout the world. In other words, we should be able to sell your technology.

I mean we have this problem in China. Why is the President negotiating with China? Because they are stealing all our intellectual capital and then turning around and competing against us and dumping those products in here. In fact, how much of our drugs today are made in China? Because they have stolen our capital and they are selling the elements to develop these drugs back to us.

Mr. GARTHWAITE. A lot are made in China. I don't want to sign on to the second part that they are made in China because they are stealing our intellectual property. They are made there because we outsource manufacturing to China and India for lots of products so—

Mr. ALLEN. They aren't proprietary.

Mr. GARTHWAITE. We outsource to them to make the drug. It is a contractual arrangement between us and them. It is a perfectly legal arrangement.

Mr. ALLEN. I see. And they are using our technology to do that?

Mr. GARTHWAITE. Our technology on how to manufacture drugs?

Mr. ALLEN. Yeah.

Mr. GARTHWAITE. That is—India has been the drug store to the world for decades.

Mr. ALLEN. Okay.

Mr. GARTHWAITE. It is not—that technology on how to make a small molecule product isn't proprietary technology unless you—you have a lot more access to information than I do so you might know something about them taking technology, but I am not sure what you are getting at.

Mr. ALLEN. Well, I just—again, this is a worldwide problem, I guess what I am trying to say as far as whether it is Europe or anybody else and the fact that in Canada you can buy insulin for much less than you can buy it here in this country, we've got to fix that, and in other words, we've got to fix it to the extent that whatever we are able to develop here and sell here, if somebody else is going to use the same—use our intellectual capital, they need to pay for that and again, I still don't understand why is it that they can sell their insulin for less than we can do it. I mean—

Mr. ISASI. Because their government negotiates price. That is why. That is literally the reason.

Mr. GARTHWAITE. It is also—I'm sorry. It is because they are willing to walk away. I know you want to talk about me living in a fantasy world, but it is not hard. They are willing to walk away, and we are unwilling to tell our seniors, in particular, that lower prices might mean less access to drugs.

Mr. ISASI. And that is why H.R. 3 is so brilliant because it actually doesn't walk away; it forces a manufacturer to either give it a reasonable price or they end up paying an excise tax.

Mr. ALLEN. I'd like to reclaim my time.

Mr. ISASI. So, they don't walk away. They make sure the drug is available. That is what we care about.

Mr. ALLEN. I'd like to reclaim a little bit of my time, Madam Chair. Well listen, I got a little something going here, right?

Now, so the last questions. So if a—the drug Mr. Mitchell is taking and I don't know how that is being paid for but say it is Medicare, okay?

Mr. GARTHWAITE. I mean I guess, yeah.

Mr. ALLEN. And so Medicare is going to negotiate the price of this drug and they are saying we are going to pay this much for this drug for Mr. Mitchell and that is all we are going to pay. The company says we are not going to sell it to you for that and they walk away from the deal, what do we do then?

Mr. GARTHWAITE. So the hard part is that we have required—so that is an oral chemotherapy drug so I believe it is in the Medicare part D. we've required that the oncology products in Medicare part D, the insurer must cover every single one so it is the decision—that is a government decision because we didn't want seniors to not have access to every oral oncology product and that is a decision that we've made and that is why—It is not about the government negotiating it. The government negotiating it under those rules, it is the same thing that is going to happen and so—

Mr. ISASI. That isn't what would happen under the bill.

Mr. ALLEN. I am not addressing you, sir.

Chairwoman WILSON. Great discussion.

Mr. ALLEN. Can he finish his answer?

Chairwoman WILSON. Finish your answer if it is a minute.

Mr. GARTHWAITE. A whole minute? We have to decide whether we are willing to walk away. There is no secret to the drug pricing. It is not about the government negotiating, it is about the government saying they'll walk away. Creating that outside option. What we are going to do under the H.R. 3 is just under H.R. 3, you will still get access to the drug because we have said we will take all the company's money away if they don't give it to us so where is the access problem going to come? It is not going to come today. It is going to come in 10 years. There are no easy answers here.

Chairwoman WILSON. Okay, thank you so much. And now our esteemed Chair, Mr. Scott.

Mr. SCOTT. Thank you. Mr. Mitchell, you know what portion of R&D is done by the private sector and what portion is done by the Federal government?

Mr. MITCHELL. The budget for NIH this year is $39 billion. Pharma claims to be spending about $90 billion, but a tremendous amount of the spending by taxpayers through the NIH is on early high-risk, basic science that is the platform that leads to these new drugs. In addition, increasingly, NIH is doing drug development right now, is running clinical trials on the sickle cell drug inside its walls and in fact the NIH paid for most of the clinical trials for this expensive CAR–T drug which was brought to market by Novartis, so NIH is doing a tremendous amount of research not just basic science but increasingly drug development.

Mr. SCOTT. And is there any potential in revisiting the decision that was made in 1995 to limit the prices for drugs that are partially developed with Federal spending?

Mr. MITCHELL. Yeah and with all due respect to Dr. Garthwaite and he can look at this document too, the fact is that the number of cooperative research and development agreements did not skyrocket in the wake of the elimination of the reasonable pricing clause in 1995.

NIH had a standard CRADA and then it created something called materials CRADAs which did not exist in 1995. Subsequent to 1995 and the elimination of the reasonable pricing clause, the increase in the number of comparables, standard CRADAs was 14 percent over the ensuing 15 years and today the number of cooperative research and development agreements has gone up by only 45 percent, while the budget of NIH has gone up 400 percent so you need to understand what actually happened in 1995 when they created a different category of CRADA and you have to compare the original CRADA and see what happened in those ensuing years. Those are the numbers.

Mr. GARTHWAITE. What is NIH's position on doing this?

Mr. MITCHELL. The NIH made their decision back in 1995 when drug companies used to have much bigger R&D departments and today, the drug companies are increasingly reliant on the NIH for the basic science that leads to these incredible breakthrough drugs, kind of like the ones that I am taking.

Mr. GARTHWAITE. But the NIH has said they don't want to do any pricing clauses.

Mr. MITCHELL. The NIH are scientists and they want to pay attention to science. We need to look after taxpayers. So, I am with them on that.

Mr. SCOTT. Mr. Mitchell, the question was should we revisit that proposal?

Mr. MITCHELL. Absolutely.

Mr. SCOTT. Dr. Socal, is there any evidence that if we reduced our prices to what other countries are paying, that prices would go up in those other countries?

Dr. SOCAL. Not necessarily, no. So the big difference is that our country, with our market-based system, we are paying the price especially for drugs that have been in the market for a long period of time. These prices are going up where everywhere else they are going down and they go down everywhere else because of two reasons, one is because the research and development costs, they are sunk costs, they are not involved in the cost of producing every new pill. It is minimal change for every new production cost so other countries, they have recognized and they have mechanisms, after the drug is on the market to control and prevent these cost increases over time so it is unlikely that costs would increase everywhere else just because we changed the price here.

Mr. SCOTT. Okay, Mr. Isasi, did you want to say something about the last discussion?

Mr. ISASI. Absolutely. Thank you. Really quickly just to say that what was being described as what the legislation does is incorrect. The legislation would not have the government walk away from drugs that our seniors need. We at Families would not support that; that is not what the bill does. What the bill says is let's negotiate. Let's negotiate and come with a fair price and if we can't reach agreement, the upper limit is 120 percent of what the rest

of the world is paying so we are still going to pay more and if we still can't agree, then you go sell your drug and we are going to take the money back from you because you are trying to rip off America's families and American taxpayers. That is what the bill does, it does not do what he says it does which is walk away from the drug and take the drug away from seniors. That is not what the bill does. It protects access and also protects the taxpayer from this extortion that is happening from drug companies.

Mr. MITCHELL. And Mr. Chairman, could I just add that one of the key reasons that drugs are available first here in the U.S. is because we are the largest market and we pay the highest prices and at 120 percent of those referenced countries, we will still be the largest market paying the highest prices. It is very difficult to see how a CEO is going to walk into his ward, as Secretary Azar said to me, and tell his board I am walking away from the biggest market with the highest prices in the world.

Chairwoman WILSON. Thank you.

Mr. SCOTT. Thank you, Madam Chair.

Chairwoman WILSON. Mr. Taylor of Texas.

Mr. TAYLOR. Thank you, Madam Chair. If I remember my economics correctly, if you want to lower prices, you increase supply. I mean dirt cheap is cheap because there's a lot of dirt, right? So if you make more of something, prices will go down.

Government price controls, tempting as they may be to try to deal with the problem, I generally haven't seen that work out very well. Generally. they have to be undone at some point because they just didn't pan out but just going to this particular government price fixing system, do you have any comments with regard to how this particular government pricing system works in your mind or how it wouldn't work in your mind. Where would it ultimately end up being a problem? I think you have alluded to this a bit in terms of research.

Mr. GARTHWAITE. Yeah, I mean I was pretty clear before, I thought, that this is not about the government walking away from drugs despite being mischaracterized by another witness. The government isn't going to walk away from the drugs today because the government could just effectively take the drugs today, it doesn't have to. Where it is going to show up is an investment to innovation for new drugs 5, 10, 15 years for now which responds to the return on it. And again, as I have tried to be very clear, we might as a society want to have fewer drugs in the future in order to get more access today.

There is no purely economic sort of platonic idea about what that is. That is a decision we should be debating. Do we want to slow the pace of innovation in order to get lower prices today?

And let's have that conversation. Let's not let the officials in London and Berlin and Paris and Sydney have that conversation.

Mr. TAYLOR. Sure. And I think what I will say is a common bind here—what binds us together is a common point as I think everybody in this room wants to see lower drug prices, right? That is something we can all agree on. I hope we can agree that the best way to go do that is again to increase supply through a series of bills that came out of energy and commerce committee unanimously that were then amended in such a way that made it unac-

ceptable to Republicans that basically were sent to the senate to go die so those are not affected bills. I would hope that we would revitalize those bills, take them up as separate bills, send them back over to the Senate so that they can actually pass them and actually help our constituents lower drug prices so there are opportunities in front of us.

They are here in this chamber, in the House of Representatives. We know what to do, we know some of the actions we need to take. We just need to be legislatively inept at getting them through in such a way that is actually go on to the President's desk.

Just speaking about research and development, which we have talked about a little bit. I see there's an estimate that R&D will be cut by 200 billion dollars over the next 10 years if we were to go into this government price fixing mechanism that is in H.R. 3. Does that strike you as broadly correct, is that—can you speak to that estimate?

Mr. GARTHWAITE. I'd say It is the first one. I don't think our goal should be about lowering prices. Our goal should be about increasing welfare or making people better off now and in the future, and figuring out what the price of an access tradeoff is there.

If our goal is simply to lower prices, we can do that. That is actually not hard. The government is a very powerful force. It can come in and say let's not make it 120 percent. Let's make it 80 percent of the foreign price so we are trying to improve welfare. Where that welfare comes in is this effect on research and development, how much would it be.

I haven't run the number of whether it is 200 billion that would go down, partly because it is a pretty complicated question because it is about how is the venture capital company going to respond and so I don't—is that in order of magnitude correct? Maybe?

Mr. TAYLOR. So then also going staying on this topic of research and how important it is for the future of creating the next innovation, I think you correctly pointed out that it is not about the present prices where your real worry is. Your real worry is about future innovations including the United States which has been a tremendous leader on that. It comes at a price. So we are—NIH is conducting research and you are looking at the private industries estimating they are doing 97 billion dollars of R&D every year, which is a tremendous sum of money to find the next generation of drugs. If we were to go on a price fixing scheme, it seems to me that you're saying that 97 billion would go down.

Mr. GARTHWAITE. I mean economic logic would dictate that if you are going to earn less money from your investment, you'll find the next best use for that dollar, particularly true for venture capital companies where literally that is what they are supposed to do. They are supposed to get a return for their investors.

Mr. TAYLOR. Well I appreciate what you are saying here today. I will just say that I am certainly here to try to lower drug costs. As I go across my district, one of the top 3 complaints I hear is the cost of healthcare and we know that drug cost is a natural component of the cost of healthcare. And again, I am focused on trying to increase the supply. To me, price fixing is a lazy legislator's answer to fixing a particular economic problem and I would challenge anybody here to tell me hey, price fixing worked great here. This

is the best because I think when they are borne out over several decades, they generally just fall apart completely and are completely undone. I don't know that this Congress has done price fixing in the past, but it has not panned out. With that, Madam Chair, I yield back.

Chairwoman WILSON. Okay. Ms. Wild of Pennsylvania, welcome back.

Ms. WILD. Thank you, Madam Chair. I apologize for stepping out. I had to attend an Ethics Committee meeting, which is an internal committee governing ethics, but I think It is an appropriate subject to sort of lead off this discussion because to me, this is an ethical issue. This is a problem that our country is having. We have people dying because they cannot afford their prescription drug prices and that to me is unethical for the richest country in the world.

It seems to me that we are just consistently putting profits over people and Mr. Taylor, I have the utmost respect for my colleague across the aisle. He and I have worked on a bipartisan basis on other matters, but I will tell you, I don't think we are legislatively inept as I think you have termed it. We are, as a body, the government is far too influenced by the pharmaceutical lobby. That is at the heart of this problem. So with that said, let me just say that Dr. Garthwaite, you said a couple of minutes ago, venture capitalists' job is to make money for their investors. Well we know that in 2016, Turing Pharmaceuticals CEO raised the price of a newly acquired drug from $13.50 to $750.

In response to this, J. Michael Pearson, the CEO of Valeant said his company's responsibility was to its shareholders, not the customers who rely on the drugs to live. In fact, we know that shareholders can bring suit for an officer's breach of fiduciary obligation owed to shareholders through shareholder derivative lawsuits so Mr. Pearson, the CEO, was right. His first duty is and was to make as much money as he can for his company.

I would respectfully submit to you that should not be our priority in saving lives, in making people healthy again. We cannot continue to have profits over people as the most important thing governing this discussion. So, I know that you, Mr. Holt and Dr. Garthwaite—first of all, do either one of you have any formal medical background or training? Formal.

Mr. HOLT. I don't.

Mr. GARTHWAITE. No, as my wife says, I am not that kind of doctor.

Ms. WILD. I didn't think so. I know you both have serious reservations about government negotiation of drug prices or tying drug prices to those of other countries, but I want to talk about something else. I want to talk about something that matters to my constituents that I hear about almost every single day. I want to talk about diabetes and the price of insulin, and you said, Dr. Garthwaite, market competition will drive down costs.

Well guess what, we have a whole lot of competition for insulin. We have a whole lot of demand for it. It is been around forever. There have been no new formularies in decades and yet the price of insulin continues to go up, so there's no market force that is influencing that other than the fact that a whole lot of people need

insulin and the manufacturers know that and so what they do is they keep raising the price on it. It is unconscionable and I can't believe we're even sitting here having this discussion. I have constituents who are dying because they don't take their insulin, or they can't afford to get it, or they are rationing it.

I don't even—I can't even believe we are having this conversation. Do either one of you, just the two of you that I am talking to know what happens physically within a diabetic patient's body when she doesn't have access to insulin or has to ration her insulin? Do you know what ketoacidosis is? Do you know what the symptoms are? I will tell you: confusion, excessive vomiting, dehydration, shortness of breath, loss of consciousness, organ failure and death and I have constituents who themselves are rationing their insulin, whose family members have died because they rationed or didn't have their insulin available to them because of the price and I am not about to go back to them and say let's leave it up to the market to determine what the price of your insulin should be because you know what, the market has completely failed them and that is why we are here now. That is why this bill is coming before the House because we, as a country, and pharmaceuticals as an industry have completely failed the American people and we can't let it continue. I yield back.

Chairwoman WILSON. Thank you very much, Ms. Wild. And now, Mr. Watkins of Kansas.

Mr. WATKINS. Thank you, Madam Chair. Dr. Garthwaite, we hear heartbreaking stories of patients in other countries who are denied access to new treatments that could improve their lives. Earlier this month, news outlets cover the story of two sisters battling cystic fibrosis in Scotland. A breakthrough drug that treats the disease isn't currently covered by the United Nations' National Health Service because the government determined that the drug is too expensive. While one of the sisters was able to receive treatment for free from the manufacturer's compassionate care program, the other was told that she was not sick enough to qualify.

Under H.R. 3 with access to these potentially lifesaving drugs be threatened for America patients?

Mr. GARTHWAITE. I think It is unlikely that access to existing drugs would be threatened for Americans because as Dr. Socol said, the cost is sunk, so there is profit to be made selling it. Where the access restriction is going to come and we can't avoid an access restriction, it is going to come on drugs in the future. That is where It is going to come, less innovation so while Ms. Wild is right, not having access to diabetes drugs today causes that to happen, causes ketoacidosis, I would submit to ask her, do you know what happens to a cancer patient who doesn't have access to oncology that treats their cancer. You sit next to their bed and you watch them die like it happened to my family members. So that access mode happens no matter what. It is a question of whether we are going to pay attention to it, or we are going to pretend it doesn't exist.

Mr. WATKINS. Mr. Holt, your testimony denotes that "the cost of successfully bringing a drug to market has been estimated at approximately 2.87 billion dollars." And that establishing an international price index similar to the one included in H.R. 3 would

lead to 9 billion dollars in lost revenue for drug manufacturers per year.

If this index is expanded to the entire United States market, how many fewer drugs could we see approved by the FDA per year?

Mr. HOLT. So the 9 billion figure was looking at the President's IPI proposal specifically limited to part B. Part B is about 10 percent of the U.S. market so you would see that increase by that—so roughly about 30 drugs per year, the amount that it cost to produce roughly 30 drugs per year would be lost.

Mr. WATKINS. How does this impact the pipeline and the development of new medicines?

Mr. HOLT. So on average, FDA approves about 33 new drugs a year so that is a big chunk of the pipeline.

Mr. WATKINS. Thank you. Madam Chair, I yield the balance of my time.

Chairwoman WILSON. Thank you very much. And now—oh, Mr. Keller, Pennsylvania.

Mr. KELLER. Thank you, Madam Chair and I'd like to thank all the members of the panel for being here today. Prescription drug pricing is an issue. We've been hearing it from everybody. I have been in my district and there are a lot of things I think go into it and a question, I guess I just want to have for Dr. Garthwaite, I know you talked a lot about the return on investment and all those kinds of things and when we look at who this impacts and who the pharmaceutical companies are, they are basically owned by shareholders, is that correct?

Mr. GARTHWAITE. It is a variety of organizational structures.

Mr. KELLER. And it would be public pensions and all that kind of stuff.

Mr. GARTHWAITE. Probably yes.

Mr. KELLER. So a lot of the times, the motivation is to make sure they get a return on investment and then we as public sector employers invest in those drug companies too so if we want to point the finger at people making money, I think we need to look at all of us and I think we need to look at all things that we can do to help this and instead of pointing the finger at one person or another, look for actual solutions which I think would be in some kind of patent reform, things that would make drugs accessible rather than trying to point the finger of blame. I guess the one thing I'd like to ask you about and I know you mentioned it, you talked about drugs or people walking away—or making certain drugs because of the innovation and so forth, that would be that the company would just stop manufacturing or might not invest money in the future. In other words, if we weren't going to let them develop drugs, somebody said the government would walk away. It wouldn't necessarily be the government, it would be that the companies wouldn't invest in R&D?

Mr. GARTHWAITE. Yeah, I mean we talk about the innovation tradeoff, it is not getting new drugs in the future. Drugs that have already developed, that we have already developed, people will make and sell at that price.

Mr. KELLER. Right, but that might not get innovation for future drugs and treatments.

Mr. GARTHWAITE. You would see a—it is not that you would get none—

Mr. KELLER. You wouldn't get as much because when you look at some of the other countries where that is happened, there's not as much R&D in Germany or other countries as there are in the United States, would that be—

Mr. GARTHWAITE. No, I wouldn't think of it that way. It doesn't matter where the R&D happens. We get lots of good drugs from Germany, we get drugs from Israel, we get an emergent Chinese biotech market. It is about where the profits can be earned, that is what dictates the investment.

Mr. KELLER. Okay. Another question I guess I would have. Part of the consideration, would that also be any kind of tort reform? Would that be helpful in this discussion?

Mr. GARTHWAITE. I mean if I started making a list, I am not sure that would get to the top 10.

Mr. KELLER. Not the top 10 but probably a portion of it. I mean—

Mr. GARTHWAITE. Honestly, I have never thought about tort reform in this context right now. There certainly are liability issues.

Mr. KELLER. There was a Columbia science and technology article in the law review between December of 2009 and June of 2010, just one company paid 3.36 billion in claims for cases, class action suits so I think there's some room—I guess my point is if you could make a list of things to do, it is just more than one thing other than just having the government negotiate prices.

Mr. GARTHWAITE. I would just say that if a company does something wrong, they might have to—I don't know the case of the 3.6 billion but just because it is a big fine, doesn't mean that it is a wrong fine.

Mr. KELLER. Right. I get that.

Mr. GARTHWAITE. Yeah, I mean we want a tort system.

Mr. KELLER. Right, I get that, but again, some kind of reform might be helpful in order to keep things in check.

Mr. GARTHWAITE. You have to point to me where the tort system is failing, I guess. I can understand the medical malpractice side—

Mr. KELLER. I get that too. I get that too.

Mr. GARTHWAITE. I just don't know what the reform you are looking for is, I guess.

Mr. KELLER. I guess we need to just look at all avenues I guess is my point. We shouldn't look at just one thing.

Mr. GARTHWAITE. I would agree that we should be comprehensive at everything we do.

Mr. KELLER. Yes, absolutely. I guess that is my point. I just don't know that this bill gets us there. This is just one of negotiating government prices rather than looking at all the solutions.

Mr. GARTHWAITE. Yeah, but we should be clear. This bill has a lot of good parts. The stuff they want to do for Medicare at part D, the stuff that the other witnesses talked about. I mean that is good. Creating an out of pocket cap, if we expanded it to think about getting rid of coinsurance, which doesn't really make a ton of sense, fixing the catastrophic but let's focus on the things that

we can do that are going to make the market work more efficiently. I'd love to be comprehensive in that, but I wouldn't say that this bill is not just about the price control. There are a lot of things in there that are analogous to what Republicans in the finance community are talking about as well.

Mr. KELLER. And again, I think those are things to look at but having the government just be the sole negotiator of price I think is—in this bill, one person, the Secretary would be the person that would select the drugs that we are going to talk about and look at negotiating the prices on that group of drugs, which I think is controlled by one person.

Mr. GARTHWAITE. That feature of the bill causes me pause, yes.

Mr. KELLER. There are some things that I think would be pretty dangerous and limit choices and so forth for people that need to help. Thank you, I yield back.

Mr. GARTHWAITE. Thank you, Ms. Davis?

Ms. DAVIS. Thank you, Madam Chair, thank you to all of you for being here. We have just very few minutes, but I wanted to give Mr. Holt, Mr. Garthwaite that chance, if you'd like to respond to my colleague because we are very passionate about this, and I have to tell you that this is not a partisan issue. Everybody is passionate and I will have a question for Mr. Mitchell as well so if you could just quickly respond if you'd like.

Mr. GARTHWAITE. I would say, Ms. Wild, I understand you're passionate. You brought up Turing Pharmaceuticals and Valiant. I was pretty specific in my testimony about those two companies, that those are examples of behavior that I believe there's a role for the government to regulate their prices. In fact, a big chunk of my testimony refers specifically to that instance and why I think for small market generics, that is something that we should regulate. We've already paid the innovation tradeoff. This idea about profits versus life. I mean there are economic realities in life.

Ms. DAVIS. Thank you I am going to—is that enough of a response? I am sorry. We are just in such a hurry. Mr. Holt?

Mr. HOLT. I also referenced the Turing Pharmaceuticals situation in my testimony. I do think that is an egregious breach and I think the single search generics are a real problem. I also am concerned about patients. My mother has diabetes. I have seen her off her insulin, so I am very sensitive to that.

I think the reality is that we see the pipeline that is coming. We are seeing biologics, gene therapy, we can negotiate 90 percent discounts and individuals aren't going to be able to pay for these so what we have to talk about is how the system is going to pay for drugs so that patients do have access.

Ms. DAVIS. Right, and that issue of access—and so I wanted to turn to Mr. Mitchell and Mr. Mitchell, I wanted to thank you for being here. I am very familiar with multiple-myeloma, it is very personal to me and I understand what you are going through so one of the questions that I have often have, I come from San Diego and so we work with pharmaceutical companies all the time but for a long period of time, patients weren't really spoken to, frankly. They weren't engaged, they weren't at the table. They weren't really encouraged to participate and provide the kind of input that I

think is important to our researchers, to the companies as a whole. Mr. Mitchell, do you feel that situation has changed? Do you feel that people feel as if there is something that they are being able to offer in this discussion?

Mr. MITCHELL. I think there is not enough of an opportunity for policymakers to hear from independent patient groups. Most of them are funded by the drug companies and that is okay. They use that money for good purpose, patient education, patient support but on drug prices they are constrained. I do want to make a couple of quick points. I agree with Professor Garthwaite that we should be maximizing welfare and the way to do that is we are going to have to lower drug prices so people can get access to the drugs they need. There is enough spending in the system to reduce crises and not impact R&D, in fact the money U.S. based drug companies made in 2015 by charging American side prices was nearly double what was needed to fund their total global R&D and so if we are going to be making decisions about where to invest based on returns for venture capitalists, instead of the needs of people like me and everybody along this table who knows someone they love, then we are making a big mistake because we are not putting the public welfare first. We are saying we are going to provide for the needs of VCs in order that we get the investment we need and the final thing is, when drug companies say we are not going to—what they are saying to me is we want to be able to set any price we demand and you pay it or you won't get the drugs you need. We can't do that. We do have to strike the balance that folks are talking about here.

Ms. DAVIS. Yeah, well thank you. I appreciate your comments. I mean one of the areas in H.R. 3 that we haven't focused too much on is how we get to that. If there is a sweet spot, I am not sure we'd call it that in negotiating with drug companies and we talked about the average international market price but in that, and I don't want to go into more detail of it, there also is this question, this concern about access. Access in other countries. Again, whether people feel like they are able to get multi-myeloma drugs elsewhere, obviously have—it doesn't mean that we have more patients of any one cancer here in the United States than anywhere else in the world so obviously they are getting some of that, I think. The other issue is patents and we haven't talked a lot about them, but you focused a lot on the fact that we should have more competition, yes, but you can't have competition if you have one company that has the monopoly on multiple, multiple drugs in any one country.

Mr. ISASI. That is the exact point that has not been said in this entire discussion about competition and worrying about squelching innovation. These companies are operating with a government-granted monopoly. This isn't a free market, it is non-efficient, it is distorted, and they are abusing the government-granted monopoly and what we should do is negotiate price in that environment.

Ms. DAVIS. Thank you very much. I know my time is up. I hope that at some point we are going to be tasking drug companies to find the cures that we need upfront.

Chairwoman WILSON. Thank you very much, Ms. Davis. I remind my colleagues that pursuant to committee practice, materials for submission for the hearing record must be submitted to the

committee clerk within 14 days following the last day of the hearing, preferably in Microsoft Word format. The materials submitted must address the subject matter of the hearing.

Only a member of the committee or an invited witness may submit materials for inclusion in the hearing record. Documents are limited to 50 pages each. A document longer than 50 pages will be incorporated into the record by way of internet link that you must provide to the committee clerk within the required timeframe but please recognize that years from now, that link may no longer work.

Again, I want to thank the witnesses for their participation today. What we have heard is very valuable. Members of the Committee may have some additional questions for you, and we ask the witnesses to please respond to those questions in writing.

The hearing record will be held open for 14 days in order to receive those responses. I remind my colleagues that pursuant to committee practice, witness questions for the hearing record must be submitted to the majority committee staff or committee clerk within 7 days.

The questions submitted must address the subject matter of the hearing. Before recognizing the Ranking Member for his closing statement, I ask unanimous consent to enter the following materials into the record.

These are letters in support of prescription drug pricing legislation from AARP, Alliance for Retired Americans, AFSCME, AFL–CIO, American Federation of Teachers, American Medical Association, and the California Medical Association. I now recognize the distinguished Ranking Member for his closing statement, Mr. Walberg.

Mr. WALBERG. I thank you, Madam Chairwoman and appreciate the hearing today. Thank you to each of the panelists for being here. Dr. Garthwaite, I'd be wrong to forget the fact that I have my oldest grandson turn 13 last week. He was born at 24 weeks at Northwestern Hospital. The result of all sorts of wonderful, wonderful care in that neonatal ICU unit as well as medications, et cetera. He's 13 strong, healthy and smarter than me. At least he would believe that so thank you, Northwestern.

Madam Chairwoman, this was a good discussion. I think in my opening comments, I tried to make it clear that this is a type of discussion that we should have. We don't disagree about everything in this legislation but there are some major glaring problems in this legislation that had we had discussions like this as opposed to a very closed, closed operation of the speaker of putting together a piece of legislation without consultation with appropriate committees, ours included, I think we might have had the opportunity for a better outcome. As I have said, I have seen that take place in Energy and Commerce Committee.

I have seen it take place in some major piece of legislation. I think we could do it. Instead of holding a hearing on this socialized drug pricing scheme, the committee's time would be better spent on finding bipartisan solutions to our nation's problems.

Governments don't negotiate, they dictate. We want negotiation. How is that done? I think there are means to do that and I would hope that this committee's leadership, as well as other committees

that are involved with this would put a slowdown on it to bring together something that indeed can pass out of this House and chart the course even for the Senate for something they could vote on and pass as well and the President could sign, so again, thank you for the time and with that, I yield back.

Chairwoman WILSON. Thank you to our witnesses for joining us today and today we heard compelling testimony on the urgent need for the Federal government to reduce the cost of prescription drugs for consumers, businesses, and taxpayers.

Americans across this country are struggling to access the prescription drugs they need to be healthy. They are forced to pay inflated prices that are far higher than those charged for the same drugs sold by the same pharmaceutical companies in other countries and they are hit with annual price hikes that far exceed the rate of inflation. But our witnesses shared prescription drug companies are not charging these exorbitantly high prices because of natural market forces, and the evidence is clear that they are not inflating prices because they are investing in research and development as some of my Republican colleagues may argue. By contrast, prescription drug companies are artificially inflating prices so that they can pay for marketing and sales, executive bonuses and stock buybacks. We cannot allow this to happen in the pharmaceutical industry. We cannot allow them to get richer while Americans across this country risk their health under the weight of unaffordable drug prices.

They are truly drug dealers, and this is criminal. Simply put, medicines are of no use if those who need them cannot afford them. That is why it is imperative that we pass the Lower Drug Cost Now Act. As our witnesses made clear, this legislation would lower drug prices, increase transparency at pharmaceutical companies, and align our drug pricing system with the rest of the developed world.

By adopting the Lower Drug Cost Now Act, Congress can take a long overdue step toward empowering all Americans, whether you get your healthcare through Medicare or your employer, to access fairly-negotiated drug prices. I look forward to working with each of my colleagues to pass this legislation and improve the health and lives of Americans for generations to come. If there is no further business, without objection, the committee stands adjourned and thank you.

[Additional submission by Mr. Levin follows:]

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INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE & AGRICULTURAL IMPLEMENT WORKERS OF AMERICA – UAW

GARY R. JONES, *PRESIDENT* RAY CURRY, *SECRETARY-TREASURER*
VICE-PRESIDENTS: TERRY DITTES • CINDY ESTRADA • RORY L. GAMBLE

September 25, 2019

The Honorable Bobby Scott
Chairman
House Education and Labor Committee
2176 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Frederica Wilson
Chairperson, Health, Employment, Labor and Pensions Subcommittee
Committee on Education and Labor
2176 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Scott and Chairperson Wilson,

On behalf of the International Union, United Automobile, Aerospace and Agricultural Implement Workers of America (UAW) and our one million active and retired members, I am writing in advance of the Subcommittee on Health, Employment, Labor and Pensions hearing, "Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency" scheduled on September 26, 2019. We are deeply concerned about the skyrocketing cost of prescription drugs and the impact it has on working families across the country. UAW members, retirees and their families are no exception. Bold, policy solutions are needed to drive down the cost of prescription drugs. We strongly believe that the Lower Prescription Drug Costs Now Act (H.R.3) is a step in the right direction.

The rising cost of prescription drugs is a major concern for UAW members and retirees. The UAW Retiree Medical Benefits Trust (the "Trust") provides health care benefits to retired UAW members who formerly worked for GM, Ford and Chrysler, along with their spouses, surviving spouses and dependents. Currently, the Trust provides health care benefits to more than 656,271 persons. The costs of health care have increased substantially over the years, while our members' retirement incomes remain fixed.

The skyrocketing costs of prescription drugs needs to be addressed. From 2014 to 2017, the Trust's single largest drug spend was for insulin. In 2018, insulin products represented our second largest drug spend (surpassed by only very expensive oncology medications). In 2018,

the Trust spent $235.2 million on insulin. Although insulin has been used in the treatment of diabetes for over 90 years, the cost of insulin has nearly doubled from 2012-2016. Lowering costs of prescription drugs and holding PHARMA accountable for price gouging is one of many fights we are fighting.

We believe that the Committee should take swift action to drive down the cost of prescription drugs. It is unfathomable that working families often ration their medication or skip life-saving drugs all together because they cannot afford the cost. UAW retirees should not have to worry about the how they are going afford their prescriptions on a fixed income when they are paying for housing, food and other needs in their golden years.

UAW has long supported various approaches to ensure working families have access to affordable health care. That is why the UAW advocated for passage of Medicare, Medicaid and the Affordable Care Act (ACA) and are now urging Congress to pass bold reforms to drive down the cost of prescription drugs. We are pleased that the Committee is discussing various approaches to make prescription drugs more affordable. The Lower Prescription Drug Costs Now Act (H.R.3) and the Medicare Negotiation and Competitive Licensing Act (H.R. 1046) hold much promise and we look forward to working with you and the Committee to make further improvements.

We hope that Congress will take steps to increase transparency on the rising cost of insulin and other high cost drugs, hold pharmaceutical companies accountable for price gouging and increase market competition to ensure that consumers can afford life-saving medications. We applaud the Committee for taking a serious look at proposals that would achieve these goals.

Sincerely,

Josh Nassar
Legislative Affairs Director

ddh
opeiu494/aflcio

[Additional submissions by Ms. Wilson follow:]

AARP
Real Possibilities

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September 19, 2019

The Honorable Frank Pallone
Chairman
U.S. House of Representatives
Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Richard E. Neal
Chairman
U.S. House of Representatives
Ways and Means Committee
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Robert C. Scott
Chairman
U.S. House of Representatives
Education and Labor Committee
2176 Rayburn House Office Building
Washington, DC 20515

Dear Chairmen Pallone, Neal and Scott:

AARP, on behalf of its nearly 38 million members and all older Americans nationwide, supports your legislation, H.R. 3, the *Lower Drug Costs Now Act of 2019*. We commend you for working to lower prescription drug prices and the out-of-pocket costs of individuals and families across the country.

There is no reason for Americans to continue paying the highest prescription drug prices in the world. We need immediate action to lower prices, as older adults are particularly hard-hit by outrageously high prescription drug prices. Medicare Part D enrollees take an average of four to five prescriptions per month, and over two-thirds have two or more concurrent chronic illnesses. When older Americans talk about the impact of high prescription drug prices, they are often talking about costs that they will face every year for the rest of their lives.

In addition, most Medicare beneficiaries live on modest incomes, with an annual median income of just over $26,000. One-quarter have less than $15,000 in savings. This is not a population that has the resources to absorb rapidly escalating prescription drug prices, and many are simply unable to afford the medications they need.

Prescription drugs do not work if you cannot afford them. AARP's recent Rx Price Watch Report focused on prescription drugs widely used by older Americans and found that their retail prices

increased by an average of 4.2% in 2017 – double the rate of inflation. AARP's report also examined how drug companies' relentless price increases add up over time and found that the average annual cost of one prescription drug – now around $19,816 – would have been just under $7,263 in 2017 if retail price changes had been limited to general inflation between 2006 and 2017, a difference of more than $12,500. The average annual price increases for brand name drugs have exceeded the corresponding rate of inflation every year since at least 2006.

Simply put, current prescription drug price trends are not sustainable. High and growing drug prices are affecting all Americans in some way. Their high costs are passed along to everyone with health coverage through increased health care premiums, deductibles, and other forms of cost-sharing. This is not only financially challenging for people who need these medicines, it is an unsustainable burden on taxpayers, as these high drug prices cost taxpayers billions of dollars more for programs like Medicare and Medicaid. Meanwhile, drug companies are working very hard to try to shift the blame to others in the health care system, leaving them free to set incredibly high prices and increase them year-after-year with little restraint. Your legislation will help to put an end to price gouging by drug companies that leave millions of older Americans unable to afford the medications they need and simultaneously shift enormous costs onto taxpayers.

AARP has been working to advance three key policy goals at the federal level: reducing drug prices, capping seniors' out of pocket costs, and increasing competition. First, we are pleased that your legislation would take important steps to lower drug prices, including providing Medicare the authority to negotiate the price of drugs. Medicare should be able to use its bargaining power to get a better deal for the 40 million Part D beneficiaries, especially for the highest-priced drugs and those drugs with little or no market competition. In addition, we support other policies in the legislation aimed at lowering prescription drug prices, such as an inflation-based rebate and an international pricing index, both reforms that will help to end the relentless price gouging by drug companies.

AARP has also advocated for an out-of-pocket cap for Medicare Part D that also protects the financial sustainability of the Medicare program, and we are pleased that this reform was included in H.R. 3. An out-of-pocket cap will provide meaningful relief to the millions of older Americans with high drug costs who are struggling to afford needed medications. Today, enrollees on expensive prescription drugs can be forced to pay several thousand dollars more in out-of-pocket costs even after they reach the current catastrophic threshold. Notably, drug manufacturers' pricing behaviors are a primary driver of the increased Medicare Part D spending that has sparked an interest in revisiting the Medicare Part D benefit structure. That is why we strongly support your proposal to require meaningful liability for prescription drug manufacturers. Without this, the new cap would simply reward drug manufacturers for their egregious pricing behavior and potentially lead to even higher prices, premium and cost-sharing increases, and higher Medicare spending.

Finally, we support proposals to lower drug prices by improving generic competition. We have endorsed legislation that the House has acted on, including the CREATES Act and legislation to ban Pay-For-Delay agreements. These proposals will help lower prices through greater competition and provide consumers with access to lower cost generic medications. We are pleased that the House of Representatives passed these bills earlier this year. These proposals will help lead to more meaningful competition in the market to help drive down drug prices.

It is long past time for Congress to take action to rein in high drug prices. H.R. 3 will help ensure that more Americans have affordable access to the prescription drugs that they need to get and stay healthy. We look forward to working with you and all Members of Congress to pass legislation to lower drug prices and reduce seniors' out-of-pocket costs this year. If you have any additional questions, feel free to contact me or have your staff contact Bill Sweeney, Senior Vice President for Government Affairs, at bsweeney@aarp.org.

Sincerely,

Nancy A. LeaMond
Executive Vice President and
Chief Advocacy and Engagement Officer

For Immediate Release
September 19, 2019

Contact: Lisa Cutler, 202-637-5394 or lcutler@retiredamericans.org

Statement by Richard Fiesta, Executive Director of the Alliance for Retired Americans, on the release of H.R. 3, The Lower Drug Costs Now Act

"Seniors and all Americans will pay less for their prescription drugs when the House legislation released today by House Speaker Nancy Pelosi becomes law. This bill is a huge step toward helping retirees and all Americans afford their medications by empowering the government to negotiate lower prices and lowering out of pocket costs. The Alliance for Retired Americans applauds Speaker Pelosi and the House Democratic leadership for their work.

"Americans pay the highest prices in the world for prescription drugs. Each month more and more seniors are not filling their prescriptions or skipping doses because they simply cannot afford them. This bill ensures that the prices Americans pay for the most expensive drugs are in line with the lower prices of the same drugs in other countries.

"Seniors who need more medications to stay healthy will get immediate relief thanks to the $2,000 annual cap on out of pocket costs. This is a great improvement over current law.

"The Secretary of Health and Human Services will be allowed to negotiate lower prices for as many as 250 of the most expensive drugs covered by Medicare -- including insulin -- and those lower prices will be available to all insurance plans in the country. Notably, pharmaceutical corporations that refuse to come to the negotiating table will be required to pay steep, escalating penalties on their gross sales that could cost them billions of dollars.

"The 4.4 million members of the Alliance for Retired Americans strongly support this bill and urge the House and Senate to pass it immediately. Retirees can't wait."

###

CALIFORNIA MEDICAL ASSOCIATION

September 19, 2019

CMA President David H. Aizuss M.D. released the following statement in strong support of Speaker Pelosi's proposal to lower prescription drug costs for Medicare patients:

"Skyrocketing costs of prescription drugs are one of the main drivers of increased health care costs. Speaker Pelosi's bill will allow Medicare to use its market power to negotiate fairer prices for patients' medication and that ensures that seniors, many of whom live on fixed incomes, will have access to the medicine they need."

1201 K Street, Suite 800, Sacramento, CA 95814 T (916) 444-5532 F (916) 444-5689 cmadocs.org

AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

September 24, 2019

The Honorable Frank Pallone
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20510

The Honorable Richard E. Neal
Chairman
Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Robert Scott
Chairman
Committee on Education and Labor
2176 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pallone, Chairman Neal, and Chairman Scott:

On behalf of the physician and medical student members of the American Medical Association (AMA), I want to express our appreciation for your leadership and efforts to address the high cost of prescription medications. Price increases for brand pharmaceuticals and biologicals continue to outpace the rate of inflation, limiting affordability and access for our patients. Furthermore, higher prices lead to insurers using increasingly onerous utilization management programs that erect additional barriers to access, raise patient out-of-pocket costs, and add administrative hurdles for both patients and stressed physician practices.

The AMA supports efforts to redesign the Medicare prescription drug benefit to ensure appropriate alignment of incentives and cost sharing while also ensuring Medicare beneficiaries have access to medically necessary treatment. We also support tailoring subsidization of prescription medication for Medicare patients based on financial need. In addition, the AMA has policy that supports drug price negotiation as well as efforts to address medication price increases that outpace inflation.

Your plan demonstrates that Congress is serious about addressing these growing concerns and to ensure that patients have access to affordable medications. We look forward to working with you and urge Congress to pass meaningful legislation this year to achieve these goals.

Sincerely,

James L. Madara, MD

American Federation
of Teachers, AFL-CIO

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Professionals

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September 26, 2019

The Honorable Frederica S. Wilson
Chairwoman
Committee on the Education and Labor,
Subcommittee on Health, Employment, Labor, and Pensions
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairwoman Wilson:

On behalf of the 1.7 million members of the American Federation of Teachers, including 130,000 nurses and other health professionals, I thank you for organizing this important hearing on the affordability of pharmaceuticals.

No one should have to choose between feeding their families and paying for lifesaving medication, but that is exactly what happens in American households because of the unjustified rising price tag of prescription drugs. A recent study reviewing 49 brand-name drugs that had more than 100,000 total claims each from 2012 to 2017 found that "the cost of 36 of the drugs increased over the six-year period by more than 50 percent, and the cost of 16 more than doubled."

I frequently hear stories from our members about patients who are skipping needed medications because they are forced to choose between their health needs and paying their mortgages or buying food. It is devastating to hear retired educators and healthcare professionals, who have spent their lives helping people, talk about the struggles they face in taking care of their own health needs. These choices occur far too often for both retirees and those still in the workforce; an AARP analysis states that 28 percent of pre-Medicare-age adults don't follow the regimen prescribed by their doctors because of the expense.

This hearing should serve as the first step toward passing legislation to reduce what patients pay for medicine. Legislation to address the medicine affordability crisis must include a mandate that the secretary of health and human services negotiate a significant number of drug prices and a penalty if pharmaceutical firms refuse to bargain in good faith. It must address high launch prices and increases over inflation, and it must establish prices that are comparable to those paid internationally or allow for the safe importation of medicine.

As a union, we have worked hard to ensure that our members have access to high-quality, affordable healthcare, which is why we have fought for the Affordable Care Act, called for repealing the excise tax on plans with high levels of coverage, worked to end surprise medical billing, and supported increased transparency and competition. It is clear, however, that

comprehensive legislative action is needed to directly address the affordability of many pharmaceuticals.

Thank you again for your important leadership on this issue. Your work is crucial to ensuring that patients have access to the medicines they need.

Sincerely,

Randi Weingarten
President

11. Retirement Life
12. Working for Government
13. Workplace Health and Safety

- AFSCME Now
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For Immediate Release

Thursday, September 19, 2019

Contact: Natalia Pérez Santos
Email: NPerezSantos@afscme.org

Lower Drug Costs Now Act Promises to Bring Down Prescription Drug Prices

WASHINGTON — AFSCME President Lee Saunders released the following statement in support of H.R. 3, the Lower Drug Costs Now Act. This legislation would allow the federal government to negotiate prescription drug prices, impose penalties on companies that refuse to negotiate, stop unjustified price hikes for existing medications and reinvest savings

back into Medicare:

“For too long, politicians have given pharmaceutical companies a free license to take advantage of working people and retirees. Every year, these companies rake in billions of dollars in profits for their CEOs and shareholders by price gouging consumers. Meanwhile, millions of Americans report skipping dosages or outright forgoing medication because of exorbitant costs.

“By introducing H.R. 3, House leadership is taking a stand for working people and retirees and promising to rein in corporate greed. AFSCME looks forward to working with this Congress to ensure that every American has access to the medication they need.”

AFSCME's 1.4 million members provide the vital services that make America happen. With members in communities across the nation, serving in hundreds of different occupations — from nurses to corrections officers, child care providers to sanitation workers — AFSCME advocates for fairness in the workplace, excellence in public services and freedom and opportunity for all working families.

###

American Federation of State, County and Municipal Employees, AFL-CIO
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- Sep 19 AFSCME Opposes Scalia Appointment
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AFSCME members provide the vital services that make America happen. With members in communities across the nation, serving in hundreds of different occupations — from nurses to corrections officers, child care providers to sanitation workers — AFSCME advocates for fairness in the workplace, excellence in public services and freedom and opportunity for all working families.

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Press Release | Health Care

Working People Deserve Affordable Prescription Medicines

September 19, 2019

Statement from AFL-CIO President Richard Trumka on House Speaker Nancy Pelosi's plan to reduce the price of prescription drugs:

We applaud Speaker Pelosi for her bold, transformative plan to significantly reduce the price of prescription drugs. We must end the outrageous price spikes we see year after year. Importantly, this legislation will lower the cost of prescriptions for working people who get their health insurance through their employer, as well as for people enrolled in Medicare. This proposal is a major advance toward enacting legislation that will provide urgently needed relief on drug prices.

Contact: Gonzalo Salvador, 202-637-5018

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[Questions submitted for the record and their responses follow:]

October 7, 2019

Mr. Frederick Isasi, J.D.
Executive Director
Families USA
1201 New York Ave, NW, Suite 800
Washington, D.C. 20004

Dear Mr. Isasi:

I would like to thank you for testifying at the September 26, 2019, Subcommittee on Health, Employment, Labor and Pensions hearing entitled *"Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency."*

Please find enclosed additional questions submitted by Committee members following the hearing. Please provide a written response no later than Tuesday, October 15, 2019, for inclusion in the official hearing record. Your responses should be sent to Daniel Foster of the Committee staff. He can be contacted at 202-225-3725 should you have any questions.

I appreciate your time and continued contribution to the work of the Committee.

Sincerely,

ROBERT C. "BOBBY" SCOTT
Chairman

Enclosure

Health, Employment, Labor and Pensions Subcommittee Hearing
"Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency"
Thursday, September 26, 2019
2:00 p.m.

Representative Lauren Underwood (D-IL)

- Mr. Isasi, your testimony provided compelling statistics that made clear that today's hearing could not come at a more critical moment: our nation is facing a drug affordability crisis. There's nothing abstract about these numbers: they represent people's lives. People like Bill and Jennifer Schrier, teachers from my district and parents to two teenage sons. Jennifer and her two sons have diabetes. The family has private insurance, but the cost of insulin has become so unaffordable that they can't access the brand that works best for them. As a result, their youngest son's blood sugar levels are increasing, and the family doesn't know where to turn.

  For the Schriers and so many American families like them who struggle to afford life-saving medication, H.R. 3 will provide the relief they need and deserve: the bill ends the ban on Medicare negotiating drug prices with manufacturers—including insulin—in a way that prioritizes the highest cost drugs and makes these prices available to all Americans. H.R. 3 also creates a new $2,000 out-of-pocket limit for prescription drugs in Medicare, which seniors sorely need. On Tuesday, I introduced additional legislation to protect patients from high out-of-pocket costs. The Chronic Condition Copay Elimination Act would require private plans to cover insulin and other common, life-saving medications for patients with chronic diseases without charging a dime in out-of-pocket costs.

  Mr. Isasi, how will the lower drug prices achieved by H.R. 3 help make drugs more affordable for families like the Schriers who have private insurance plans?

Representative Andy Levin (D-MI)

- Mr. Isasi, Can you elaborate a bit on why it's so important for there to be incentives – and, perhaps, penalties – to ensure drug manufacturers can't raise prices above the rate of inflation for all consumers, not just Medicare beneficiaries?

- Mr. Isasi, You mentioned in your testimony that ensuring all consumers are protected from price spikes was especially important for pediatric drugs. Would you explain in a little more detail why that is?

- Mr. Isasi, Can you offer any recommendations as to how we might strengthen these provisions to ensure drug manufacturers can't raise prices above the rate of inflation for all consumers, not just Medicare beneficiaries?

COMMITTEE ON
EDUCATION AND LABOR
U.S. HOUSE OF REPRESENTATIVES
2176 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6100

October 7, 2019

Mr. David Mitchell
Founder
Patients For Affordable Drugs Now
7820 Hampden Lane
Bethesda, MD 20814

Dear Mr. Mitchell,

I would like to thank you for testifying at the September 26, 2019, Subcommittee on Health, Employment, Labor and Pensions hearing entitled *"Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency."*

Please find enclosed additional questions submitted by Committee members following the hearing. Please provide a written response no later than Tuesday, October 15, 2019, for inclusion in the official hearing record. Your responses should be sent to Daniel Foster of the Committee staff. He can be contacted at 202-225-3725 should you have any questions.

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Chairman

Enclosure

Health, Employment, Labor and Pensions Subcommittee Hearing
"Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency"
Thursday, September 26, 2019
2:00 p.m.

Representative Lauren Underwood (D-IL)

- Mr. Mitchell, thank you for your courage in fighting for affordable drugs amidst your own battle with cancer. As someone facing an incurable disease, you understand firsthand the need for innovation in the pharmaceutical industry. But you also know that cutting-edge drugs can't help if people can't afford them. How do you respond to those who claim that lowering drug prices comes at the expense of innovation?

Representative Kim Schrier (D-WA)

- You mentioned in your testimony that drug spending from 2011-2016 grew 2.5 times more than inflation and highlighted the importance of the provisions in both the Senate Finance package and HR 3 to stop companies from increasing prices faster than inflation. Can you talk a little bit about the importance of this piece and offer any recommendations about how far back the retroactive penalty should go to truly make a difference?

  If we take my insulin as an example, some of the largest price increases occurred between 2011-2016, where prices more than doubled in 5 years. To me, anchoring the price increases to 2016 wouldn't truly address some of the most egregious increases.

Representative Haley M. Stevens (D-MI)

- Mr. David Mitchell, in your testimony, you briefly discuss your experience as a small business owner and the challenges you faced in affording health coverage at your company. Could you briefly talk about how drug prices contribute to this problem for businesses in this country?

COMMITTEE ON
EDUCATION AND LABOR
U.S. HOUSE OF REPRESENTATIVES
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October 7, 2019

Ms. Mariana P. Socal, MD, MS, MPP, Ph.D.
Assistant Scientist
Johns Hopkins Bloomberg School of Public Health,
Department of Health Policy and Management
624 N Broadway, Hampton House, Suite 301
Baltimore, MD 21205

Dear Dr. Socal:

I would like to thank you for testifying at the September 26, 2019, Subcommittee on Health, Employment, Labor and Pensions hearing entitled *"Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency."*

Please find enclosed additional questions submitted by Committee members following the hearing. Please provide a written response no later than Tuesday, October 15, 2019, for inclusion in the official hearing record. Your responses should be sent to Daniel Foster of the Committee staff. He can be contacted at 202-225-3725 should you have any questions.

I appreciate your time and continued contribution to the work of the Committee.

Sincerely,

ROBERT C. "BOBBY" SCOTT
Chairman

Enclosure

Health, Employment, Labor and Pensions Subcommittee Hearing
"Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency"
Thursday, September 26, 2019
2:00 p.m.

Representative Lauren Underwood (D-IL)

- Dr. Socal, the legislation that I introduced, the Chronic Condition Copay Elimination Act, will eliminate out-of-pocket costs for common, life-saving prescription drugs, including insulin, for patients with chronic conditions. Based on your background as a physician, when patients can afford their medications and adherence increases, what are the implications for their health outcomes?

Representative Haley M. Stevens (D-MI)

- Dr. Mariana Socal, one theme that has consistently come up in our discussion of drug prices is that in essentially every other country on the planet patients pay less – often much less – than Americans do for the exact same drugs. Dr. Socal, you have done quite a bit of research on this issue, and I think this Subcommittee would benefit from learning more about it. What are some of your key findings with respect to the price of drugs – including older drugs that have been on the market for years – in the United States versus other countries? What are some of the reasons that other countries pay so much less?

COMMITTEE ON
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WASHINGTON, DC 20515-6100

October 7, 2019

Ms. Bari Talente, J.D.
Executive Vice President, Advocacy
National Multiple Sclerosis Society
1100 New York Avenue, NW, Suite 440
Washington, D.C. 20005

Dear Ms. Talente:

I would like to thank you for testifying at the September 26, 2019, Subcommittee on Health, Employment, Labor and Pensions hearing entitled *"Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency."*

Please find enclosed additional questions submitted by Committee members following the hearing. Please provide a written response no later than Tuesday, October 15, 2019, for inclusion in the official hearing record. Your responses should be sent to Daniel Foster of the Committee staff. He can be contacted at 202-225-3725 should you have any questions.

I appreciate your time and continued contribution to the work of the Committee.

Sincerely,

ROBERT C. "BOBBY" SCOTT
Chairman

Enclosure

Health, Employment, Labor and Pensions Subcommittee Hearing
"Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency"
Thursday, September 26, 2019
2:00 p.m.

Representative Lauren Underwood (D-IL)

- Ms. Talente, in 2013, the average median price of MS disease-modifying therapies was $60,000. In 2018, it had risen to $80,000. As a result, health plans have increasingly relied on strategies that limit access to drugs—like step therapy–to manage the rising cost of prescription drugs. Many of these therapies have been available for 20 years, yet patients can't afford them. The market's ability to negotiate lower prices isn't working in this instance. Ms. Talente, how would giving the HHS Secretary the authority to negotiate drug prices improve access and affordability for patients living with MS specifically?

FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

October 15, 2019

The Honorable Bobby Scott, Chairman
House Committee on Education and Labor
U.S. House of Representatives
Washington, DC 20005

Dear Chairman Scott:

On September 26, 2019, the House Education and Labor Subcommittee on Health, Employment, Labor and Pensions held a hearing on "Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency," at which I testified on behalf of my organization, Families USA (FUSA). After the hearing, you submitted questions for the record to all witnesses. Below, please find responses to these questions prepared by the FUSA Staff.

Thank you again for the opportunity to testify. If any Committee Members or staff would like to discuss these answers further or need any other support, we would be very happy to provide assistance. Please feel free to reach out to me or Shawn Gremminger, FUSA Senior Director of Federal Relations at SGremminger@familiesusa.org or 202-628-3030.

Sincerely,

Frederick Isasi
Executive Director

FamiliesUSA.org
1225 New York Avenue, NW, Suite 800
Washington, DC 20005
main 202-628-3030 / fax 202-347-2417

Frederick Isasi, Executive Director, Families USA
Answers to Questions for the Record

House Education and Labor Subcommittee on Health, Employment, Labor and Pensions
"Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency"
Thursday, September 26, 2019
2:00 p.m.

REPRESENTATIVE LAUREN UNDERWOOD (D-IL)

Mr. Isasi, your testimony provided compelling statistics that made clear that today's hearing could not come at a more critical moment: our nation is facing a drug affordability crisis. There's nothing abstract about these numbers: they represent people's lives. People like Bill and Jennifer Schrier, teachers from my district and parents to two teenage sons. Jennifer and her two sons have diabetes. The family has private insurance, but the cost of insulin has become so unaffordable that they can't access the brand that works best for them. As a result, their youngest son's blood sugar levels are increasing, and the family doesn't know where to turn.

For the Schriers and so many American families like them who struggle to afford life- saving medication, H.R. 3 will provide the relief they need and deserve: the bill ends the ban on Medicare negotiating drug prices with manufacturers—including insulin—in a way that prioritizes the highest cost drugs and makes these prices available to all Americans.

H.R. 3 also creates a new $2,000 out-of-pocket limit for prescription drugs in Medicare, which seniors sorely need. On Tuesday, I introduced additional legislation to protect patients from high out-of-pocket costs. The Chronic Condition Copay Elimination Act would require private plans to cover insulin and other common, life-saving medications for patients with chronic diseases without charging a dime in out-of-pocket costs.

- **Mr. Isasi, how will the lower drug prices achieved by H.R. 3 help make drugs more affordable for families like the Schriers who have private insurance plans?**

There are several provisions of H.R. 3 that will help make drugs more affordable for families with private insurance coverage. First, in considering which drugs will be selected for negotiation, the Secretary will be choosing from a pool of drugs that includes the 125 costliest drugs to the entire health care system, including private insurance plans. Second, H.R. 3 requires the Secretary to negotiate lower prices for at least 25 of these drugs and for insulin, and drug manufacturers must agree to make the negotiated prices available to private insurance plans. Third, H.R. 3 includes a strong enforcement mechanism to ensure that drug manufacturers follow through on making the negotiated prices available to private plans—if they refuse, manufacturers will face a civil monetary penalty equal to 10 times the difference between the prices charged and negotiated prices for those drugs. Further H.R. 3 preserves the ability of private insurance plans to continue to negotiate for even lower drug prices for their members if they are able to. Finally, the bill institutes mandatory inflation rebates to discourage drug makers from increasing the price of existing drugs beyond inflation. Although the rebates only apply to Medicare, for drugs in

which Medicare is a significant purchaser, this rebate will likely disincentivize price spikes, meaning that people in private plans will indirectly benefit from this provision.

REPRESENTATIVE ANDY LEVIN (D-MI)

- **Mr. Isasi, Can you elaborate a bit on why it's so important for there to be incentives – and, perhaps, penalties – to ensure drug manufacturers can't raise prices above the rate of inflation for all consumers, not just Medicare beneficiaries?**

Prescription drug spending has been rising at a faster rate than overall health spending, and this trend is only expected to continue in the coming years.[i, ii] Though this increased spending is partially due to high "launch" prices,[iii] much of this increase is due to frequent, substantial price increases on existing drugs.[iv] When manufacturers decide to raise list prices year after year, they do so for all payers, not just for Medicare.

More than 60 percent of all adults report taking prescription drugs, and nearly three in ten adults report not taking medicine as directed because of cost.[v] For almost 30 percent of these individuals, their condition worsened as result of not taking medicine as directed.[vi] The age group that reports the most difficulty affording their drugs is people between the ages of 50 and 64, people who are not yet eligible for Medicare.[vii] Thirty percent of people in this group report difficultly affording medicine, compared to 23 percent of people over the age of 65 who have Medicare coverage.[viii] One fifth of people under the age of 50 also report difficulty affording their drugs.[ix]

In addition to making drugs unaffordable for consumers, rising drugs prices also contribute to rising insurance premiums. In fact, prescription drug costs now account for up to 25 percent of spending by commercial health plans.[x] To protect the health and financial security of all consumers, manufacturers must be constrained from raising prices above the rate of inflation for all consumers, not just for Medicare beneficiaries.

- **Mr. Isasi, You mentioned in your testimony that ensuring all consumers are protected from price spikes was especially important for pediatric drugs. Would you explain in a little more detail why that is?**

Nearly a quarter of children take at least one prescription drug per month.[xi] For children under the age of 11, the most commonly used drugs are those used to treat asthma and other breathing conditions. Before it was repatented, the asthma drug albuterol cost about $15 per inhaler; now it can be $100 or more.[xii] The per dose spending in Medicaid for one brand name albuterol drug approved for use in children increased by more than 30 percent between 2013-2017.[xiii] Because Medicaid is relatively insulated from price increases through the Medicaid inflationary rebate,[xiv] the effect of price increases on this drug in the commercial market is likely to be substantially greater. For children between the ages of 12 and 19, drugs that treat ADHD are the most commonly used drugs,[xv] and the price for one of these drugs rose 118 percent in 2019 alone.[xvi]

If consumers without Medicare coverage are left unprotected from price spikes, drug makers may also choose to raise the price of the pediatric version of drug and not the adult version. This would allow the

manufacturer to avoid paying little if any inflationary Medicare rebates, as the price of the adult version has not increased at a rate above inflation, while keeping their additional revenue from the pediatric version that is not subject to an inflationary rebate.

- **Mr. Isasi, Can you offer any recommendations as to how we might strengthen these provisions to ensure drug manufacturers can't raise prices above the rate of inflation for all consumers, not just Medicare beneficiaries?**

Families USA recommends either of the following changes to strengthen H.R. 3's ability to constrain price increases for all consumers:

  - The Secretary could be directed to negotiate the price of drugs with year-over-year above inflation price increases, even if those drugs are not otherwise eligible for negotiation under H.R. 3. The Secretary could be given discretion to negotiate these drugs in Years 1 and 2, but should be required to do so by Year 3.
  - Manufacturers who increase the price of their drugs above inflation could pay a 100 percent excise tax on the difference for their sales outside of Medicare. This is similar to H.R. 1093, the Stop Price Gouging Act, which has been introduced in this Congress.[xvii]

---

[i] Office of the Secretary for Planning and Evaluation. (March 8, 2016). Observations on Trends in Prescription Drug Spending. Department of Health and Human Services. https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf.

[ii] G.A. Cuckler, et al. (Feb. 14, 2018). National Health Expenditure Projections, 2017–26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth. Health Affairs, 37(3): 482–492. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.1655.

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[x] M. Sherman, G.D. Curfman, J. Parent, and A.K. Wagner. (August 24, 2018). Prescription Medications Account for One in Four Dollars Spent by a Commercial Health Plan. Health Affairs Blog. https://www.healthaffairs.org/do/10.1377/ hblog20180821.820628/full/.

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David Mitchell Responses to Questions for the Record
House Education & Labor Subcommittee Hearing
"Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency"
Thursday, September 26, 2019

Representative Lauren Underwood (D-IL)
Mr. Mitchell, thank you for your courage in fighting for affordable drugs amidst your own battle with cancer. As someone facing an incurable disease, you understand firsthand the need for innovation in the pharmaceutical industry. But you also know that cutting-edge drugs can't help if people can't afford them. How do you respond to those who claim that lowering drug prices comes at the expense of innovation?

A. Multiple studies show there is no correlation between the cost of research and development (R&D) and the price assigned to a drug.[1] Drug companies charge as much as they can because they can.

Many drug corporations spend more on marketing and advertising than they do on R&D.[2]

Taxpayers foot a huge portion of the investment in basic science that leads to new drugs. The NIH is the single largest source of biomedical research in the world. All 210 drugs approved by the FDA from 2010-2016 were based in some part on science paid for by taxpayers through the NIH.[3]

Instead of investing in innovative new drugs, drug companies direct resources on repurposing old medicines to preserve profits. Between 2005 and 2015, at least 78% of the new drug patents issued were for drugs already on the market.[4]

[1] https://www.healthaffairs.org/do/10.1377/hblog20170307.059036/full/
[2] https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5878010/
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Lower prices do not require cuts to R&D by drug corporations. Pharma reaps about 63% of total US health care profits on only 23% of the health care revenue.[5] They enjoy profits that are two-three times the average of the S&P 500.[6] They used tax cuts for stock buybacks—not R&D.[7]

There is overwhelming evidence that the cost to develop new drugs does not justify the high prices.[8,9,10] There is plenty of room in the system to lower prices while maintaining R&D.

Representative Kim Schrier (D-WA)

You mentioned in your testimony that drug spending from 2011-2016 grew 2.5 times more than inflation and highlighted the importance of the provisions in both the Senate Finance package and HR 3 to stop companies from increasing prices faster than inflation. Can you talk a little bit about the importance of this piece and offer any recommendations about how far back the retroactive penalty should go to truly make a difference?

If we take my insulin as an example, some of the largest price increases occurred between 2011-2016, where prices more than doubled in 5 years. To me, anchoring the price increases to 2016 wouldn't truly address some of the most egregious increases.

A. While we would be supportive of a longer lookback period for some of the most egregious cases like insulin, we believe the three year timeframe for retroactive penalties is a step in the right direction. We believe further savings can be achieved on drugs like insulin through the negotiating mechanism using international reference pricing. Insulin is far less expensive in the reference countries, and further savings will be achieved.

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[5] https://www.axios.com/pharma-health-care-economy-q3-profits-53b950b2-5515-4d79-b1f5-7067bf3652d1.html

[6] https://www.gao.gov/assets/690/688472.pdf

[7] https://www.nytimes.com/2017/07/14/business/big-pharma-spends-on-share-buybacks-but-rd-not-so-much.html

[8] https://www.axios.com/cancer-drug-prices-world-health-organization-8c302ebd-896e-42c0-bffc-64cbaa2311a7.html

[9] https://jamanetwork.com/journals/jama/article-abstract/2545691

[10] https://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug

Representative Haley M. Stevens (D-MI)

Mr. David Mitchell, in your testimony, you briefly discuss your experience as a small business owner and the challenges you faced in affording health coverage at your company. Could you briefly talk about how drug prices contribute to this problem for businesses in this country?

A. For more than 30 years, I helped start and build a small business. Health care always figured prominently in our benefits package to attract and retain talent. As drug costs rose, they became more of a factor in our premiums and benefit structure. For example, to restrain costs, we shifted to placing drugs on tiers. This is not the best outcome for employees. As costs continued to rise, we spent more of our total compensation dollar on health care—including prescription drug coverage—and so had less money for paychecks and other benefits. We operated in a competitive market, but brand drug companies enjoy monopolies and can therefore impose price increases without repercussions. It is an asymmetrical relationship in which employers and their employees subsidize outsize profits for Big Pharma.

Baltimore, April 30, 2020

JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

Department of Health Policy and Management

To: Mr. Robert C. "Bobby" Scott
Chairman
Committee on Education and Labor
U.S. House of Representatives

Dear Chairman Scott,

Thank you so much for having provided me with the opportunity to testify as a witness at the September 26, 2019 hearing "Making Health Care More Affordable: Lowering Drug Prices And Increasing Transparency." It was a great honor to have participated. I would like to provide responses to two additional questions that I received from members of the subcommittee, which I transcribe and address below:

1. Question from Representative Lauren Underwood (D-IL)

"Dr. Socal, the legislation that I introduced, the Chronic Condition Copay Elimination Act, will eliminate out-of-pocket costs for common, life-saving prescription drugs, including insulin, for patients with chronic conditions. Based on your background as a physician, when patients can afford their medications and adherence increases, what are the implications for their health outcomes?"

- Thank you so much for this question. Affordability is key to increase adherence, which in turn is essential to improve health outcomes. Increased treatment adherence has been proven by numerous scientific studies to reduce morbidity and mortality associated with most disease states. In the case of diabetes, for example, increased adherence to insulin allows patients to postpone or avoid long-term complications such as peripheral neuropathy, chronic kidney failure and others. Increased adherence also allows patients to avoid diabetes exacerbations that might require hospitalization or even lead to death. From a societal perspective, in addition to the health gain for the individuals who have the health condition, increased treatment adherence also helps lower overall health care costs, because costly procedures and treatments to mitigate complications can be avoided.

2. Question from Representative Haley M. Stevens (D-MI)

"Dr. Mariana Socal, one theme that has consistently come up in our discussion of drug prices is that in essentially every other country on the planet patients pay less – often much less – than Americans do for the exact same drugs. Dr. Socal, you have done quite a bit of research on this issue, and I think this Subcommittee would benefit from learning more about it. What are some of your key findings with respect to the price of drugs – including older drugs that have been on the

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Baltimore, April 30, 2020

JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

Department of Health Policy and Management

market for years – in the United States versus other countries? What are some of the reasons that other countries pay so much less?"

- Thank you so much for the opportunity of providing greater detail on this issue. My research has examined the top spending branded drugs utilized in Medicare Part D. We found that drug prices in the United States were, on average, 3.2 – 4.1 times higher than other developed countries, even after drugs rebates were considered. For each individual drug that we examined, the price differential varied from 1.3 to more than 70, meaning that a drug could be anywhere between 30% more expensive to up to 70 times more expensive in the US than in other developed countries. In addition, we found that the longer a drug was available on the US market, the greater its price differential as compared to the other countries. This happens mostly because all other developed nations have mechanisms to control the price of drugs after the drugs have been on the market for some time, which we do not have in the US. Finally, my research estimated that, if the Medicare Part D program were to adopt the average price of drugs in the reference countries that we studied, the savings to Medicare could have been greater than $72 billion in 2018 alone.[1]

Thanks again for the honor to contribute to the important work that you do. If you have any further questions, please do not hesitate to contact me.

Sincerely,

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(410) 502-9238
msocal1@jhu.edu

[1] Further information is available in my publication:
Using External Reference Pricing In Medicare Part D To Reduce Drug Price Differentials With Other Countries. Kang SY, DiStefano MJ, Socal MP, Anderson GF. Health Aff (Millwood). 2019 May;38(5):804-811. doi: 10.1377/hlthaff.2018.05207.

National
Multiple Sclerosis
Society

October 15, 2019

The Honorable Lauren Underwood
1118 Longworth House Office Building
Washington, DC 20515

Dear Rep. Underwood:

I appreciate your question regarding Medicare negotiation and would like to again thank the House Education and Labor Health, Employment, Labor, and Pensions Subcommittee for inviting me to testify at the September 26th hearing. The National Multiple Sclerosis Society believes that all stakeholders must come to the table with solutions within their industry to address the high cost of drugs for those living with multiple sclerosis (MS).

The price of MS medications is unsustainable for the country and the person living with MS who needs to access their medications to manage the MS disease course, prevent accumulation of disability and protect the brain from damage due to MS. In 2017, two of the MS disease-modifying therapies (DMTs) ranked in the top 25 medications by total spending and accounted for over $2.5 billion in total spending, according to the Centers for Medicare and Medicaid Services (CMS) dashboard. People with MS on Medicare may spend as much as $6,000 out-of-pocket just for their MS disease modifying medication (see Appendix 2).

Medicare negotiation has the potential to lower the prices of drugs for those with MS and the Lower Drug Costs Now Act (H.R. 3) is a step in the right direction. Over the past several years we have seen sharp increases in the list prices for MS medications (see Appendix 1). Many MS medications have had multiple increases over the course of a year, bringing their total increase well above inflation (see Appendix 3). In other industries we would expect the price of goods to stabilize or go down in price as technology improves and production efficiencies are realized. That has not been the experience for those living with MS.

As currently structured Part D plans negotiate with drug manufacturers--and it is clear based on the upward trajectory of prices--that this is not having the intended effect of driving down the prices of medications for those living with MS. You are correct to state that the "market's ability to negotiate lower prices isn't working in this instance." If Medicare were able to negotiate on behalf of its nearly 60 million beneficiaries, we could see real savings for the taxpayer, government, and importantly the individual living with a chronic disease like MS. Recently, the Congressional Budget Office (CBO) released a preliminary analysis of Title I of H.R. 3 and found that the negotiation provisions "would reduce federal direct spending for Medicare by $345 billion over the 2023-2029 period…The largest savings would come from lower prices for existing drugs that are sold internationally, for which the price ceiling would be binding in most but not all cases."

Title I is also unlikely to reduce access to existing medications, the analysis states that "a manufacturer that was dissatisfied with a negotiation could pull a drug out of the U.S. market entirely, though CBO expects that would be unlikely for drugs already being sold in the United States." That said, Congress needs to be mindful of the effects on newer drugs coming to market. According to CBO the reduction in manufacturer revenues "would lead to a reduction of 8 to 15 new drugs coming to market". More information is needed as to how CBO reached this assessment.

In addition to yielding savings to the federal government, it could lower the price of MS medications based on current examples of other countries that use negotiation. The House Committee on Ways and Means published a report comparing the price of MS medications in the United States with international prices. The Committee found that the "average U.S. list price for MS drugs was $769.92 per dose, compared to only $133.99 per dose internationally, making these drugs 5.75 times more expensive in the U.S. compared to the average international price".[i] The Committee report was extensive and included drugs to treat other conditions. The countries cited in the report use negotiation as a tool to lower drug prices. Importantly, H.R. 3 does not include a formulary as some countries do, but the legislation has significant enforcement mechanisms to ensure that manufacturers negotiate in good faith. We also appreciate that the legislation would apply the prices resulting in negotiation to employer and individual market plans.

One area for improvement to H.R. 3 could be including language to ensure that generic competition is not a sole reason to exclude a drug from consideration in negotiation. Currently, only one MS brand DMT has generic competition. There are two generics for this DMT, which are also expensive (especially when compared into price with traditional generics). We believe that generics with "specialty" pricing operate more like specialty medications than generics and there is an opportunity to account for this in the bill. Specifically, the Society recommends that if a drug is ranked among the top 50 spending on the CMS dashboard and has a generic competitor that is priced above $10,000 per year it shall be negotiated by the Secretary.

There are other provisions in H.R. 3 that could also help improve access and affordability for those living with MS. We are pleased to see that H.R. 3 included provisions to curb drug price increases by providing rebates for increases above the rate of inflation (CPI-U). We also support capping Part D out-of-pocket costs at $2,000. Medicare beneficiaries living with MS often reach the catastrophic phase early in the year, but still face significant cost sharing throughout the remainder of the year (see Appendix 2). Capping out of pocket costs would significantly ease their burden.

The time is now to reform Medicare Part D so that Medicare beneficiaries living with MS have access to affordable medications. H.R. 3 is a strong step in the right direction and we urge Congress to advance this legislation.

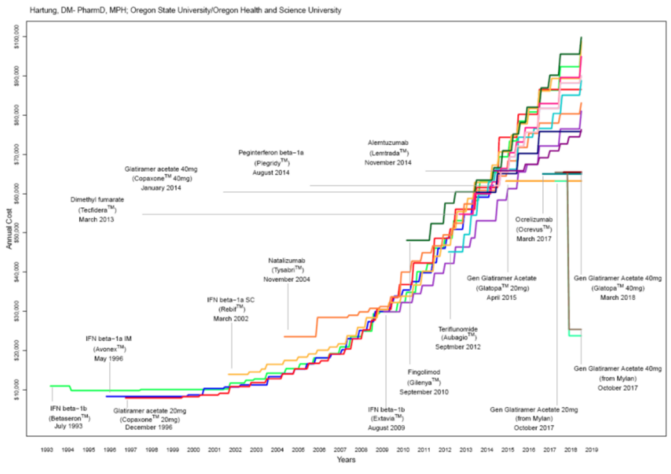
If you have any additional questions, please feel free to contact Grant Couch, Senior Director of Federal Government Relations at grant.couch@nmss.org.

Sincerely,

Bari Talente

Bari Talente, Esq.
Executive Vice President of Advocacy
National MS Society

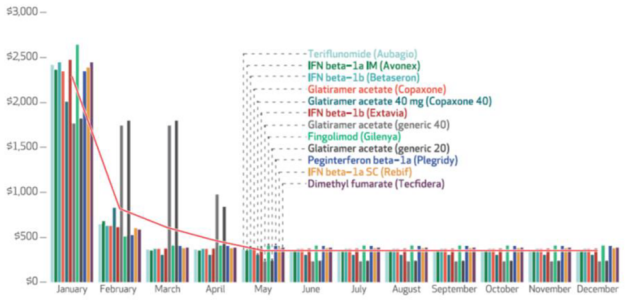
Appendix 1


Hartung, DM- PharmD, MPH; Oregon State University/Oregon Health and Science University
Annual Cost
Years
Dimethyl fumarate (Tecfidera™) March 2013
Glatiramer acetate 40mg (Copaxone™ 40mg) January 2014
Peginterferon beta-1a (Plegridy™) August 2014
Alemtuzumab (Lemtrada™) November 2014
Natalizumab (Tysabri™) November 2004
IFN beta-1a SC (Rebif™) March 2002
IFN beta-1a IM (Avonex™) May 1996
IFN beta-1b (Betaseron™) July 1993
Glatiramer acetate 20mg (Copaxone™ 20mg) December 1996
Fingolimod (Gilenya™) September 2010
IFN beta-1b (Extavia™) August 2009
Teriflunomide (Aubagio™) September 2012
Ocrelizumab (Ocrevus™) March 2017
Gen Glatiramer Acetate (Glatopa™ 20mg) April 2015
Gen Glatiramer Acetate 40mg (Glatopa™ 40mg) March 2018
Gen Glatiramer Acetate 20mg (from Mylan) October 2017
Gen Glatiramer Acetate 40mg (from Mylan) October 2017

Appendix 2

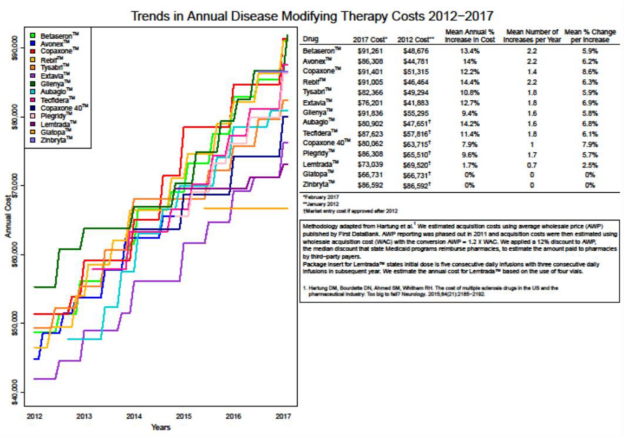
EXHIBIT 4

Projected out-of-pocket spending for beneficiaries without a low-income subsidy for multiple sclerosis disease-modifying therapies, by month, 2019



SOURCE Authors' analysis of data from the Prescription Drug Plan Formulary files of the Centers for Medicare and Medicaid Services (CMS), and CMS enrollment data in 2016 (the most recent data available); and 2019 basic Part D benefit plan parameters. Drug prices are derived from the Medicare Plan Finder, using the nationwide plan that reported the lowest retail costs in the Portland, Oregon, metropolitan area. **NOTES** The solid line is average projected out-of-pocket spending across drugs. Appendix exhibit A6 shows details by drug (see note 20 in text). IFN is interferon. SC is subcutaneous. IM is intramuscular.

Appendix 3



Drug	2017 Cost*	2012 Cost**	Mean Annual % Increase in Cost	Mean Number of Increases per Year	Mean % Change per Increase
Betaseron™	$91,261	$48,676	13.4%	2.2	5.9%
Avonex™	$86,308	$44,781	14%	2.2	6.2%
Copaxone™	$91,401	$51,315	12.2%	1.4	8.6%
Rebif™	$91,005	$46,464	14.4%	2.2	6.3%
Tysabri™	$82,366	$49,294	10.8%	1.8	5.9%
Extavia™	$76,201	$41,883	12.7%	1.8	6.9%
Gilenya™	$91,836	$55,295	9.4%	1.6	5.8%
Aubagio™	$80,902	$47,651†	14.2%	1.6	6.8%
Tecfidera™	$87,623	$57,816†	11.4%	1.8	6.1%
Copaxone 40™	$80,062	$63,715†	7.9%	1	7.9%
Plegridy™	$86,308	$65,510†	9.6%	1.7	5.7%
Lemtrada™	$73,039	$69,520†	1.7%	0.7	2.5%
Glatopa™	$66,731	$66,731†	0%	0	0%
Zinbryta™	$86,592	$86,592†	0%	0	0%

*February 2017
**January 2012
†Market entry cost if approved after 2012

Methodology adapted from Hartung et al.[1] We estimated acquisition costs using average wholesale price (AWP) published by First DataBank. AWP reporting was phased out in 2011 and acquisition costs were then estimated using wholesale acquisition cost (WAC) with the conversion AWP = 1.2 X WAC. We applied a 12% discount to AWP, the median discount that state Medicaid programs reimburse pharmacies, to estimate the amount paid to pharmacies by third-party payers.
Package insert for Lemtrada™ states initial dose is five consecutive daily infusions with three consecutive daily infusions in subsequent year. We estimate the annual cost for Lemtrada™ based on the use of four vials.

1. Hartung DM, Bourdette DN, Ahmed SM, Whitham RH. The cost of multiple sclerosis drugs in the US and the pharmaceutical industry: Too big to fail? Neurology. 2015;84(21):2185–2192.

[i] A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices. Prepared by Ways and Means Committee Staff. September 2019. https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf

[Whereupon, at 4:21 p.m., the subcommittee was adjourned.]

○