

**IMPROVING DRUG PRICING TRANSPARENCY AND
LOWERING PRICES FOR AMERICAN CONSUMERS**

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED SIXTEENTH CONGRESS

FIRST SESSION

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IMPROVING DRUG PRICING TRANSPARENCY AND LOWERING PRICES FOR AMERICAN CONSUMERS

TUESDAY, MAY 21, 2019

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:34 a.m., in the John D. Dingell Room 2123, Rayburn House Office Building, Hon. Anna G. Eshoo (chairwoman of the subcommittee) presiding.

Members present: Representatives Eshoo, Engel, Butterfield, Matsui, Sarbanes, Luján, Schrader, Kennedy, Cardenas, Welch, Ruiz, Dingell, Kuster, Kelly, Barragán Blunt Rochester, Burgess (subcommittee ranking member), Upton, Shimkus, Guthrie, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Carter, Gianforte, and Walden (ex officio).

Also present: Representative Schakowsky.

Staff present: Jacquelyn Bolen, Professional Staff; Waverly Gordon, Deputy Chief Counsel; Tiffany Guarascio, Deputy Staff Director; Josh Krantz, Policy Analyst; Una Lee, Senior Health Counsel; Aisling McDonough, Policy Coordinator; Joe Orlando, Staff Assistant; Alivia Roberts, Press Assistant; Tim Robinson, Chief Counsel; Samantha Satchell, Professional Staff Member; C. J. Young, Press Secretary; Mike Bloomquist, Minority Staff Director; S. K. Bowen, Minority Press Assistant; Margaret Tucker Fogarty, Minority Staff Assistant; Peter Kielty, Minority General Counsel; Ryan Long, Minority Deputy Staff Director; James Paluskiewicz, Minority Chief Counsel, Health; and Brannon Rains, Minority Staff Assistant.

Ms. ESHOO. Good morning, everyone. The Subcommittee on Health will now come to order. The Chair now recognizes herself for five minutes for an opening statement.

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

Last week, our subcommittee held a hearing to essentially follow the money in the drug supply chain. We came away with much valuable information, but we also found there are many secrets, secret decisions about how drugs are priced, secret deals between drug companies and the PBMs, and secret agreements between PBMs and insurers.

Today, we're considering seven bipartisan bills that essentially unmask the secrets, that secret process, and ensure that low-income seniors can afford their medications and build on the drug-pricing package passed by the House last week.

The first and very important bill ensures that seniors can afford their drugs. Representatives Cunningham and Bilirakis introduced the Creating Lower Cost Alternatives for your Prescription Drugs Act. The bill eliminates cost-sharing for generic drugs for low-income Medicare enrollees and caps their out-of-pocket costs for other drugs. Nearly 25 percent of seniors who take drugs report it is difficult for them to afford their medications. This bill will not only save seniors money, it will also help save their lives in many instances.

The second group of bills exposes how drug prices are set. The SPIKE Act, proposed by Representatives Horsford and Reed, and the Fair Drug Pricing Act, proposed by Representatives Schakowsky and Francis Rooney, require drug manufacturers to justify large spikes in drug prices.

The Reporting Accurate Drug Prices Act, proposed by Representatives Doggett and Buchanan, requires manufacturers to report the average sales price of Medicare Part B, "B" as in boy, drugs. This bill makes sure Medicare is paying the right price for Part B drugs.

The Sunshine for Samples Act, proposed by Representatives Chu and Nunes—all kinds of partners in this—directs companies to report the price and quantity of the free samples of drugs, devices, and medical supplies they give to healthcare providers. The bill does not prohibit free samples. Instead, it will help us to see how free samples influence drug pricing and distribution.

The third group of bills exposes the deals between PBMs and the other stakeholders in the drug supply chain. The Public Disclosure Act of Drug Discounts Act, authored by Representatives Spanberger and Holding, requires PBMs to report the discounts they negotiate with drug manufacturers. This transparency will help to ensure the discount is passed down through the chain to patients. To patients—I want to underscore that.

The Prescription Pricing for the People Act, authored by Representatives Nadler and Collins, directs the FTC to review PBMs' behavior and whether it is anticompetitive or not. At our hearing last week, we learned that three PBMs control the majority of the market, and those PBMs own large pharmacy chains and specialty pharmacies, and we believe that has potential conflicts of interest. With this bill, the FTC will scrutinize PBMs to ensure there are not any distortions of the market.

Last week, I said we needed to examine the system from beginning to end because, in order to fix it, we have to understand all the parts of it first, and then act. With these seven bills today, I think we are taking important action. Each bill is directed to reform the drug supply chain, and transparency is only as good as the accountability and enforcement that has to follow.

So, I want to welcome our witnesses, thank them for being here today with us. We look forward to your important testimony.

[The prepared statement of Ms. Eshoo follows:]

PREPARED STATEMENT OF HON. ANNA G. ESHOO

Last week, our Subcommittee held a hearing to follow the money in the drug supply chain. Instead of answers, we found secrets.

Secret decisions about how drugs are priced. Secret deals between drug companies and the PBMs, and secret agreements between PBMs and insurers.

Today, we consider seven bipartisan bills that unmask the secrets and ensure that low-income seniors can afford their medications. The bills build on the drug pricing package passed by the House last week.

The first and most important bill makes sure seniors can afford their drugs. Representatives Cunningham and Bilirakis introduced the Creating Lower Cost Alternatives for Your Prescription Drugs Act. The bill eliminates cost-sharing for generic drugs for low-income Medicare enrollees and caps their out-of-pocket costs for other drugs. Nearly 25 percent of seniors who take drugs report it is difficult for them to afford their medications. This bill will not only save seniors money, it can also save lives.

The second group of bills expose how drug prices are set.

The SPIKE Act, proposed by Representatives Horsford and Reed, and the FAIR Drug Pricing Act, proposed by Representatives Jan Schakowsky and Francis Rooney require drug manufacturers to justify large spikes in drug prices.

The Reporting Accurate Drug Prices Act, proposed by Representatives Doggett and Buchanan require manufacturers to report the average sales price of Medicare Part B drugs. This bill makes sure Medicare is paying the right price for Part B drugs.

The Sunshine for Samples Act, proposed by Representatives Chu and Nunes, directs companies to report the price and quantity of the free samples of drugs, devices, and medical supplies they give to healthcare providers. The bill does not prohibit free samples. Instead, it will help us see how free samples influence product pricing and distribution.

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The Public Disclosure of Drug Discounts Act authored by Representatives Spanberger and Holding requires PBMs to report the discounts they negotiate with drug manufacturers. This transparency will help to ensure the discount is passed down through the chain to patients.

The Prescription Pricing for the People Act authored by Representatives Nadler and Collins directs the Federal Trade Commission to review PBMs' anticompetitive behaviors. At our hearing last week, we learned that three PBMs control the majority of the market and those PBMs own large pharmacy chains and specialty pharmacies, a potential conflict of interest. With this bill, the FTC will scrutinize PBMs to ensure there are not any distortions of the market.

Last week I said we needed to examine the system from beginning to end because in order to fix it, we have to understand it, and then we will act. With these seven bills today, we're taking important action. Each bill is directed to reform the drug supply chain, but transparency is only as good as the accountability and enforcement that must follow.

Welcome to our witnesses and we look forward to your testimony.

Ms. ESHOO. And now I recognizes the ranking member of the Subcommittee on Health, Mr. Burgess, for five minutes for his opening statement.

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

Mr. BURGESS. I thank the chairwoman for the recognition.

We have convened this morning once again to address an issue that affects and complicates the lives of many of our constituents, that of drug pricing. When I return home to north Texas and conduct meetings in my district office, I frequently hear the very personal stories of individuals and families who are struggling to afford their medications.

Unfortunately, solving this problem is not as straightforward as you might hope. As exemplified by our recent drug supply chain

hearing, there are a number of stakeholders and they are interwoven throughout the supply chain, making up the existing convoluted system.

Our counterparts on the Ways and Means Committee have taken a first pass at addressing transparency in H.R. 2113, the STAR Act. On its face, transparency sounds like a useful and good thing. In other markets in the United States, people can shop around for goods and seek the best price or value. In healthcare, that is more easily said than done because of the intricate nature of the system, especially the drug supply chain. It is especially important that, as we evaluate this legislation, we consider the possibility of unintended consequences for both the patient and for the market.

This committee laid the groundwork in 21st Century Cures for the development and treatments and cures that really—until the passage of that bill, some of those things were science fiction and now they are becoming reality. Two and a half years after Cures was signed into law, I am receiving meeting requests from stakeholders who bring good news about how this law is producing real results for patients.

We must strike this delicate balance with the policies that we pass through this committee to ensure that they do not dampen the success or deter future investment in biomedical research and innovation. No surprise, I do have some thoughts about Section 2 of H.R. 2113, which requires a notification and public posting of companies that launch a drug at a price of \$26,000 or more. So, there are some newer therapies, and these may be a single dose or a single shot, that can cure an individual of a rare disease. The cost of research and development and clinical trials that goes into these treatments is immense. We must consider the potential impact that this requirement could have on the industry. The incentives for drug development in this space are working, but scaring companies away from investing in such drugs does not serve patients who might benefit from this innovation.

I am reminded of the comments of a former colleague who served before I got here, J. C. Watts of Oklahoma, who said, “you can attribute a lot of things to capitalism and capital, but it’s not necessarily courageous.” So, if we make it difficult, capital will go elsewhere. And yet, we want the innovations in this space. So, the FAIR Act does not include this launch-price trigger, and I think that is a good place to start.

I would also like to take a minute and express some concerns about Section 3 of H.R. 2113. This policy would require manufacturers of drugs, devices, biologics, and medical supplies to report on the samples they give to healthcare providers each year, and this information would be publicly posted. I fear that this policy could lead to a sort of public shaming of companies that are trying to benefit patients. Should such a policy deter manufacturers from providing samples to physicians, I promise you, patients will be harmed.

As a physician, I can say that I have seen the benefits of samples for patients firsthand. Sometimes a patient’s insurer requires a prior authorization process that delays the patient’s access to medication. A sample of the medication allows the patient to begin receiving timely treatment. Additionally, physicians may use samples

in clinical decision making. For example, if a new drug has come to market that may work better for a patient, the doctor can use the sample to establish whether or not the patient responds in an improved way to the new drug without subjecting the patient to financial burden or, if side effects develop, to an unnecessary purchase.

Again, I appreciate the bipartisan work that the Ways and Means Committee has done. However, we are the Energy and Commerce Committee. We should be in the vanguard. We should be in the lead. And I believe there are some areas in this policy that we need to think through a little more thoroughly.

I want to thank all of our witnesses in advance for their thoughts on this legislation, and I look forward to working in a bipartisan fashion.

I yield back my time.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Thank you, Madam Chair. We have convened this morning once again to address an issue that affects and complicates the lives of many of our constituents—drug pricing. When I return home to North Texas and conduct meetings in my district office, I frequently hear the personal stories of individuals and families who are struggling to afford their medications.

Unfortunately, solving this problem is not as straightforward as we all would hope. As exemplified by our recent drug supply chain hearing, there are various stakeholders interwoven throughout the supply chain, making up the existing convoluted system. Our counterparts on the Ways and Means Committee have taken a first pass at addressing transparency in H.R. 2113, the STAR Act.

On its face, transparency sounds like a useful and good thing. In other markets in the United States, individuals can shop around for goods and seek the best price or value. In healthcare, that is more easily said than done because of the intricate nature of the system, especially the drug supply chain. It is especially important that as we evaluate this legislation we consider the unintended consequences for both the patient and the market.

This Committee laid the groundwork in 21st Century Cures for the development of treatments and cures that Americans have, until now, only dreamed were possible. Nearly two and a half years after Cures was signed into law, I am receiving countless meeting requests from stakeholders who bring good news about how this law is producing real results for patients. We must strike a delicate balance with the policies we pass through this Committee to ensure they do not put a damper on this success or deter investment in biomedical research and innovation.

I do have some thoughts about Section 2 of H.R. 2113, which requires a notification and public posting of companies that launch a drug at a price of \$26,000 or more. There are one-shot therapies that can cure individuals of rare diseases, and the cost of research and development that goes into these treatments is immense. We must consider the potential impact that this requirement could have on the industry. The incentives for drug development in this space are working and scaring companies away from investing in such drugs does not serve patients who might benefit from this innovation. I am pleased that Ms. Schakowsky's FAIR Act does not include this launch price trigger.

I would also like to take a minute to express some concerns about Section 3 of the H.R. 2113. This policy would require manufacturers of drugs, devices, biologics, and medical supplies to report on the samples they give to healthcare providers each year, and this information would be publicly posted. I fear that this policy too could lead to a sort of public shaming of companies that are trying to benefit patients. Should such a policy deter manufacturers from providing samples to physicians, patients will be harmed.

As a physician, I can say that I have seen the benefit of samples for patients firsthand. Sometimes a patient's insurer requires a burdensome prior authorization process that delays a patient's access to medication. A sample of the medication allows the patient to receive more timely treatment. Additionally, physicians may use samples in clinical decision making. For example, if a new drug has come to market that may work better for a patient, a physician can use a sample to establish wheth-

er or not the patient responds better to the new drug without subjecting the patient to whatever the financial burden of the drug may be.

Again, I appreciate the bipartisan work that the Ways and Means Committee has done, but I do believe that there are some areas of this policy that we need to think through thoroughly. Thank you to our witnesses for offering their thoughts on this legislation, and I look forward to working on this in a bipartisan manner.

Ms. ESHOO. The gentleman yields, and I thank him for his opening statement.

I now would like to recognize the gentleman from South Carolina, who is going to offer the chairman of the full committee's opening statement.

Mr. BUTTERFIELD. Thank you, Ms. Eshoo.

Let me correct the record. I am from North Carolina.

Ms. ESHOO. I am sorry.

Mr. BUTTERFIELD. I know you Californians, whenever you hear the word "Carolina," you think of the South.

Ms. ESHOO. Well, we have north and south in California, too. So, I should have been—I am sorry for not being accurate.

Mr. BUTTERFIELD. Thank you for your friendship.

Ms. ESHOO. A great State.

Mr. BUTTERFIELD. Thank you.

Ms. ESHOO. The great State of, right?

[Whereupon Mr. Butterfield read Mr. Pallone's statement.]

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

Mr. BUTTERFIELD. Thank you, Ms. Eshoo, for holding this latest hearing in our series on prescription drug pricing. I say "latest hearing" because this is not the first and certainly will not be the last.

Democrats are serious about the problem of rising drug prices. It is a complicated problem, I acknowledge that. Its consequences are very far-reaching.

I represent the 1st District of North Carolina, where many hard-working families are struggling every day to afford the basic necessities of life. Steep price hikes have the potential to force these communities into decisions between paying their bills and purchasing medications that are vital to their health. All too often, these circumstances result in rationing prescription drugs or the abandonment of treatment altogether.

And so, Madam Chair, I have long held that quality and affordable healthcare is a basic necessity, a right that every American must have equal access. Consumers should be able to anticipate the price of their prescriptions and must be able to rely on those prices to remain stable from year to year.

All of us understand that corporations exist to make a profit. I have acknowledged that in many hearings and I understand that dynamic. Pharmaceutical investment and innovation have led to unprecedented breakthroughs in treatments that have improved health outcomes and patient quality of life.

However, unlike most consumer products, for many a prescription is the literal difference between life and death. Therefore, the need to fund new innovations must be balanced. It must be bal-

anced with the obligation to make medications widely available and affordable to the public.

And so, we find ourselves here today, hopefully in a bipartisan way, in pursuit of that goal; as Congress continues to work with every entity along the pharmaceutical supply chain to find practical solutions to the pricing issue that both support innovation and reduce costs for consumers.

I look forward to today's discussion. I thank those who have authored these amendments. And, in particular, I thank the gentlelady from Illinois for her passion and her leadership on this issue.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Thank you, Chairwoman Eshoo, for holding this latest hearing in our series on prescription drug pricing.

The problem of rising drug prices is a complicated one and its consequences are far reaching. I represent the First District of North Carolina, where many hard-working families are struggling to afford basic necessities like housing, childcare, and more than ever, their prescription drugs.

Steep price hikes have the potential to force these communities into decisions between paying their bills and purchasing medications that are vital to their health. All too often these circumstances result in rationing prescriptions or the abandonment of treatment altogether.

I have long held that quality and affordable healthcare is a basic necessity, a right that every person in the United States must have equal access to. Consumers should be able to anticipate the price of their prescriptions and must be able to rely on those prices to remain stable from year to year.

All of us understand that corporations exist to make a profit. Pharmaceutical investment and innovation have led to unprecedented breakthroughs in treatment that have improved health outcomes and patient quality of life. However, unlike most consumer products, for many, a prescription is the literal difference between life and death. Therefore, the need to fund new innovations must be balanced with the obligation to make medications widely available and affordable to the public.

We find ourselves here today in pursuit of that goal as Congress continues to work with every entity along the pharmaceutical supply chain to find practical solutions to the pricing issue that both support innovation and reduce costs for consumers. I look forward to today's discussion.

Ms. ESHOO. I yield at this time to the gentlelady from Illinois, Ms. Schakowsky.

OPENING STATEMENT OF HON. JAN SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. I thank the gentleman for yielding. And I thank the chairwoman of this subcommittee for allowing me to wave on to this hearing on a topic so important to all of us.

The pharmaceutical industry is worth almost \$1 trillion, and I believe they are holding American consumers hostage. Our constituents are suffering and some are dying—we actually have the names of the dead, some of them—because they can't afford life-saving and life-enhancing drugs that they need.

And why have drug prices skyrocketed, sometimes a thousand percent? Well, that is a really good question. And because drug companies have hidden the price policies, consumers have no choice but to pay the price, if they can—until now. My legislation, the Fair Drug Pricing Act, H.R. 2296, is a bipartisan, bicameral bill

that will force the drug companies to be transparent, which is the very least that we can expect from them.

The bill does two things. Pharmaceutical manufacturers must notify HHS and submit a transparency and justification report 30 days before they raise the price of certain drugs by more than 10 percent or by more than 25 percent over three years. The report will require manufacturers to provide the manufacturing, research, and development costs for the drug, net profits attributed to the drug, marketing and advertising spending on drugs, and others.

Unlike H.R. 2069, the SPIKE Act, which is also being considered today, my bill does not allow manufacturers to pick and choose what information that they would like to disclose. And unlike the SPIKE Act, my bill requires HHS to make all of the nonproprietary information from these reports' public and available to everyone online for everyone to see.

For the first time ever, this bill will offer taxpayers nationwide notice of price increases and bring basic transparency to the market for prescription drugs. The bills being considered today are only a start, and transparency is only a piece of the puzzle in bringing down the cost of prescription drugs.

These bills are all bipartisan, and I am proud that Representative Rooney joined me in reintroducing this. Senator Baldwin and Senator Braun in the Senate are also doing this bill. So, I hope that we will have positive consideration of it.

And let me also enter into the record a very important letter from the National Multiple Sclerosis Society, representing people who are having trouble paying for the spiked prices in their drugs.

I yield back.

[The prepared statement of Ms. Schakowsky follows:]

PREPARED STATEMENT OF HON. JAN SCHAKOWSKY

And thank you to both the Chairman and Subcommittee Chair for allowing me to waive on to this hearing on a topic that is deeply important to me.

PhRMA is opposed to any legislation that would require pharmaceutical manufacturers to provide basic transparency to the American people.

The pharmaceutical industry is worth almost ONE TRILLION dollars and they are holding American consumers hostage.

Our constituents are suffering, and some are dying.

We have their names.

Because they can't afford the live-saving, life enhancing drugs they need.

Why have drug prices skyrocketed?

Sometimes by 1000 percent?

That's a really good question.

And because drug companies hide their pricing policies, consumers have no choice but to pay the price.

Until now.

My legislation, the FAIR Drug Pricing Act, H.R. 2296, is a bipartisan, bicameral bill that will force the drug companies to be transparent-which is the least we can expect from them.

The bill does two things.

Pharmaceutical manufacturers must notify HHS and submit a transparency and justification report 30 days before they increase the price of certain drugs by more than 10 percent-or by more than 25 percent over three years.

The report will require manufacturers to provide:

- the manufacturing, research and development costs for the drug;
- net profits attributable to the drug;
- marketing and advertising spending on the drug;
- and other information that the Secretary decides is necessary.

Unlike H.R. 2069, the SPIKE Act, which is also being considered today, my bill does not allow manufacturers to pick and choose what information they would like to disclose.

And unlike the SPIKE Act, my bill requires HHS to make ALL of the non-proprietary information from these reports publicly available online for anyone to access.

For the first time ever, this bill will offer taxpayers nationwide notice of price increases and bring basic transparency to the market for prescription drugs.

The bills being considered today are only a start, and transparency is only one piece of the puzzle in bringing down the cost of prescription drugs.

These bills are all bipartisan, and I am proud that Representative Rooney joined me to reintroduce my bill this Congress.

Senator Baldwin reintroduced the FAIR Drug Pricing Act in the Senate earlier this month and was also joined by Senator Braun.

The American people are crying out.

Prescription drug prices are literally killing them.

We must act, and we are being given the opportunity to do so right now.

When the FAIR Drug Pricing Act passes, PhRMA will finally have to answer to the American people.

I believe that we have a responsibility to protect and serve the best interests of the American people.

Not the interests of extraordinarily wealthy pharma executives and Wall Street investors.

Ms. ESHOO. The gentlewoman yields back. And now, I would like to recognize the ranking member of the full committee and offer my condolences to him on your Trailblazers. They played well, but not good enough.

[Laughter.]

Mr. WALDEN. Really? This is how we are going to start?

[Laughter.]

Yes. Boy, and I was going to say nice things about you this morning.

[Laughter.]

Ms. ESHOO. The gentleman is recognized for five minutes for his opening statement.

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

Mr. WALDEN. It was tough in overtime last night.

Ms. ESHOO. It was. It was.

Mr. WALDEN. And it was close.

Ms. ESHOO. It was a great game.

Mr. WALDEN. "Close" only counts in horseshoes, not basketball, but we appreciate that, Madam Chair. Yes, thanks for that reminder this morning.

[Laughter.]

Now let's get on about our serious business.

Patients need our help. They need our help to force down the price of their medical care, especially when it comes to the cost of drugs. And what good is a prescription if a patient cannot afford to pay for their medicine? I mean, that is how it kind of comes down. Drug pricing is, obviously, of great concern to all Americans and to our President. It has come up at nearly every one of the 20 town halls I have done so far this year in my district. Blockbuster drugs come with budget-busting prices.

Too often, prices continue to rise, and while there are numerous reasons given, patients rely on these medications. When market forces weaken or fail, then we need to step in with Federal common-sense legislation.

And we have taken steps recently by passing into law a requirement that companies pay the proper rebate under the Medicaid program. We have passed the Orange and Purple Book reforms on the House Floor. And while I remain dismayed by the unnecessarily partisan approach, when the bill came to the floor, we did reach agreement here through bipartisan negotiations on several other provisions that will increase the availability of generic drugs.

This subcommittee has also built off the foundation we laid last Congress by examining how the Medicare program pays for drugs and peeling back the layers of pharmaceutical pricing and supply chain. And I thank the Chair for her leadership in that regard.

I am glad we are examining legislation I hope we can find bipartisan agreement on, but we must also ensure that in these efforts we are actually pursuing policies that will provide a benefit for patients. We have got to put the patient first. We need to ensure that, as we work to shine a light on how drugs come to market and are priced, that we realize that the market must also be sustainable to produce the next generation of cures and treatments.

We are living in an amazing time of innovation. It is producing cures for conditions we didn't even have a name for 30 years ago. The promise of what lies ahead is truly staggering in their ability to relieve human suffering from conditions from hemophilia, to sickle cell, to muscular dystrophy. We are on the cutting edge of solving all of those.

So, in our efforts to bring more transparency to the system, which I support, we must inherently first do no harm. For example, I am concerned that provisions of some of the bills before us could actually allow manufacturers to back in the rebates paid by their competitors or allow wholesaler stockpiling that could lead to shortages in an attempt to provide notification of price increases.

As I mentioned, this committee has been a leader, a leader in encouraging the innovation that patients are benefitting from today through our work on the FDA user fees and from the work to pass the 21st Century Cures, led by my friend and colleague, Fred Upton. While the results of those efforts are truly remarkable, we also know that the cost of bringing a drug to market, especially one that targets an orphan or neglected disease, is high. We cannot ignore that. We should not randomly categorize as bad actors those who have done what this committee has, frankly, encouraged them to do, investing in cutting-edge therapies like gene editing and regenerative medicine, because their list price is over an arbitrary amount. Because I can tell you, these new drugs improve or save lives, and that is better than investing in just another me-too drug.

In that light, I believe any policies pursued by this committee must put the patient front and center. That is why, as currently drafted, I am concerned about some of the policies that could have the risk of decreasing the ability of physicians to provide patients samples of drugs, to help those who cannot afford their medication, those who have prior-authorization or coverage issues, from starting treatment, to inform medical judgment, or help patients manage side effects related to their current medication. Now I think working in a bipartisan spirit, as we have done before, with the help of our witnesses today, I am hopeful we can address these concerns.

And on a final note, thanks to Chairman Eshoo and thanks to Chairman Pallone for exercising our committee's jurisdiction on these bills. That is important, too. While most have been marked up by other committees, we are, after all, the committee of primary jurisdiction.

So, with that, Madam Chair, thanks for the hearing. Thanks for your condolences on the Blazers. And I will yield back the balance of my time.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Patients need our help to force down the price of their medical care, especially when it comes to the cost of drugs. What good is a prescription if a patient cannot afford to pay for their medicine?

Drug pricing is of great concern to all Americans. It's come up at nearly every one of the 20 town halls I've held this year in my district. Blockbuster drugs come with budget-busting prices. Too often prices continue to rise, and while there are numerous reasons given, patients rely on these medications. When market forces weaken or fail, then we need to step in with federal, commonsense legislation.

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In that light I believe any policies pursued by this committee must put the patient front and center. That is why as currently drafted I am concerned about policies that could have the risk of decreasing the ability of physicians to provide patients samples of drugs to help those who cannot afford their medication, those who may have prior authorization or coverage issues from starting treatment, to inform medical judgement or help patient's manage side effects related to their current medication.

Working in a bipartisan spirit, with the help of our witnesses today, I'm hopeful we can address my concerns.

On a final note, thanks to you, Chairwoman Eshoo and Chairman Pallone for exercising our Committee's jurisdiction on these bills. While most have been marked up by other committees, we are the committee of primary jurisdiction.

Ms. ESHOO. I thank the gentleman and he yields back.

I would like to remind all Members that, pursuant to committee rules, all Members' written opening statements shall be made part of the record.

I now would like to introduce our witnesses that have willingly come forward today, and we appreciate each one of you being here.

Ms. Lisa Joldersma—did I pronounce your name correctly? Is here. She is the senior vice president, insurance and State issues, for the Pharmaceutical Research and Manufacturers of America.

And her son Garrett is here with us, too. So, I hope you find this interesting, Garrett. If nothing else, you will know the complicated business your mother is in. So, welcome to both of you.

Ms. Kristin Bass, the chief policy and external affairs officer with the Pharmaceutical Care Management Association, welcome to you.

Dr. Madelaine Feldman, she is the president of the Coalition of State Rheumatology Organizations, the Alliance of Specialty Medicine. Thank you to you.

Mr. Frederick Isasi, executive director of Families USA, welcome to you.

Dr. Mark Miller, the executive vice president of healthcare, Arnold Ventures, welcome to you, sir.

And Dr. Douglas Holtz-Eakin, president of the American Action Forum, welcome to you.

And our thanks to each one of you again for joining us today.

At this time, the Chair will recognize each witness for five minutes. So, the light that means the most is the red light. That means, like when you are driving, you stop.

I think several of you have already testified. So, you know what the system is.

Now I would like to call on Ms. Joldersma. You are recognized for five minutes for your testimony, and we thank you again for being here with us today. You may begin.

STATEMENTS OF LISA JOLDERSMA, SENIOR VICE PRESIDENT, INSURANCE AND STATE ISSUES, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; KRISTIN BASS, CHIEF POLICY AND EXTERNAL AFFAIRS OFFICER, PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION; MADELAINE FELDMAN, M.D., PRESIDENT, COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS, ALLIANCE OF SPECIALTY MEDICINE; FREDERICK ISASI, JD, MPH, EXECUTIVE DIRECTOR, FAMILIES USA; MARK MILLER, PH.D., EXECUTIVE VICE PRESIDENT OF HEALTHCARE, ARNOLD VENTURES; AND DOUGLAS HOLTZ-EAKIN, PH.D., PRESIDENT, AMERICAN ACTION FORUM

STATEMENT OF LISA JOLDERSMA

Ms. JOLDERSMA. OK. Thank you very much and good morning, distinguished members of the subcommittee. And thank you, Chairman Pallone, Chairwoman Eshoo, Ranking Member Walden, and Ranking Member Burgess, for the invitation to testify today.

I am Lisa Joldersma, and I am senior vice president at the Pharmaceutical Research and Manufacturers of America, or PhRMA. As

many of you know, PhRMA represents the leading research-based biopharmaceutical companies.

Since the year 2000, our companies have collectively invested half a trillion dollars in the search for new treatments and cures, including more than \$70 billion in 2017, which I would note is an amount twice the entire operating budget of the NIH. These investments yield breakthroughs and continuous progress against both chronic and acute conditions.

Creating, discovering, and developing a new therapy is a challenging, high-risk endeavor, with just 12 percent of those molecules that enter clinical trials ultimately securing FDA approval. In other words, of those molecules entering the clinical trial phase, 9 times out of 10 we fail, and it is not for lack of trying. The average cost to develop a new medicine is \$2.6 billion, and the entire process takes an average of 10 to 15 years from start through FDA approval. Despite these difficult odds and increasingly challenging science, PhRMA members persist, supported by private investment, and in collaboration with others, including the NIH.

While medicine's importance to healthcare has grown considerably over the years, the share of U.S. healthcare spending attributed to drugs has been largely stable. Prescription drugs consume roughly 14 percent of national health expenditures today. That includes both drugs dispensed at retail and administered in the hospital, and these are CMS numbers from the National Health Expenditures data.

Growing reliance on generic medicines, which currently represent 90 percent of all prescriptions filled in this country, is a key element to keeping our prescription drugs system affordable overall. And I would note that growth in biosimilars, thanks to the leadership of many on this committee, is expected to further help constrain costs moving forward.

And yet, patients are really, really struggling to afford their medicines. And I want to be really clear today that, for our part, PhRMA accepts that a product's list price does influence what patients pay. In today's world of multi-tiered formularies, drug exclusion lists, and rising cost-sharing, however, there are other entities that play a significant role in what patients pay as well.

PhRMA is focused on changing the status quo and bringing forward solutions that will sustain innovation, ensure safety, and help patients. For too many patients today, even those with insurance, they are struggling to afford their medicines, as you all know well. This is the most pressing issue that we need to work collectively to solve.

With regard to specific measures before the subcommittee today, I will say that PhRMA supports greater transparency across the healthcare system. We believe our industry already makes a fair amount of information publicly available, but we do understand that policymakers and purchasers are looking for more from us. We will come to the table to help shape meaningful transparency across the drug supply chain.

When evaluating alternative proposals, we really have three questions in mind that help shape specific feedback that we provide. First, is the measure likely to yield information that will be helpful or meaningful to patients? Always patients first. Second,

does the measure give companies a reasonable opportunity to comply? Is it prospective in nature? And finally, are there appropriate protections for confidential and proprietary information, so we can prevent harmful interference in the market?

In closing, I would like to say that we do believe greater transparency is an important part of the solution to the problems we are discussing today, but they will not be enough on their own. We also need to take steps to promote competition, to address misaligned incentives in our current system, and to explore ways to make insurance work better for sick patients who need today's medicines and those who are waiting for tomorrow's.

Thank you very much.

[The prepared statement of Ms. Joldersma follows:]

**Testimony of Lisa Meengs Joldersma
Senior Vice President
Pharmaceutical Research and Manufacturers of America**

**Hearing on “Improving Drug Pricing Transparency and
Lowering Prices for American Consumers”**

**United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health
May 21, 2019**

Good morning and thank you Chairwoman Eshoo, Ranking Member Burgess, and distinguished Members of the Subcommittee for inviting the Pharmaceutical Research and Manufacturers of America (PhRMA) to testify at today’s hearing. I am Lisa Joldersma, Senior Vice President at PhRMA, and I am honored to be here before you today.

At biopharmaceutical companies across America, people go to work every day with the mission of advancing innovative treatments and cures that will make a difference in millions of patients’ lives. Since 2000, PhRMA’s member companies have invested half a trillion dollars in the search for innovative treatments and cures,ⁱ including more than \$71 billion in 2017 alone. These investments have helped transform the way we think about disease prevention and management, and in recent years have brought forth curative therapies and pioneering approaches to defeating sickness and disease. Today there are about 7,000 medicines in development.ⁱⁱ Of those medicines in the pipeline, an estimated 74 percent have the potential to be first-in-class treatments.ⁱⁱⁱ

These innovations typically happen through years of collaborative biomedical research, with biopharmaceutical companies playing a central role. The level of risk undertaken by biopharmaceutical innovators often is overlooked, but the fact is that just 12 percent of medicines entering clinical trials are ultimately approved by the Food and Drug Administration (FDA). In other words, almost 9 in 10 fail – and this excludes all the candidates that never even reach the clinical trial stage. One estimate of the cost to develop a new medicine projects it to be \$2.6 billion when accounting for the need to recoup the cost of failures.

Continued advances in medicines are indispensable to addressing some of our society's biggest health and economic challenges. While medicines' role in effective health care has grown and many new treatments and cures have been brought to patients over the years, medicines have remained a consistent 14 percent of total United States (U.S.) health spending.^{iv} However, even though net costs for brand medicines are growing at the slowest rate in years, patients often are unable to access the therapies they need due to cost burden.

Many factors impact what a patient pays for medicine. A product's list price – or “wholesale acquisition cost” – is one factor, but other factors are also important, including insurance plan design, formulary placement, and whether there are assistance programs available. PhRMA applauds the subcommittee for ongoing interest in making prescription drugs more accessible and affordable for all Americans. PhRMA shares that goal. Thank you for bringing a broad range of stakeholders to the table for these important discussions – both today and at last week's hearing.

Transparency

Several of the measures highlighted for discussion today call for greater transparency from manufacturers and pharmacy benefit managers. PhRMA supports greater transparency across the health care market. In fact, we have taken steps – voluntarily – to provide public access to information that patients may need or want when making health care decisions. Our Medicine Assistance Tool, or MAT, is an online platform that complements our member companies' new approach to direct-to-consumer (DTC) television advertising announced in October 2018. As part of this effort, the PhRMA board of directors adopted enhancements to its voluntary DTC principles to state that “[a]ll DTC television advertising that identifies a prescription medicine by name should include direction as to where patients can find information about the cost of a medicine, such as a company-developed website, including the list price and average, estimated, or typical patient out-of-pocket costs, or other context about the potential cost of the medicine.” MAT provides patients, caregivers and providers with links to these new websites and includes a search engine to connect patients with medicine-specific financial assistance programs. In addition, MAT has resources to help patients navigate their insurance coverage, found at www.MAT.org.

PhRMA recognizes that many policymakers have already taken steps towards legislating greater transparency for manufacturers. We would not presume that MAT is a substitute for those approaches or that it will satisfy individual every member's goals. We do hope, however, that it demonstrates the sincerity with which PhRMA enters this discussion. We are committed to working with Congress to take meaningful steps to address patient concerns.

When considering legislative approaches to transparency – including the several states that have passed or considered transparency measures – three, high-level questions help shape PhRMA's thinking. First, is the proposal likely to yield information that will be meaningful or useful to patients? Second, does the proposal give individual manufacturers clear notice about the scope of information at issue and would it be reasonable to implement? And third, is there adequate protection for confidential and proprietary information or could there be unintended consequences in the market as a result of the disclosure of certain types of information? PhRMA also strongly believes that transparency efforts should look beyond manufacturers and consider the role several other entities play in shaping drug spending, including pharmacy benefit managers (PBMs), health insurers, and even hospitals.

Additional reforms needed to promote affordability for patients

Greater transparency can help promote better decision making and affordability, but two additional – and more significant – issues could negatively impact affordability for patients: misaligned incentives in the prescription drug distribution and payment system, and increased shifting of costs onto patients.

Many Patients Do Not Directly Benefit from Significant Price Concessions in the Market Today

Since the beginning of the Medicare Part D program in 2006, it has been a resounding success. According to Congressional Budget Office (CBO) estimates, total Part D costs were 45 percent (\$349 billion) lower than projected for the initial 2004 to 2013 forecast period.^v Average monthly beneficiary premiums are \$32.50 in 2019,^{vi} substantially lower than the \$54.47 originally projected.^{vii} Powerful Part D purchasers negotiate discounts and rebates with manufacturer and the Medicare Trustees report that “many brand-name prescription drugs carry substantial rebates,”^{viii} which have increased each year of the program.^{ix} However, patients do not always benefit directly from these rebates in the form of lower cost sharing, resulting in

affordability challenges for some Part D beneficiaries taking brand-name medicines with large manufacturer discounts.

To improve patient affordability, more of the discounts and rebates insurers and PBMs negotiate with biopharmaceutical companies should be shared directly with patients at the point-of-sale. Once medicines are researched, developed, and approved for use, the process by which prescription medicines move from biopharmaceutical manufacturers to patients involves multiple stakeholders and numerous financial transactions. This process has evolved significantly in recent years, as supply chain entities have grown to play a larger role in drug distribution and payment. In fact, three large, sophisticated PBMs manage more than 75 percent of all prescriptions filled.^x They use brand competition to obtain discounts from manufacturers and take full advantage of the presence of generics to drive savings. In fact, the use of generic medicines, which accounts for 90 percent of prescription medicines dispensed in the U.S., saved \$1.79 trillion between 2008 and 2017,^{xi} and these dynamics will continue to produce savings. Between 2019 and 2023, competition from generics and biosimilars is expected to result in an estimated \$105 billion reduction in U.S. brand sales.^{xii} Additionally, biosimilar competition in the biologics market will increase substantially over time as the market matures.^{xiii} There is no similar type of cost containment for other health care services.

Consolidation and increased negotiating power give middlemen like PBMs leverage to extract growing price concessions from manufacturers. The magnitude of these rebates, discounts, and other reductions in price have more than doubled since 2012, totaling over \$166 billion in 2018.^{xiv} For certain medicines used to treat chronic conditions like asthma, high cholesterol, hepatitis C, and diabetes, these discounts and rebates can reduce list prices by as much as 30 to 70 percent.^{xv} According to a study by the Berkeley Research Group, on average, more than one-third of the initial list price of a brand medicine is rebated back to insurance companies, PBMs, and the government, or retained by other stakeholders along the biopharmaceutical supply chain.^{xvi}

Even though payers often receive deep discounts on a brand medicine's price, they rarely directly pass along those savings to the patients obtaining those medicines at the pharmacy counter. Instead, health plans typically use some portion of negotiated rebates to reduce premiums for all enrollees. As the actuarial firm Milliman has pointed out, this dynamic results

in a system of “reverse insurance” where payers require sicker patients using brand medicines with rebates to pay more out-of-pocket, while rebate savings are spread out among all health plan enrollees in the form of lower premiums.^{xvii} Asking sicker patients with high medicine costs to subsidize premiums for healthier enrollees is the opposite of how health insurance is supposed to work.

This problem is particularly striking for patients with diabetes taking insulin. Robust competition among insulin manufacturers has resulted in increasing levels of discounts and rebates that have kept net prices flat to declining over the past several years.^{xviii} That is because payers leverage competition among a broad range of long-, short-, rapid-acting insulin to negotiate lower prices. These dynamics can lower the net price of insulin by 70 percent or more.^{xix, xx} Although media reports commonly give the false impression that biopharmaceutical companies retain all revenue from list price increases, flat net price growth indicates that all or almost all of insulin list price increases are returned to payers, the government, and other medicine supply chain entities through rebates, fees, or other discounts.

While robust competition in the market has been successful in constraining net prices for insulins, government and industry analysts have observed that supply chain intermediaries may have incentives to favor medicines with high list prices and large rebates,^{xxi} leading to affordability challenges for patients who pay cost sharing based on the list price. Helping patients access the treatments they need by passing through rebates at the point-of-sale to reduce patient cost sharing could improve medicine adherence for conditions like diabetes, which could ultimately generate savings by reducing costly avoidable health complications. A recent study by IHS Markit found that passing through a share of rebates to Medicare Part D patients taking diabetes medicines could reduce overall health care spending (including spending in Parts A and B) for Medicare beneficiaries with diabetes by \$20 billion over the next 10 years.^{xxii}

A proposed rule from the U.S. Department of Health and Human Services’ (HHS) Office of the Inspector General (OIG)^{xxiii} is an important step towards an improved Part D program. OIG reports that, on average, Medicare Part D beneficiaries who do not receive low-income subsidies (LIS) would pay 10 to 19 percent less in cost sharing over the next 10 years under the Administration’s proposed system to encourage upfront discounts.^{xxiv} And patients who take brand medicines with relatively large rebates, such as medicines for diabetes, would be likely to

see larger-than-average reductions in out-of-pocket costs because they would now directly benefit from those rebates.^{xxxv}

The principles underlying the OIG's proposed rule to reform the rebate system could restore payers' incentives to favor lower cost medicines while strengthening incentives to negotiate deep discounts on medicines. In the absence of the existing rebate system, Part D plans would still have strong incentives to minimize costs. As Milliman notes, plans would be incentivized to achieve lower net costs to minimize premium increases and maintain LIS auto-enrollment.^{xxxvi} Actuaries have also suggested that under the changes proposed by the OIG, some manufacturers "may have more success marketing biosimilars in Part D if manufacturer rebates are eliminated," due to the incentives for plans to achieve lower net costs.^{xxxvii}

Increased Cost-Shifting to Patients

A growing distortion in the market is the increased shifting of costs to patients. Patients pay cost sharing for health care services, including prescription medicines, through deductibles, copays, and coinsurance. When a patient fills a prescription in the deductible phase, the patient pays the entire list price of the medicine up to the deductible amount. Patients with copays pay a fixed amount for each prescription (e.g., \$30), while those with coinsurance pay a percentage of the medication's total list price (e.g., 30 percent).

In the last decade, in the commercial market, the share of patient out-of-pocket drug spending represented by coinsurance has more than doubled, while the share accounted for by deductibles has tripled.^{xxxviii} Since 2006, deductibles for patients in employer health plans have increased by 300 percent.^{xxxix} Patient out-of-pocket spending on coinsurance has increased 67 percent while spending on copays has decreased.^{xxx} The share of employer health plans requiring a deductible for prescription medicines has more than doubled from 23 percent in 2012 to 52 percent in 2017.^{xxxi} As one recent analysis shows, patients are required to pay 12 percent of overall pharmaceutical costs versus only 4 percent of hospital costs – even though medicines can help keep patients out of the hospital.^{xxxii}

Deductibles and coinsurance leave patients with high and often unpredictable costs, particularly for their medicines. Average commercially insured patient out-of-pocket costs for deductible and coinsurance claims for brand medicines are much higher than copay claims.^{xxxiii} In 2017,

more than half of commercially insured patients' out-of-pocket spending for brand medicines was for medicines filled while a patient was in the deductible or with coinsurance, an increase of 20 percent from 2013.^{xxxiv} Patients with chronic conditions are disproportionately impacted by high out-of-pocket costs.^{xxxv}

In Medicare Part D, there has been a substantial increase in the use of coinsurance and complex, multi-tiered formularies. Today, 93 percent of stand-alone Part D plans (PDPs) use formularies with five coverage tiers, and 7 percent are now using a sixth tier.^{xxxvi} The percentage of Part D drugs subject to coinsurance jumped by nearly 20 percentage points between 2016 and 2019. Today, 62 percent of all medicines covered by PDPs are covered on a coinsurance tier.^{xxxvii}

When patients receive medical care from an in-network hospital or physician, deductible and coinsurance payments are based upon discounted rates negotiated between the health plan and the provider. Yet this is not the case for prescription medicines. Health plans (and the PBMs that represent them) negotiate discounts on brand medicines, but the discounts are usually given in the form of rebates paid directly to the health plan or PBM after the prescription is purchased by the patient. These discounted prices are not available to patients with deductibles or coinsurance at the time they fill prescriptions; instead, their cost sharing is generally calculated by the health plan based on the medicine's full list price.

Research shows that rebates paid by biopharmaceutical companies often substantially reduce the list prices of brand medicines.^{xxxviii} However, since list prices do not reflect rebates, these savings are not directly passed on to patients through lower cost sharing, and patients' out-of-pocket costs for prescriptions filled in the deductible or with coinsurance are higher than they otherwise would be if instead they were based on the discounted cost of the medicine. Thus, the growing use of deductibles and coinsurance for medicines has exposed patients to undiscounted list prices and created affordability challenges for many.^{xxxix}

As the Subcommittee continues its work on policy solutions to help drive greater transparency and prescription drug affordability, we hope there remains an unwavering commitment to biomedical innovation. We urge the Committee to avoid overly broad policies that may seem designed to "shame" manufacturers while doing little to make prescriptions more affordable for

patients. PhRMA appreciates the opportunity to testify and looks forward to continuing to engage with the Committee on these critically important issues.

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- ⁱ PhRMA annual membership survey, Washington DC: PhRMA, 2007-2017.
- ⁱⁱ Adis R&D Insight Database, June 2018.
- ⁱⁱⁱ Analysis Group, The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development, July 2017.
- ^{iv} Altarum Institute. Projections of the prescription drug share of national health expenditures including non-retail. May 2018.
- ^v Congressional Budget Office. April 2014 Medicare Baseline, and CBO Medicare baselines for 2004-2013.
- ^{vi} CMS Press Release. "Medicare Part D Premiums Continue to Decline in 2019." July 2018.
- ^{vii} 2010 Medicare Trustees Report, Table V.C2, p. 234.
- ^{viii} See 2018 Medicare Trustees Report, p. 144, footnote 66.
- ^{ix} See 2014 Medicare Trustees Report, p. 150, footnote 63; 2018 Medicare Trustees Report, p. 143, Table IV. B8; and Medicare Trustees Reports for 2007 through 2016.
- ^x Fein AJ. Drug Channels Institute. 2014-15 Economic Report on Retail, Mail, and Specialty Pharmacies. January 2015.
- ^{xi} Generic Pharmaceutical Association. Generic Drug Savings in the U.S. 2018.
- ^{xii} IQVIA. Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023. May 2019.
- ^{xiii} IQVIA. 2019 Global Use and Spending on Medicine. January 2019.
- ^{xiv} Fein AJ. "Don't Blame Drug Prices on 'Big Pharma'." Wall Street Journal. February 2019.
- ^{xv} Quintiles IMS Institute. "Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates." October 2016; Gronholt-Pedersen J, et al. "Novo Nordisk Defends U.S. Diabetes Drug Pricing." Reuters. November 2016.; Silverman E. "What the 'Shocking' Gilead Discounts on its Hepatitis C Drugs Will Mean." Wall Street Journal. February 2015.; Barrett, P, and Langreth, R. "The Crazy Math Behind Drug Prices: Intermediaries that Negotiate to Lower Prices May Cause Them to Increase Too." Bloomberg Businessweek, June 2017.
- ^{xvi} Berkeley Research Group. "The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholder." January 2017.
- ^{xvii} Girod CS et al. "2017 Milliman Medical Index." May 2017.
- ^{xviii} Evans R, Hinds S. "US Rx Net Prices Fall 5.1 percent (real) in 3Q18." SSR Health. December 2018.
- ^{xix} Barrett P, and Langreth, R. "The Crazy Math Behind Drug Prices: Intermediaries that Negotiate to Lower Prices May Cause Them to Increase Too." *Bloomberg Businessweek*. June 2017; Langreth R et al. "Decoding Big Pharma's Secret Drug Pricing Practices." *Bloomberg*. June 2016.
- ^{xx} SSR Health. "US Brand Net Pricing Growth 0.2% in 3Q17." Published December 18, 2017. Accessed April 2018.
- ^{xxi} 82 Fed. Reg. at 56336; Medicare Payment Advisory Commission. Report to the Congress: Medicare Payment Policy. Chapter 14: The Medicare Prescription Drug Program (Part D): Status Report. March 2018; 84 Fed. Reg. at 2341; Fein A. Don't Blame Drug Prices on "Big Pharma." Wall Street Journal. February 3, 2019. <https://www.wsj.com/articles/dont-blame-drug-prices-on-big-pharma-11549229031>
- ^{xxii} IHS Markit. "Passing a Portion of Negotiated Rebates Through to Seniors with Diabetes Can Improve Adherence and Generate Savings in Medicare." May 2018.
- ^{xxiii} Department of Health and Human Services, Office of Inspector General. "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees." 83 Fed. Reg. 2340 (Feb. 6, 2019).
- ^{xxiv} 83 Fed. Reg. 2340. See regulatory impact analysis, Table 2.B.
- ^{xxv} 83 Fed. Reg. 2340.
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Ms. ESHOO. We thank you, Ms. Joldersma.

And now, I would like to recognize Ms. Kristin Bass for five minutes of her testimony.

Welcome again and thank you.

STATEMENT OF KRISTIN BASS

Ms. BASS. Thank you, Chairwoman Eshoo, Ranking Member Burgess, and members of the subcommittee.

I am Kristin Bass, the chief policy and external affairs officer for PCMA, which is the trade association for the PBM industry. I am pleased to be here today to talk about the important transparency bills before the subcommittee and to discuss how PBMs lower prescription drug costs for 200 million Americans with health coverage through employers, labor unions, health plans, Medicare, and Medicaid.

Every day in this country, people go to the pharmacy to get needed drugs to make their lives better. PBMs' only mission is to increase affordability and access to those drugs for consumers and our clients. PBMs are an important link in a chain that includes manufacturers, wholesalers, physicians, pharmacies, and pharmacy service administrative organizations, all working to get needed therapies to patients.

Within that chain, our companies are the only ones whose mission is to help control costs. PBMs can only help lower prescription drug costs for patients when there is sufficient competition among drug companies. Where there are competing clinically-equivalent brand drugs that will work equally well for patients, PBMs negotiate rebates or discounts off the manufacturer's list price to arrive at the lowest net-cost drug. The rebates are, then, used by health plan sponsors to reduce patient premiums, out-of-pocket costs, or both.

We are proud that our industry has delivered results. According to Federal data, in 2018, overall U.S. spending on drugs increased only 3.3 percent and, in 2017, four percent. One large PBM reported a decline in costs for its clients in 2017. That is our industry's mission.

Yet, we know that today too many individuals still find their drugs unaffordable. Driving more competition among drug companies is the key to providing relief for patients. I want to commend the subcommittee for your work on the CREATES Act and legislation limiting pay-for-delay agreements.

Greater transparency can also be part of the solution, and the PBM industry is supportive. We support transparency to empower patients and their physicians. Our industry provides real-time benefits tools, so physicians and patients know immediately in the doctor's office what drugs are on formulary and what the patient's cost-sharing will be.

PBMs are transparent to our clients, including how the PBM is paid for its services and the negotiated rebates. And we support transparency to policymakers. PBMs already report on all price concessions, costs and fees in Medicare to CMS, and we support legislation that would provide that data to congressional advisors at MedPAC and MACPAC. And that is just for our industry.

We would support additional transparency for others in the supply chain, manufacturers, wholesalers, and the PSAOs. And this gets us to the bills under consideration today. With respect to H.R. 2115, we support aggregate reporting of rebates. We urge the subcommittee to make sure manufacturers cannot use public reports to calculate competitor's discounts and avoid competition, and, thus, keep drug costs high, a risk that has been validated by the FTC. We want to empower patients, not drug companies. We have some ideas for how to ensure maximum transparency without risking higher drug costs, premiums, and cost-sharing, and are happy to work with subcommittee staff on those.

With respect to H.R. 2376 and its provisions to direct FTC to scrutinize our industry's business practices and level of competitiveness, we welcome and support this review. While the FTC has previously examined PBMs extensively and concluded that we operate in a competitive market, to the benefit of consumers and our clients, we are confident that additional FTC study of our industry will further validate previous conclusions.

We strongly encourage the subcommittee to expand FTC's review to all others in the prescription drug supply chain to ensure a complete and transparent picture of all those who play a role. In addition, increased manufacturing reporting can help bring sunshine into their pricing and marketing practices, as addressed in the bills that are the subject of today's hearing.

I will conclude by again commending the subcommittee for considering ways to reduce prescription drug costs. We appreciate the opportunity to testify, and I look forward to answering your questions.

[The prepared statement of Ms. Bass follows:]



Testimony of

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Submitted to the

UNITED STATES HOUSE OF REPRESENTATIVES
ENERGY AND COMMERCE COMMITTEE,
SUBCOMMITTEE ON HEALTH

***“Improving Drug Pricing Transparency and Lowering Prices
for American Consumers”***

May 21, 2019

Introduction

Good Morning. I am Kristin Bass, the Chief Policy and External Affairs Officer for the Pharmaceutical Care Management Association (PCMA). PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for 270 million Americans with health coverage provided through employers, health insurers, labor unions, state and local governments, Medicare, Medicaid, and the Federal Employees Health Benefits Program.

PBMs are the primary advocate for consumers and health plans, working to keep prescription drugs accessible and affordable. PBMs negotiate on behalf of consumers and work to keep down premiums and costs for prescription drugs. Our companies use market-based tools that encourage competition among drug manufacturers and pharmacies and incentivize consumers to take the most cost-effective and clinically appropriate medication.

PBMs Are the Only Entity in the Drug Supply Chain Dedicated to Lowering Costs

By leveraging competition among drug manufacturers, PBMs save patients and health plans an average of \$123 per prescription and will negotiate prescription drug costs down \$654 billion over the ten years ending 2025.ⁱ PBMs reduce drug costs by:

- Offering clinical programs to drive medication adherence and health outcomes that address the nearly \$300 billion in annual cost associated with non-adherence.
- Promoting the use of generics and more affordable brand medications.
- Negotiating price concessions from drug manufacturers and pharmacies.
- Providing home delivery of prescription drugs and promoting high-quality, affordable pharmacy networks.
- Reducing fraud, waste, and abuse.

PBMs operate in an extremely competitive marketplace and work hard to satisfy the market demand of both current and potential clients.ⁱⁱ Research by the Pharmacy Benefit Management Institute shows that there are 66 full-service PBMs and 80 organizations offering PBM services operating today in the U.S.ⁱⁱⁱ The presence of so many industry participants engender tremendous competition to drive costs down.

We welcome the opportunity to provide our thoughts to the Committee about how to provide transparency in pharmaceutical pricing for American consumers. It is important to understand that manufacturers alone set the price of prescription drugs. The key to lowering drug prices is a competitive marketplace. This Committee has already taken great steps toward addressing the challenge of lack of competition. The BLOCKING Act, Purple Book Continuity Act, Orange Book Transparency Act, Protecting Consumer Access to Generic Drugs Act, and CREATES Act are all important steps toward ending market abuses to block competition as well as to promote a transparent and competitive pharmaceutical marketplace. But we agree with the Committee that still more can be done and the appropriate level of transparency across the full supply chain is

important.

PBMs' Role in the Drug Delivery System

Through negotiated savings and benefit administration services, PBMs play a crucial role in lowering prescription drug costs for health plan sponsors and government programs – hereafter referred to as clients or payers – and plan enrollees. There are no requirements that plan sponsors utilize a PBM. PBM clients choose to contract for these services because of the value they provide both to the plan and to the patients that the plan serves.

Plan sponsor clients themselves decide how actively they want their PBM to manage the pharmacy benefits they provide to the patients in their enrollee populations. For example, they select formulary coverage, copayment tiers, utilization management, and pharmacy channel options. In addition, PBMs use a variety of tools for their clients, such as drug utilization review and medication management. These tools are crucial to encourage the best clinical outcomes for the patients PBMs serve.

In retaining PBM services, PBM clients' contracts typically include thorough audit rights and may include other terms, such as protections against drug manufacturer price inflation, and price concessions at the point of sale.

PBMs may be a business-to-business enterprise, providing services to plan sponsors. But the core of their mission is to serve patients through lower costs, affordable access to medications, and administrative services that provide a seamless experience at the pharmacy counter.

PBMs Drive Savings by Creating Market Competition among Brand Manufacturers

The first link in the drug supply chain is the drug manufacturer, which alone sets the price for the drug. The manufacturer sells the drug to a wholesaler, who then sells the drug to a pharmacy. PBMs are not involved in the physical supply chain. Rather, PBMs drive competition among drug manufacturers. For generics, which are commodities, PBMs in their pharmacy contracts negotiate payment terms that give pharmacies the incentive to purchase their generic drugs at the lowest price possible. For brand drugs, PBMs negotiate price concessions with brand manufacturers directly, typically in the form of retrospective rebates, an artifact of a class action settlement between pharmacies and manufacturers several decades ago.

Pharmacy benefit management is a scale business. The PBMs competing in the marketplace have leverage with manufacturers because they are negotiating on behalf of significant total patient populations.^{iv} The price concession a manufacturer may be willing to offer is generally based on the market share a PBM can demonstrate it will move to a drug.

These negotiations can only take place where there are competing, clinically equivalent drug therapies offered by different manufacturers. Where competition exists, PBMs can use their leverage to encourage the use of the lowest net cost option. According to the HHS Inspector

General, roughly 61 percent of brand drugs in Medicare Part D have a PBM rebate associated with them^v – 39 percent do not. This underscores the need for more competition among manufacturers.

Negotiated price concessions are not correlated with price increases. A recent study found no correlation between the prices that drug manufacturers set on individual drugs and the rebates that they may negotiate with PBMs on those products.^{vi} At the same time, separate research by Credit Suisse shows that the size of drug rebates is positively correlated with the extent to which a given brand drug faces competition in the market.^{vii} Thus, evidence shows that PBMs use price concessions to harness competition in the market to bring down costs for patients and clients.

Plan sponsors determine how PBM-negotiated price concessions are utilized. Payers can choose to apply the savings to offset overall benefits costs, to reduce premiums for plan enrollees, or to reduce out-of-pocket costs. For plan sponsors who receive rebates as a part of their contractual arrangement with PBMs, 100 percent rebate pass-through is the most common rebate arrangement.^{viii} In Medicare Part D, price concessions have been used to lower premiums, keeping them stable over the last decade of the Part D program.

For 2019, CMS announced that Part D's base beneficiary premium was \$33.19, a 5 percent drop from \$35.02 in 2018,^{ix} and the average Part D base premium has been between \$30 and \$32 since 2010.^x

PBMs Use Formularies to Encourage Patients to Use High-Value Drugs

In addition to negotiated price concessions from manufacturers, PBMs recommend drug formularies to encourage patients to take the most cost-effective, clinically appropriate drug for their disease or condition. Typically, drugs are placed on tiers with cost-sharing assigned according to the drug's value. The primary purpose of the formulary is to encourage patients and prescribers to choose the lowest cost, clinically effective drug.

In developing formularies, PBMs rely on independent Pharmacy and Therapeutics (P&T) committees comprising physicians, pharmacists, and other clinicians. P&T committees evaluate all available evidence in clinical and medical literature to recommend which drugs must be covered and which drugs may have therapeutically substitutable alternatives. This vital first step in developing a formulary ensures that the first question asked is whether patients will have access to the clinically necessary therapy for their condition.

With respect to brand drugs, where the P&T committee has identified at least two therapeutically equivalent drugs, PBMs can use competition among manufacturers – who prefer that their drugs be offered to patients with lower cost sharing – to reduce the net cost of the drug. The more favorable a drug's placement on the formulary, the more market share a drug will realize, and the greater a concession the drug's manufacturer may agree to. PBMs use the prospect of moving market share to a given drug and the threat of excluding drugs from

formularies to simultaneously drive competition among the manufacturers and offer a value-based prescription drug formulary to the clients they serve.

PBM Negotiations with Pharmacies Reduce Costs for Consumers and Payers

PBMs also use value-based contracting to build networks of high-performing pharmacies. Based on negotiated, agreed-upon performance metrics, PBMs hold pharmacies accountable for performance on certain activities such as generic dispensing, cost-effective dispensing, improving medication adherence, and reducing inappropriate drug use. In turn, pharmacies performing well on such metrics earn bonus payments and preferred status. The ability of health plans and PBMs to construct networks that include some, but not all, providers, including pharmacies has long been used to increase quality of care and lower costs for patients.

PBM pharmacy networks include independent pharmacies, the vast majority of whom hire pharmacy services administrative organizations (PSAOs) to negotiate and contract with PBMs and other third-party payers on their behalf. A typical PSAO represents thousands of pharmacies. The eight largest PSAOs represent more than 24,000 pharmacies.^{xi} PSAOs provide access to pooled purchasing power, negotiating leverage, and contracting strategies similar to those of large, multi-location chain pharmacies.

As this Committee considers a comprehensive look at pharmaceutical intermediaries, the relationship of PSAOs and wholesalers is equally important to consider.

Transparency

The PBM industry supports transparency that can help lower costs and improve quality of care. PBMs support transparency to empower patients and their physicians. Our industry provides real-time benefits tools (RTBT) so physicians and patients know, immediately in the doctor's office, what drugs are on formulary and what the patient's cost-sharing will be. Prescribers and patients can work together to choose the drug that works best for the patient.

PBMs support transparency to their clients, so that both sides have a clear understanding of their contract terms, including how the PBM is paid for its services, the amounts of negotiated rebates and the portion the client chooses to have the PBM pass along.

And PBMs support transparency to policymakers. PBMs already report on all price concessions, costs and fees in Medicare to CMS, and support legislation that would provide that data to congressional advisors at MedPAC and MACPAC.

In addition, PBMs support additional transparency for others in the supply chain – manufacturers, wholesalers, and the PSAOs, to enable policymakers, payers, and consumers to understand costs throughout the supply chain.

Comments on Specific Bills and Concepts

H.R. 2115: Public Disclosure of Drug Discounts Act: As the Committee considers public reporting of aggregate PBM rebates, which we generally support, we urge you to make sure manufacturers cannot use public reports to calculate competitors' discounts and thus avoid competition, a risk that has been validated by the Federal Trade Commission (FTC). The FTC has said that if rebates or price concessions are known among business competitors, the competitors will engage in tacit collusion to keep net prices higher and thus not offer as deep price concessions as they otherwise might have.^{xii}

Public reporting of rebates by drug or even by drug class, in classes with fewer than three drugs, would allow manufacturers to figure out the rebates offered by other manufacturers and result in tacit collusion behavior. In addition, all rebates, discounts, and remuneration are reported to the Centers for Medicare & Medicaid Services (CMS) in Part D, which keeps all but the aggregate percentage of rebates across the program confidential.

H.R. 2376: Prescription Pricing for the People Act: PBMs welcome FTC scrutiny of the industry. The FTC has studied the PBM industry extensively and consistently found that PBMs indeed lower costs in the drug supply chain and that the industry is competitive. We encourage the Committee to add others in the supply chain to this bill, so the FTC can examine not only the PBM industry, but also manufacturers, wholesalers, and PSAOs.

H.R. 2064: (Re: Product Samples): PCMA supports the Sunshine Act and agrees that reporting of aggregate product sample value is a commonsense way to build on drug manufacturer sunshine requirements.

In addition, increased manufacturer reporting can help bring sunshine into their pricing practices, as well as their marketing practices, as addressed in **H.R. 2069, H.R. 2296, and H.R. 2087.**

LIS Cost-Sharing: PCMA supports reducing Medicare Low Income Subsidy beneficiary cost-sharing for generic drugs.

Conclusion

Thank you for the invitation to appear before the Committee today. In the search for solutions to address high drug costs, the Committee and Congress would be best served in pursuing policies that foster and encourage competition to keep prescription drug costs and pharmacy benefits more affordable for employers, enrollees, taxpayers, and government programs. Transparency in the drug supply chain can be a valuable tool to enhance such competition, but not if it allows tacit collusion, which leads to higher prices.

PCMA member companies welcome continuing discussion among all stakeholders to create a robust, sustainable market that will continue to deliver needed cures and treatments for patients

who suffer through disease and chronic illness. To that end, PCMA staff will be happy to speak with you and your staffs on any of the specific bills discussed today or any other matter that comes before the Committee.

ⁱ Visante, "Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers," February 2016.

<https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf>

ⁱⁱ Eversana, "A Highly Competitive PBM Market Spurs Consolidation and Emerging Competitors," February, 2013

ⁱⁱⁱ Pharmacy Benefit Management Institute (PBMi), Information compiled and provided to PCMA, March 28, 2019.

^{iv} Health Strategies Group, "Pharmacy Benefit Manager Research Agenda 2015,"

<http://www.healthstrategies.com/download/file/1892>

^v HHS OIG, "Increases in Reimbursement for Brand-Name Drugs in Part D," June 2018. <https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf>

^{vi} Visante, "Increasing Prices Set by Drugmakers Not Correlated With Rebates: An Analysis Prepared by Visante on behalf of PCMA, June 2017

^{vii} Credit Suisse Equity Research, "Global Pharma and Biotech," April 18, 2017

^{viii} Drug Channels, "Solving the Mystery of Employer-PBM Rebate Pass-Through," January 14, 2016.

^{ix} MedPAC, March 2019 Annual Report to Congress, p. 399.

^x MedPAC, March 2018 Annual Report to Congress, p. 408.

^{xi} Drug Channels, "[McKesson Leads Another Round of PSAO Consolidation](#)," May 17, 2018

^{xii} Ibid.

Ms. ESHOO. Thank you, Ms. Bass.

I now would like to recognize Dr. Feldman. You have five minutes for your testimony, and thank you again for being here today with us. You can proceed.

STATEMENT OF MADELAINE FELDMAN, M.D.

Dr. FELDMAN. Chairman Eshoo, Ranking Member Burgess, and distinguished members of the subcommittee, thank you for inviting me to testify on behalf of the Alliance for Specialty Medicine, a nonpartisan coalition of national medical societies representing more than 100,000 specialty physicians.

My name is Madelaine Torregano Feldman. I am president of the Coalition of State Rheumatology Organizations and have been a rheumatologist for 30 years. I practice full-time in New Orleans.

I treat a variety of autoimmune diseases, but perhaps the one I see the most often is rheumatoid arthritis, or RA. Treatment for RA has changed dramatically since I graduated from medical school. We used to be able only to provide symptomatic relief, but now there are therapies that actually help us halt the disease activity, stop joint destruction, and even reduce the cardiovascular risks associated with rheumatoid arthritis.

Lower-priced generics are always used first before the specialty drugs. Now the list prices of these specialty drugs have risen to the point where many patients can no longer afford even their co-insurance, based on that list price. I hope you will find it helpful my feedback as a practicing physician.

I would like to first talk about the samples provision in the prescription drug STAR Act. Section 3 would broaden the scope of the Sunshine Act to include the total quantity and value of samples in manufacturers' reporting. We are concerned that this provision might have serious unintended consequences for patient care. Let me tell you how we use these samples in rheumatology.

It is important to stress the physicians; we derive no financial benefit from the samples and, in fact, it costs us resources in staffing and managing this very complex inventory. Because patients can wait weeks to over a month before getting final approval and, then, actually getting the prescribed medicine, it is extremely important to have on hand these samples to start the patients right away. I mean, it can make the difference between saving a joint or not. We are also able to see if the drug causes any tolerability issues, and all of this at no cost to the patient or the payor.

In its June 2017 report, MedPAC recommended reporting on samples to oversight agencies, researchers, payers, and health plans under confidential data use agreement. They did not recommend publishing it publicly online. I fear that broadening MedPAC's recommendation to public online publishing will have a chilling effect on manufacturers' willingness to provide us with these samples because of the potential of false shame campaigns on Twitter and the like. This can be harmful to the doctor-patient relationship and undermines patients' trust in their physicians. And I can tell you, sometimes that trust is more important than the medication itself. In light of these concerns, we urge Congress to more closely follow MedPAC's recommendations to accomplish the

important goals of H.R. 2113 without the bill's unintended consequences.

Next, I would like to briefly discuss Section 5 that would increase transparency of PBMs. The current rebate system creates perverse incentives to increase list prices that everyone in the drug delivery system profits on except for the patients. I would be happy to explain why competition actually increases prices as opposed to decreasing them. I have seen where some drugs with lower list prices are not allowed to be on the preferred formulary.

Full transparency of price concessions to PBMs would shed light on how the preferred formularies are designed and why they can change every 6 to 12 months for no clinical reason and actually stop payment for drugs that have stabilized my patients.

Less egregious than that behavior is something that happened a week and a half ago to one of my patients who it took us nearly two years to find the right drug for his rheumatoid arthritis. We had given him the generics and even other specialty drugs. He was sent a notification from his PBM asking him to switch to a completely different specialty drug, one that had a completely different mechanism of action, like asking a cancer patient in the middle of successful treatment to change their drug.

In order to help us fully understand the financial considerations that are overriding the clinical ones, we support transparency, not only for the formulary rebates, but all of the price concessions, admin fees, price-protection fees, even if disclosures are only to regulatory agencies.

I have provided comments on two additional policies and would be happy to answer any questions on those.

The Alliance for Specialty Medicine is truly encouraged by Congress' bipartisan attention to drug pricing. While we believe some policies under consideration may need changes to avoid unintended consequences, we are supportive of increased transparency in the drug supply chain.

Thank you so much for your consideration of our viewpoints.

[The prepared statement of Dr. Feldman follows:]

**TESTIMONY OF MADELAINE FELDMAN, M.D.
ALLIANCE OF SPECIALTY MEDICINE
PRESIDENT, COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS**

**COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH
UNITED STATES HOUSE OF REPRESENTATIVES**

**HEARING ON
“IMPROVING DRUG PRICING TRANSPARENCY AND LOWERING PRICES FOR
AMERICAN CONSUMERS”
MAY 21, 2019**

Chairwoman Eshoo, Ranking Member Burgess, and distinguished Members of the Subcommittee, thank you for inviting me to testify on behalf of the Alliance of Specialty Medicine. My name is Madelaine Feldman. I have been a rheumatologist for thirty years and I practice full-time in New Orleans. I am the current President of the Coalition of State Rheumatology Organizations, which is a member of the Alliance of Specialty Medicine (“Alliance”). The Alliance is a coalition of national medical societies representing more than 100,000 specialty physicians from fifteen national specialty and subspecialty societies. We are a nonpartisan group dedicated to the development of sound federal health policy that fosters patient access to the highest quality care.

Drug Pricing

The treatment of rheumatoid arthritis (RA) has changed dramatically since I graduated from medical school in the eighties: we have evolved from being able to provide only symptomatic relief to the discovery of therapies that actually impact disease activity and slow down or even halt joint damage. The difference this has made to RA patients is nothing short of miraculous. Not that long ago, an RA diagnosis would lead to inevitable disability. That is no longer true. With appropriate disease management, people with RA can lead long and physically active lives.

In the last decade, however, the out-of-pocket cost for these treatments has risen to the point where many patients can no longer afford them. Even products that have been on the market for over a decade continue to rise in price each year, all while patients are being asked to shoulder ever-increasing deductibles and coinsurances. This has a direct impact on patient care: I have seen far too many patients ration doses or forego a prescription due to cost.

This Subcommittee has the difficult job of having to balance protection of innovation for future patients with current patients' need for relief from high costs. I hope you will find it helpful to hear my feedback as a practicing physician on some of the policies under consideration by the Subcommittee, as you work to strike this balance.

Reporting on Pharmaceutical and Device Samples¹

The Physician Payments Sunshine Act ("Sunshine Act") was enacted as part of the Affordable Care Act, with the purpose of increasing transparency of relationships between manufacturers and the prescribing community. Section 3 of the Prescription Drug STAR Act (H.R. 2113) would broaden the scope of the Sunshine Act to include the total quantity and value of pharmaceutical and device samples in manufacturers' reporting.

¹ H.R. 2113 ("Prescription Drug STAR Act"), Section 3: Requirement for Manufacturers of Certain Drugs, Devices, Biologicals, and Medical Supplies to Report on Product Samples Provided to Certain Health Care Providers.

Samples in Rheumatology

In rheumatology, we do not receive samples of infused products. We receive samples of self-injectables or small molecule pills. The choice of treatment is not determined by what samples the office has because we receive samples of all specialty medications. In our specialty and many others, the out-of-pocket cost of the available products can be incredibly high: in some Medicare Advantage plans, patients may pay a 30% coinsurance. Since some of these products have list prices in the thousands of dollars, this puts treatment out of reach for many patients.

Even those who can afford these out-of-pocket costs are subject to aggressive utilization management by insurers and their pharmacy benefit managers (PBMs). Patients may wait weeks or even months before getting final approval and actually obtaining the medication. Prior authorizations have gone so far that they are sometimes required before a neurosurgeon can treat a gunshot wound to the head. To someone outside of the medical profession, this may sound absurd. For those of us who practice at the intersection of expensive drugs and complex, chronic disease, it is sadly unsurprising. Yet, similar to patients in need of high-level trauma care, in the case of a progressive, irreversible disease like rheumatoid arthritis, patients do not have the luxury of time. In these cases, when time is of the essence, we can offer samples of the proper medicine to the patient and teach them how to use it, all at no cost to the patient or the insurer while waiting for approval and delivery of the needed medication. Before even trying to get approval for specialty medicines for which there are no lower cost alternatives, all of the less expensive medicines have been tried and failed. Access to these samples make the difference between a patient beginning the timely treatment necessary to save their joints, or not.

Another equally important aspect of having in-office samples, particularly of expensive drugs, is that it offers the ability to check for side effects and tolerability before the patient or the payer incur significant costs. Access to samples enables us to evaluate the product's efficacy and tolerability in a way that is financially risk-free to the patient.

Physicians derive no financial benefit from samples. In fact, samples require staff resources to receive, store, and manage inventory.

MedPAC Recommended Limited Publication of Data

Data disclosed via the Open Payments program has helped shed light on the relationships between manufacturers and the prescribing community. And while MedPAC has been cited as recommending reporting on samples, MedPAC never recommended gathering this information and publishing it on a public website. In its June 2017 report, MedPAC recommended that “the Secretary should make information reported by manufacturers on free drug samples available to oversight agencies, researchers, payers, and health plans.” MedPAC recommended that Congress authorize and require the Secretary to make this information available to these entities *under data use agreements*: any entity requesting access to this data would have to sign confidentiality and data use agreements. In its discussion of samples, MedPAC noted that “samples clearly offer benefits for many patients.”²

The provisions in H.R. 2113, however, would go much farther than the MedPAC recommendation, by publishing the information publicly online, for any member of the public to characterize as they see fit. I fear that this will have a chilling effect on manufacturers' willingness to provide these samples. There is little value in this approach other than enabling the creation of

² MedPAC Report to the Congress: “Medicare and the Health Care Delivery System” (June 2017), Chapter 6, “Payments from drug and device manufacturers to physicians and teaching hospitals in 2015”.

shame campaigns against physicians and manufacturers by Twitter experts, bloggers, and the like and, as a result, potentially reducing the availability of samples. I hope that the information provided above illustrate why that would be detrimental to patients.

Physicians in no way profit from having these samples in their offices and the false implication that they do, by publishing the cost of the samples, is harmful to the doctor-patient relationship and undermines patients' trust in their physicians. We urge the Congress to more closely follow MedPAC's recommendations to accomplish the important goals of H.R. 2113 without the bill's unintended consequences for patients.

Disclosure of Rebates³

Section 5 of H.R. 2113 would require publication of generic dispensing rates and price concessions by class of drug. Like many other stakeholders, the Alliance has noted in the past that the current rebating system creates perverse incentives that are not serving patients well. Most notably from the perspective of our patients, there is data to suggest that beneficiaries are not currently benefiting from price concessions in the form of reduced cost-sharing, as their coinsurances are based on list prices. Additionally, as I described earlier in my testimony, our member physicians report ever-increasing and aggressive utilization management tactics by PBMs that are interfering with the practice of medicine.

Further, as physicians, we wonder why formularies change constantly when the clinical value of the various products stays the same. In rheumatology, this is particularly pronounced. I have patients who are stable on a biologic treatment who have received letters from PBMs urging them to switch to a completely different medication, often another biologic, because it may be a

³ H.R. 2113 ("Prescription Drug STAR Act"), Section 5: Public Disclosure of Drug Discounts.

less costly alternative. But the letters fail to note that such a switch would not always be less costly for the *patient*, nor is it good clinical practice or standard of care to switch a stable rheumatoid arthritis patient for non-medical reasons. This just happened to a long-time patient of mine, who is stable on a medicine with a unique mechanism of action: his PBM sent him a letter urging him to switch to a medication with a totally different mechanism of action, even though there is no clinical reason to do so. These letters are usually the PBM attempting to drive the patient to the product that provides a bigger price concession to the PBM. Sometimes, that product will actually have a *higher* list price.

It would be beneficial to disclose the financial transactions that play a role in formulary design because then we can begin to understand to what extent financial considerations are trumping clinical ones. This includes not only the formulary rebates but all of the price concessions, including those kept by the PBMs such as administration and price protection fees. Since price concessions are the basis for formulary design, the resultant utilization management requirements do not appear to be clinically driven. Rational utilization management would be based on safety, efficacy, and lowest list price. In light of these concerns, we support disclosure of rebates and other price concessions made to PBMs by manufacturers.

Drug Pricing Transparency⁴

Section 2 of H.R. 2113 would require drug manufacturers to submit justifications for price increases over a certain percentage or launch prices over a certain threshold amount. We believe in transparency in pricing across the board. If manufacturers must justify their prices, however,

⁴ H.R. 2113 (“Prescription Drug STAR Act”), Section 2: Drug Manufacturer Price Transparency.

they should be allowed to include information related to the price concessions in their contracts with PBMs, even if that information is otherwise confidential or proprietary.

Out-of-Pocket Cap in Medicare Part D

The Part D benefit design did not contemplate the prescription drug market as it is today. In rheumatology, we are in a unique position in that the drugs we prescribe are covered by Parts B and D, depending on the administration of the product. For Medicare beneficiaries, Part B is much more preferable because many beneficiaries have some type of supplemental coverage, which is not the case in Part D. Additionally, Part B is free of middlemen, resulting in an open formulary structure with annual spending growth rates increasing at a slower pace than those of Part D drugs.

When an RA patient ages into Medicare and is stable on a drug covered by Part D, they often can no longer afford the Part D drug and must either switch to a Part B medication or hope they qualify for a foundation to pay for their medication. This happens because, while they previously had the benefit of copay assistance programs, this type of assistance is prohibited in Medicare. Thus, the patient suddenly has to pay a full 25% coinsurance on the list price of a product that used to cost them a more manageable out-of-pocket amount. Once they reach the catastrophic cap, the patient still owes 5% of these expensive products – and, given the high list prices, even that is often too much for the average Medicare beneficiary. This economically driven “forced” switch can result in loss of control of the disease which ultimately can lead to higher medical costs in the long run. If for some reason the patient cannot take a part B medication, they may lose all access to any medication that works for them, leading again to increased costs to the patient and the system.

Some reform of cost-sharing in Part D is desperately needed. This is especially critical for those suffering from chronic, complex illnesses, living on a fixed income, who resort to rationing their medications to pay for other living expenses.

Conclusion

The Alliance of Specialty Medicine is encouraged by the Congress' bipartisan attention to and action on drug pricing. While we believe some policies under consideration may need changes to avoid unintended consequences, we are supportive of increased transparency in the drug supply chain. Thank you for your consideration of our viewpoints.

Ms. ESHOO. Thank you, Dr. Feldman.
I now would like to recognize Mr. Frederick Isasi for five minutes for your testimony. Welcome and thank you.

STATEMENT OF FREDERICK ISASI

Mr. ISASI. Thank you so much, Chairman Eshoo and Ranking Member Burgess. And members of the Subcommittee on Health, thank you for this opportunity to speak with you today.

I am Frederick Isasi, executive director of Families USA. For nearly 40 years, we have served as one of the leading national voices for healthcare consumers, both in D.C. and on a State level.

We are here today because American people are hurting. Families across this nation are being put in terrible positions, choosing between securing prescription drugs for themselves, and their children, and their financial security. The problem is growing worse every year. And what is most important to say is that this problem was created by Congress in our Federal patent and exclusivity laws, and only Congress can solve it.

Our families needed you to act. Today's bills are a step in the right direction, and we need much bolder action as well. Let me give you a sense of what the suffering of our families looks like.

Approximately one in three families, 80 million people, have not taken prescription drugs as prescribed because they simply cannot afford them. Some skip a dose, cut their pills in half, and others simply get sicker.

We are one of the wealthiest nations in the world. We are spending two or three times more than other wealthy nations on healthcare. And yet, this is the life to which we subject our nation's families.

So, what does it look like to be a family struggling with drug costs? Let me tell you about Catherine from Wheeling, Illinois. She worked hard. She had a career as a secretary. And then, in her late fifties, she developed a cough and it wasn't going away. How many of us have had similar problems? But, then, within three months of going to the doctor for the cough, 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. Her condition worsened.

Her doctors prepared her to die and Catherine prepared herself to die. And then, she got the call; a new lung had been found. 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. Catherine takes 36 pills a day, including anti-rejection and pain medication. Catherine, a Medicare beneficiary, has to ration her medications to make them last. She spends an astounding \$1,000 each month on her medications, which is exactly half of her income. Think about what this means. Catherine, 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 Catherine sold her home. She moved in with her parents. Her mom is 86 and her dad just passed away 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 she will find the money to pay for the drugs keeping her alive. That is the life that Catherine lives with amazing grace and courage, as do so many other Americans.

As Catherine struggles each day, the drug industry continues to enjoy some of the highest margins in the nation, making billions upon billions of dollars. And remember, the reason their profits are so astronomically high is not that they are inventing the best drugs for our families. It is because Congress, all of you, continue to grant them the ability to charge whatever they possibly can get. They abuse Federal laws to extract higher prices. They can only do this because of Congress' inaction.

And despite the astounding amounts of money they are making, you will hear industry say that, if Government Acts to stop these abuses, innovation will dry up. It is not true. Do not be fooled.

How much are they spending on so-called innovation right now? Of their trillion dollars—a trillion dollars in worldwide revenue—are they spending 3-quarters on innovation? No. Are they spending half? No. Are they spending at least a third? No. Are they spending a fourth? No. Industry is spending less than a fourth of their revenue on innovation, much more on marketing and on profit. And, of course, all of their innovation is on the backs of taxpayers who funded the underlying research.

Instead of innovating in drug development, they innovate in their legal strategies to extend exclusivity. In fact, more than 3-quarters of new patents are for existing drugs. Think about that. From an industry glutted with money, where, indeed, is the innovation?

Thank you for your work on the bills being considered today. I am pleased to say that Families USA supports all the bills under consideration. We believe that price transparency can help families and policymakers better understand how prices are set. However, these bills alone will not meaningfully affect the price of drugs.

We strongly support the Doggett bill and other proposals aimed at bringing down price. In the midterms a few months ago, the American people sent a strong signal to Capitol Hill. 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 this Congress. Now is the time for Congress to act boldly on behalf of their constituents.

Thank you for this opportunity to testify.

[The prepared statement of Mr. Isasi follows:]



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

Before the House Energy and Commerce Committee
Subcommittee on Health

May 21, 2019

Families USA
1225 New York Avenue, NW
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Chairwoman Eshoo, Dr. Burgess, and members of the House Energy and Commerce Committee, Subcommittee on Health: 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.

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, nearly one in three consumers facing increased drug costs cut-back on buying food to account for the increase.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 For example, 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 measly 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

Even Competitive Markets Need Strong Oversight

While generic substitution has helped to somewhat ameliorate continued higher spending on pharmaceuticals, it is not a panacea. Between 2008 and 2016, the average costs of oral generics increased by 4.4 percent annually.¹⁹ The cost of injectable generic drugs increased by more than 7 percent annually.²⁰ While these price increases are lower than those for drugs without competition, the consumer price index for urban areas (CPI-U) during that period was just 1.69 percent.²¹ To be clear: the costs of generics is rising much more quickly than inflation and affordability of generics may soon be out of reach for many American families.

The reason for the failure of generic markets to fully moderate drug price increases is not fully known. Some point to the consolidation of generic manufacturers as a serious concern.²² Even more problematic, states across the nation are positing that generic drug makers have actively colluded to keep prices high. Just last week, the attorneys general of 43 states and Puerto Rico filed suit against 20 generic drug makers, alleging the companies colluded to fix and inflate the price of more than 100 generic drugs.²³ According to the suit, some drugs saw price increases of more than 1000 percent.²⁴

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, many of which are focused on enhanced price transparency.²⁵ 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.²⁶ Additionally, Oregon, California, Connecticut, Nevada, and Vermont, recently enacted drug price transparency laws to require drug makers to justify dramatic price increases.²⁷

While most state drug price transparency laws are too new to have produced meaningful data, in conformance with a law enacted in 2017, the State of California now publicly reports on the Wholesale Acquisition Price of new prescription drugs with a monthly course of treatment exceeding \$670.²⁸ Under the California law, manufacturers must justify price increases on certain drugs. The findings from these disclosures will begin to be made public later this year.²⁹

Legislation Under the Committee's Consideration

The subcommittee is considering four different bills today. Three of the bills, namely: H.R. 2113 - *Prescription Drug STAR Act*, H.R. 2296 - *FAIR Drug Pricing Act*, and H.R. 2376 - *Prescription Pricing for the People Act*, focus on enhancing transparency in how drug makers set prices. The fourth bill, H.R. 2757 - *Creating Lower Cost Alternative for Your (CLAY) Prescription Drug Act*, seeks to limit out-of-pocket drug costs for low-income Medicare beneficiaries. Taking them in order:

The *Prescription Drug STAR Act* was affirmatively reported out of the Ways and Means Committee last month on a bipartisan vote. Per the Ways and Means Committee's summary, the STAR Act:

- “Requires drug manufacturers to publicly justify large price increases for existing drugs and high launch prices for new drugs.
- Requires applicable manufacturers to report to the Secretary the total aggregate monetary value and quantity of samples provided to covered entities.
- Requires the Secretary to conduct a study on inpatient (Medicare Part A) drug costs, including trends in the use of inpatient drugs by hospital type.
- Requires the Secretary of Health and Human Services to publicly disclose the aggregate rebates, discounts, and other price concessions achieved by pharmaceutical benefits managers (PBMs) on a public website, so consumers, employers, and other payers can understand and compare the discounts PBMs receive.
- Requires all drug manufacturers to submit information to the Secretary on the average sales price (ASP) for physician-administered drugs covered under Medicare Part B.”³⁰

Families USA supports the STAR Act, though we recommend one change: Currently, the STAR Act requires drug makers to justify the launch price of a drug if its annual cost exceeds \$26,000. Such a high threshold would allow nearly all high priced drugs to escape scrutiny. We urge the committee to consider lowering this threshold to a more reasonable level. One option would be to require manufacturers to justify any launch price that exceeds the threshold in Medicare to qualify as a specialty drug, currently \$670 per month (\$8,040 annually).

The *FAIR Drug Pricing Act* is a corollary to the STAR Act's provisions requiring justification for large price increases. The two bills both require manufacturers to justify price increases of more than 10 percent in a single year or 25 percent over three consecutive years. The STAR Act further requires manufacturers to justify price increases of more than \$10,000 in a single year or \$25,000 over three years. This would capture smaller percentage increases on very expensive drugs. While the FAIR Act does not include this provision, we support its inclusion in legislation marked up by the committee. Further, while both bills stipulate financial penalties for failure to disclose required information, the STAR Act also requires manufacturer executives to certify the

accuracy of their disclosure and mandates financial penalties for knowingly providing false information. We support this provision.

H.R. 2376 - *Prescription Pricing for the People Act* – was approved by the Judiciary Committee on April 30. The bill requires the Federal Trade Commission to issue a report on the prescription drug supply chain. We support this legislation.

H.R. 2767- *CLAY Act* - would eliminate cost-sharing for generic drugs for low-income Medicare beneficiaries. We support efforts to promote the use of generics, where available and appropriate, and are happy to support legislation that provides relief for low-income seniors.

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.³¹ 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.³²

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. A recent public polling finds that:

- 86 percent of Americans support requiring drug companies to release information to the public on how they set their drug prices – particularly salient for today’s conversation.³³
- 86 percent of Americans favor allowing Medicare to negotiate with drug companies to get a lower price on medications.³⁴
- 75 percent of Americans favor shortening the length of monopoly granted on prescription drugs so that cheaper generic drugs are made available sooner.³⁵

Transparency Alone is Insufficient – Consumers Demand Real Action

I want to be very clear: while Families USA supports the legislation under consideration by the subcommittee and believes that price transparency can help families, policymakers, researchers, and other stakeholders better understand how drug prices are set, these bills alone will not significantly affect the price of drugs. We are pleased that the House recently passed meaningful legislation, approved by this committee, to hasten generic competition. Yet even the CREATES Act and banning pay-for-delay schemes, while significant, are nowhere near the level of reform needed to really help families access affordable drugs.

The American people are fed up with the games drug makers play and are suffering mightily under the weight of high drug costs. Now is the time for Congress to act boldly

on behalf of their constituents. As a next step, we strongly encourage Congress to allow Medicare to negotiate with drug makers on the price of drugs. We support legislation sponsored by Rep. Lloyd Doggett (D-TX), which now has more than 120 cosponsors.³⁶ I am pleased that to date the legislation passed by this committee and under its consideration today has been bipartisan in nature.

The pain of high drug costs is felt in communities across the country. There is no reason why a real solution to this seemingly intractable problem cannot be bipartisan. We 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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¹⁶ Engelberg. Op. Cit.

¹⁷ Bach, Peter B. "Could High Drug Prices Be Bad for Innovation?" Forbes.com. October 23, 2014. <https://www.forbes.com/sites/matthewherper/2014/10/23/could-high-drug-prices-be-bad-for-innovation/#6083d6285a80>.

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Ms. ESHOO. Thank you, Mr. Isasi.

I now would like to recognize Dr. Mark Miller for five minutes of his testimony, and thank you for being here. You may proceed.

STATEMENT OF MARK MILLER, PH.D.

Dr. MILLER. Chairman Eshoo, Ranking Member Burgess, and distinguished members of the committee, I appreciate you asking Arnold Ventures to testify today.

Arnold Ventures is a philanthropy dedicated to reforming dysfunctional markets and programs to assure a better return on investment. We work to develop evidence and ideas to improve public policy. We believe strongly in markets, but we also believe in evidence-based intervention when markets fail.

With respect to drugs, our objective is to protect innovation, but to explicitly lower the cost for the employer, the taxpayer, and, most importantly, the patient. We believe that there are strong reasons for the Congress to act. We spent \$470 billion on drugs in 2016. That number is expected to grow 24 percent by 2020. In Medicare Part D, we spend \$100 billion after rebates. That number is projected to double in the next 10 years. In Medicare Part B, we spend \$30 billion. That number has doubled since 2010. In Medicaid, we spend \$30 billion net. That number has increased 50 percent since 2011.

Meanwhile, at the Federal level, this is deficit-financed. Three in 10 Americans can't afford their prescriptions, and 40 percent of U.S. families can't produce \$400 in an emergency.

To that end, we urge the Congress to act comprehensively on the drug issue.

No. 1, to curb patent abuses and other anticompetitive behaviors, so that when a drug is available as a competitor, it can actually get to market.

No. 2, remove market distortions through greater transparency and reforming price inflationary actions, such as the misuse of rebates and fees and the misuse of coupons.

No. 3, directly address high launch prices and price increases for those drugs that do not have competitors through such actions as reference pricing, negotiation, or inflation rebates.

More precisely, with respect to Medicare Part D, consistent with MedPAC recommendations, the committee should consider a series of reforms to change the payment structure to increase pressure on the PBMs to more aggressively negotiate for lower-cost drugs; for example, by requiring the PBMs and the manufacturers to pick up substantially all of the Part D catastrophic cost. Concurrently, that policy should offer greater protections to the beneficiary when they hit the catastrophic cap.

Those proposed reforms also include modifications to the copayment for the LIS, for the low-income subsidy population, in order to encourage them to use lower-cost drugs when they are available. That is the right policy direction, but those policies need to be designed very carefully to assure that they result in taxpayer savings and don't cut off access to important drugs.

Where there is no competition and PBMs have no leverage over prices, we would suggest that you consider such tools as an inflation rebate, pricing to the clinical value of the drug, or a negotia-

tion strategy. These tools would allow the Medicare program to address situations where the manufacturer has set excessive prices in the absence of competition.

With respect to Part B, we would suggest moving from a percentage-based payment to a flat fee, empowering physicians to form their own purchasing groups to negotiate prices, and consider lowering the overall payment using the average sales price blended with an international price index.

Turning to the public justification of price increases, there is value in that information as a policy source and as a motivation for policy action. But, without additional action, that in and of itself will not curb drug prices.

That said, a well-designed policy should set a minimum drug price, trigger reporting on both a percentage and an absolute dollar basis, require legal attestation of a ranking company official, and avoid disclosing proprietary information.

With respect to the Sunshine Act, we recommend reporting payments made to patient groups who often act as a proxy for the manufacturers, and we would report the economic value of the samples provided to physicians. However, if public reporting can't be reached, at a minimum, the sample value should be made available to oversight organizations and researchers.

In closing, any policy that you undertake will involve a number of difficult tradeoffs across stakeholders, and we know that there will be stiff resistance from the status quo. But we also know that the status quo has produced noncompetitive behaviors, higher taxpayer spending, and higher prices for the patients.

Arnold Ventures and its grantees stand ready to work with you on these difficult issues. I would like to thank you for your attention. I will look forward to your questions.

[The prepared statement of Dr. Miller follows:]

Mark Miller, PhD
Arnold Ventures

Improving Drug Pricing Transparency and Lowering Prices for American Consumers

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

May 21, 2019

Chairwoman Eshoo, Ranking Member Burgess, and distinguished members of the Subcommittee, my name is Mark Miller, and I am the Executive Vice President of Health Care at Arnold Ventures. Arnold Ventures is a philanthropy dedicated to addressing some of the most pressing problems in the United States. We invest in sustainable change based on a strong foundation of evidence. We drive public conversation, craft policy, and inspire action through education and advocacy. Until recently, I was privileged to serve the Congress for 15 years as Executive Director of the Medicare Payment Advisory Commission (MedPAC) by providing analyses and policy recommendations. I want to thank you for inviting me to testify today on policies designed to address the unsustainable prescription drug cost burdens to public programs.

Arnold Ventures is dedicated to reforming dysfunctional programs and systems to ensure a better return on investment for the people they serve and those who finance them. To that end, we work to develop an array of evidence and ideas to improve public policy that can drive reform in the areas such as health care, pensions, education, and criminal justice – areas we believe are not serving target populations or taxpayers well. Arnold Ventures is drawn to issues characterized by a lack of evidence, dysfunctional markets, inefficiently run and/or under-resourced government programs, and strong interests protecting the status quo. We strongly believe in markets, but we also believe in evidence-based interventions when markets are failing and competition is lacking. Within health care, we have seen market failures cause stress to patients and their families; to federal and state budgets; to employers; and to taxpayers.

Our objective in health care is to lower cost while maintaining and enhancing access to needed, high-quality care. Across the health care system, we focus on opportunities to achieve more affordable care while securing better health outcomes. We focus on four areas where we see the greatest problems and opportunities. These four areas are 1) reducing hospital and physician prices and costs, 2) rationalizing prescription drug prices and purchasing approaches, 3) identifying and avoiding low-value and/or unsafe care, and 4) improving the care for Americans with complex health conditions and needs.

We know that health care costs are a top issue for Americans. Rising health care spending is squeezing government, business, and household budgets. Nearly half of Americans are concerned that a major health event may bankrupt them, while 77 percent are concerned that the rising cost of health care will significantly damage the US economy.¹ The immediate economic consequences of high health care costs can be staggering. In the last year, Americans borrowed \$88 billion to help pay for health care.² In fact, these costs actively prevent patients from seeking the medical care they need with 65 million adults reporting that they did not seek treatment in the past year due to costs.³ It is not surprising that the most important issue for American voters in 2018 was health care, and within health care, one of voters' highest priorities is lowering prescription drug prices and costs.⁴

With respect to drugs, our ultimate goal is to strike a fair balance between the industry's incentive to innovate and the affordability of medications that improve, extend, and sometimes literally save lives.

We believe the science behind new medications is the best it has ever been. Diseases that in the recent past would be debilitating or life threatening can now be managed through medication. The predicted life expectancy of a child born with cystic fibrosis has risen from 29 years in 1986 to 47 years in 2016.⁵ A 12-week regimen can now cure hepatitis C. Advanced therapies like CAR-T hold the potential to cure cancer in a single treatment, and there is a growing pipeline of gene therapies on the horizon that hold the promise of treating or curing a variety of once-deadly genetic conditions.

However, we have several concerns. First, these treatments are launching at increasingly unsustainable prices that are not justified by their research and development costs. Life-extending cystic fibrosis treatments cost nearly \$300,000 a year.⁶ The cost of curing hepatitis C can be tens of thousands of dollars per treatment.⁷ CAR-T therapy can easily top \$500,000, and several companies have discussed pricing gene therapies above \$2 million dollars per person treated.^{8,9,10} Second, the pipeline is shifting to high priced, specialty drugs, which are expected to comprise nearly half of pharmaceutical industry revenues by 2022.¹¹ Third, given the complexity of these drugs and the dysfunction in our current system, they will often face limited competition, which will keep prices high. These drugs only work if patients can afford to take them and if the cost of these drugs does not crowd out other needed medical care or other necessities such as housing and food.

Arnold Ventures funds research to address high drug prices in a few key areas:

- Identifying the drivers of innovation and developing alternative incentive structures that drive innovation;
- Encouraging competition by reforming our current patent and exclusivity system that grants monopolies to pharmaceutical companies for decades. This includes ending abuses such as pay-for-delay settlements, product hopping, patent thickets, evergreening, and other techniques intended to keep competitors off the market;
- Rethinking the way we pay for drugs to move away from high list prices and price increases and move towards alternative methods of payment including reference pricing, paying on the basis of the clinical value of a drug, and some form of negotiation; and
- Increasing transparency throughout the drug delivery and payment system. This includes ensuring accountability to the public for launch prices and price increases, understanding how money flows from manufacturers to pharmacy benefit managers (PBMs) and supply chain middlemen, and clear reporting of payments by manufacturers to providers and patient groups.

We believe America can remain at the vanguard of medical research and innovation while also ensuring the affordability of the fruits of this research.

Americans Demand Action

The American public believes unequivocally that drug prices are too high. Eight in ten adults feel that the cost of prescription drugs is unreasonable.¹² The same overwhelming majority of adults also believe that drug company profits are a major factor contributing to high prices.¹³ Nearly a third of American adults report not taking a prescription as directed because of cost.¹⁴ Unsurprisingly, there is overwhelming support for strong Congressional action to address the mounting drug-pricing crisis.

Sixty eight percent of Americans, including most Democrats and Republicans, say that lowering prescription drug costs should be the top health care priority for Congress.¹⁵ An overwhelming majority of Americans, both Republicans and Democrats, support aggressive action to lower drug prices including

making it easier for generic drugs to come to market and allowing the government to negotiate prices in Medicare.¹⁶ Voters across party lines and in a variety of Congressional districts have supported government intervention in drug patent monopolies and manufacturing to help speed affordable prescriptions to market.¹⁷

Congress has taken some initial steps to respond to the public's call to action. Congressional committees have held over a dozen hearings and several markups in 2019 focused on drug prices, patent abuses, and the drug supply chain. The Energy and Commerce Committee alone has held 6 of these hearings.¹⁸ Federal legislators have introduced 66 bills to address drug pricing this year from both sides of the aisle. There is legislation addressing new tools like negotiation, importation, and international reference prices that have policy goals that are consistent with voters' demands. In a few instances, these proposals are embraced on a bipartisan basis.

The House of Representatives recently passed the CREATES Act, the Protecting Consumer Access to Generic Drugs Act of 2019, and the BLOCKING Act of 2019, all of which work to bring lower cost generics and biosimilars to market more quickly.

These bills are only a first step, but more work needs to be done to bring immediate relief to taxpayers, employers, and to patients.

The Cost of Doing Nothing

In 2016, the United States spent \$471 billion on prescription drugs.¹⁹ This includes both retail and non-retail drug spending. National Health Expenditures data show that retail drug spending alone grew by over 30 percent over the 2010-2016 period.²⁰ Total drug spending (including non-retail) is expected to rise by nearly a quarter to \$584 billion by 2020.²¹ This expenditure must be taken in the larger context of spending in America. Federal debt held by the American public currently stands at about 78 percent of GDP and is expected to approach 100 percent by 2029.²² Spending on health care is about 18 percent of GDP.²³ Both of these numbers are expected to grow in the near future. In fact, the Congressional Budget Office projects that rising health care costs, along with payments to service the federal debt, are among the largest drivers of increasing federal spending in the future.²⁴ Budget tightening is being felt at the state level as well, and states are being asked to choose between health services and schools, roads, or public safety services.

This spending growth is mirrored in federal and state programs like Medicare and Medicaid. In Medicare Part D, total net spending on prescription drug claims grew from about \$55 billion in 2007 to nearly \$120 billion in 2017.²⁵ From 2007 through 2017, reinsurance payments to Part D plans, which are financed largely by the taxpayer, rose at a rate of nearly 17 percent per year.²⁶ The program's costs to the taxpayer are rising faster than premiums paid into Part D.²⁷

Medicare Part B, which covers physician-administered drugs, experiences similar drug spending growth. Spending on Part B drugs neared \$30 billion in 2016, which is nearly double the amount spent in 2010.²⁸ MedPAC notes that price increases account for two-thirds of the growth of Part B drug spending (excluding vaccines).²⁹ Between 2009 and 2016, spending on drugs in Part B grew 10.7 percent per year while the average payment per drug increased by 6.9 percent per year, which reflects increases in the prices of existing drugs and shifts in the mix of drugs to new, higher priced drugs.³⁰ Together, this is part of the reason why 15 percent of an average Medicare household's total spending is on health care.³¹

Medicaid programs are under pressure from rising drug costs as well. Net spending on retail drugs grew nearly 60 percent over the 2011 to 2017 period.³² In total, the federal government and states spent \$33 billion on drugs in 2017 after rebates.³³ This growth, driven by Medicaid expansion and high cost

therapies like those that treat hepatitis C and cystic fibrosis, puts unnecessary pressure on taxpayers and has outstripped traditional pharmacy cost containment measures.

Ultimately, drug spending is placing an increasing burden on patients, employers, and taxpayers to cover the bill. About one in three Americans chose not to fill a prescription last year because of cost.³⁴ Specialty medications cost, on average, over \$50,000 a year at retail prices, and many people with employer-sponsored health insurance have to pay, on average, 27 percent of this amount, or nearly \$14,000.^{35,36} This is particularly concerning considering that 40 percent of households would find it hard to produce \$400 in an emergency.³⁷

Whether we like to admit it or not, we do ration drugs in our country. If a drug manufacturer with a monopoly chooses to set an excessive price, it forces patients and payers to make difficult tradeoffs. Here are two examples.

- *Insulin.* There are more than 30 million Americans with diabetes.³⁸ Insulin list prices have tripled in the United States over the last decade, while out-of-pocket costs per prescription doubled.³⁹ List prices for insulin seem to be rising in lockstep, which prompted several lawsuits alleging that insulin manufacturers are price-fixing.⁴⁰ These prices require some people with diabetes to ration or skip doses. Researchers at Yale recently found that one-quarter of those studied used less insulin than prescribed due to high out-of-pocket costs.⁴¹ As highlighted in recent press stories, high costs are requiring some people with diabetes to ration, which makes them incredibly ill and, in some cases, causes death.^{42, 43, 44}
- *Hepatitis C Treatments.* Several new products cure hepatitis C. They initially cost nearly \$100,000 per course of treatment. The high price of these regimens and high demand for them led payers to restrict access due to affordability concerns.⁴⁵ Most state Medicaid programs were only making these drugs available to patients whose condition had advanced considerably. Additionally, two-thirds of states required drug testing before they would cover the medication. These limitations on access were inconsistent with clinical recommendations and FDA guidelines. As a result, many people who would have benefitted from these drugs did not gain access.⁴⁶

In 2015, Washington state estimated that even with discounts, treating everyone on Medicaid with hepatitis C would cost three times the state's total pharmacy budget.⁴⁷ In 2017, if Louisiana wanted to treat its entire Medicaid and uninsured populations with hepatitis C, it would necessitate reallocating more than half of the amounts spent on public education, social services, and infrastructure.⁴⁸

Given these issues, it is not surprising that most Americans, their employers, and even the doctors who prescribe treatments believe our prescription drug market is broken. They cannot explain or understand why we pay as much as three times or more for the same drugs than patients in other developed nations.⁴⁹

Research and Development Does Not Explain Drug Prices

A common refrain from the drug industry is that high prices are necessary to drive innovative research and drug development, making drugs is hard and risky and America subsidizes research for the rest of the world. Developing drugs is difficult, expensive, and risky. However, the money U.S.-based drug companies make by charging Americans high prices is 176% greater than what is needed to fund their global R&D.⁵⁰ Many patented products were first discovered through taxpayer-funded NIH research and grants, which contributed to the development of all new molecular entities approved by FDA between

2010 and 2016.⁵³ Rather than embodying the ideals of competition and choice, the American system, when examined closely, appears to be rife with market failures and perverse incentives.

Manufacturers Block Competition.

Instead of encouraging research into the next generation of cures, firms with drugs approved by the Food and Drug Administration (FDA) are incentivized to hold on to their monopolies as long as possible and deploy as many anticompetitive tactics as possible to ensure generics or biosimilars are not available. The FDA and the United States patent system were designed to create a virtuous cycle: innovator companies are granted certain exclusivities through the FDA and United States Patent and Trademark Office for their work, and when those exclusivities expire, cheaper alternatives like generic drugs or biosimilars become available. Ideally, this would, over time, ensure there is budgetary room for future products, but this is not happening.

Between 2005 and 2015, over 75 percent of drugs associated with new patents were for drugs already on the market.⁵² Of the roughly 100 bestselling drugs, nearly 80 percent obtained an additional patent to extend their monopoly period at least once—nearly 50 percent extended it more than once.⁵³ For the 12 top selling drugs in the United States, manufacturers filed, on average, 125 patent applications and were granted 71.⁵⁴ For these same drugs, invoice prices have increased by 68 percent.⁵⁵ Manufacturers also engage in pay-for-delay schemes, in which payment is made to generic firms to not compete for a product. Even in cases where the Federal Trade Commission fines a company for these tactics, the profits made from the delay may outstrip the fine, effectively incentivizing illegal behavior.⁵⁶

Pharmaceutical companies will often point out that, despite invoice and list prices increasing at an alarming rate, the net price paid for drugs has been increasing much more slowly. This begs a further question, why is the gulf between list and net prices widening? The answer may often lie in the pharmaceutical supply chain. PBMs and wholesalers within the supply chain may retain some of the rebates paid off list price. In exchange for these rebates, branded drugs often receive favorable treatment on formularies and are sometimes placed preferentially ahead of generic or biosimilar versions. In the end, patients often pay coinsurance based on the higher list price despite the discounts offered to these other players.⁵⁷

Policy Solutions Must be Comprehensive

It is encouraging that bipartisan support for legislative and regulatory fixes is growing. Doing nothing is a policy decision, and it is a decision that has led to ongoing patent abuse and market dysfunction; an opaque supply chain characterized by spread pricing; higher costs of doing business for employers; increasingly unsustainable public programs; and higher out of pocket expenditures for families. As political momentum builds, it is important that policy solutions be comprehensive and address three broad issues:

1. Patent abuses and anticompetitive behaviors by brand name drug manufacturers.
2. Market distortions that create inefficiencies in the way drugs are purchased.
3. High brand name drug launch prices and unjustified annual price increases.

While the focus of today's hearing is on Medicare and legislative efforts to bring greater transparency to drug pricing, we offer several solutions in this section that go beyond the scope of the hearing, but are critical to address in a legislative package aimed at lowering drug prices. We explore changes to the Medicare program and transparency efforts in depth later in the testimony.

1. Patent Abuses and Anticompetitive Behaviors. The Federal government grants patent and market exclusivity monopolies, which manufacturers constantly fight to extend. As mentioned previously, manufacturers are employing in a variety of anticompetitive tactics to maintain their monopoly. The following are additional changes that could be contemplated as part of a larger package that would encourage greater competition:

- Allowing FDA the authority to import a generic drug when there are fewer than three manufacturers in that drug's class;
- Restricting the orphan drug market exclusivity period to one period for a given drug, or alternatively, allow the market exclusivity period to last only to the point that the patient population exceeds 200,000 for a given drug;
- Removing the interchangeability designation for biosimilars to encourage substitution of lower priced alternatives to biologic medicines. If interchangeability is not removed, the FDA should clarify its scientific approach to the designation;
- Shortening the FDA exclusivity granted to biologics;
- Mitigating product hopping by requiring manufacturers to keep the original formulation of the branded product on the market past the date of generic entry to ensure sufficient market share can move to the generic product;
- Prohibiting citizen petitions filed by competitors that are usually found to be frivolous or, alternatively, fine manufacturers when their citizen's petition is found to be frivolous;
- Reducing Medicare Part B payment for brand drugs from average sales price (ASP) plus 6 percent to ASP minus 33 percent when a manufacturer files a pay-for-delay agreement or takes another anti-competitive action after the primary patent or market exclusivity period expires, whichever date is earliest.⁵⁸

2. Market Distortions. The way drugs are paid for and delivered in the US can have an outsized impact on the prices and availability of drugs to the patients who need them. PBMs are paid in part through rebates negotiated off of list prices, which can incentivize the use of higher cost therapies. Manufacturers also use rebates, in addition to co-pay coupons, and free samples to incentivize the use of higher cost therapies, and manufacturers pay millions of dollars a year to patient groups to advocate on their behalf.

- *Co-Pay Assistance and Direct-to-Consumer (DTC) Advertising.* Co-Pay assistance programs and DTC advertising can steer individuals with insurance to higher cost, brand medications.^{59, 60} Expenses related to DTC advertising and co-pay assistance programs used by individuals with insurance are calculated as business costs that are subtracted from pharmaceutical company revenues and subsequently reduce the company's tax liability. In turn, the federal government is losing corporate tax revenue because of the way these expenses are treated. There are a few options to address this:
 - Require that DTC and direct patient financial assistance to those with comprehensive insurance be a taxable expense.
 - Ban financial assistance in competitive markets. This could either be a ban if a product has a generic or biosimilar competitor or a ban if there are a certain number of products in a class.
- *Transparency.* Manufacturers are not required to disclose their prices, discounts given to intermediaries, or their contributions to patient groups advocating on their behalf. The Committee marked-up and reported H.R. 1781, the Payment Commission Data Act of 2019, which allows MedPAC and MACPAC access to rebate data. This is an important first step to

ensure that all the agencies supporting Congress provide members with complete information to inform the policymaking process.

We go into some detail about expansions to the Sunshine Act and price transparency below. Both are important to informing the government, patients, and taxpayers about the business decisions that affect drug prices, but transparency legislation alone will not be sufficient to lower high drug prices.

3. High Launch Prices and Unjustified Price Increases. As discussed earlier, drugs are launching at higher prices each year, particularly for specialty products, which are becoming a larger percentage of the pipeline and, in turn, drug spending. Below are some policy options to consider that would help lower drug prices for Medicaid and the commercial sector:

- Medicaid Prices
 - Allow states more flexibility in managing their drug benefit while maintaining access to the statutory rebate.
 - Increase the statutory rebate cap, which caps a manufacturer's rebate liability at 100 percent of its price. The cap in current law protects manufacturers from paying more rebate if their prices continue to grow faster than inflation.
 - Include authorized generics in the statutory definition of a "line extension" for purposes of the Medicaid rebate program.
- Commercial Prices
 - Eliminate Medicaid's best price provision to give commercial plans more leeway to negotiate lower prices while increasing the Medicaid statutory rebate to ensure drug prices paid by the Medicaid program do not go up.
- Medicare policy options are addressed in the next section.

Policy Options to Lower Drug Spending and Increase Affordability in Medicare

The remainder of the testimony will focus on potential fixes to the way Medicare Part B and Part D purchase drugs and efforts to increase drug pricing transparency. Consistent with the mission of Arnold Ventures, we offer an array of credible ideas for Congress to consider in crafting a solution to these problems. The status quo represents a series of choices and trade-offs that we believe are unfair to the taxpayer and the patient. Any new policy will also require choices and tradeoffs across patients, taxpayers, PBMs, and manufacturers. These tradeoffs demand careful consideration, but we feel that a balance can be found that more equitably benefits each of these groups.

Medicare Part B

In Medicare Part B, drugs and biologics dispensed by physicians are reimbursed using a buy-and-bill system. Under this structure, physicians are paid for the price of a drug based on its average sales price plus a set percent. Because the set percent paid to the physician is based on the drug's price, it can encourage providers to use higher cost medications in order to bring in higher revenue.⁶¹ The types of drugs used in Part B also complicate matters. These physician-administered products are often high cost, specialty drugs or biologics. The top 11 drugs by spending in Part B in 2017 were biologics representing nearly half of all drug spending in the program.⁶² These drugs typically face very limited competition.

A number of payment reforms could move away from incentivizing the use of high cost drugs and instead encourage the use of the most clinically appropriate product, regardless of price, or the use of lower-cost alternatives.

1. *Reduce or reform the average sales price (ASP) add-on payment for physician-administered drug reimbursement.* This could either be calculated as a lower percentage add on (e.g., from 6 percent to 3 percent) or as a flat add-on fee.
2. *Require manufacturers to pay Medicare a rebate when their ASP growth exceeds an inflation benchmark.* This type of inflation penalty is used in Medicaid to recover excessive price growth. It would reduce both the prices paid for Part B drugs and the associated beneficiary cost sharing.
3. *Require that Medicare use the same billing code for biosimilars and their reference biologic product.* This would force head to head competition between products that would drive down prices.
4. *Allow physicians to form purchasing groups and negotiate their own formularies for physician-administered drugs.* This would mimic some of the cost-containment techniques already used in the Part D benefit and by private plans and would allow groups to leverage purchasing power and market forces to negotiate for lower prices.
5. *Improve ASP data reporting by requiring all manufacturers to report ASP data.*
6. *Reduce the amount Part B pays for new single-source drugs from 106 percent of wholesale acquisition cost to 103 percent.*

Recently, the Administration introduced the International Price Index (IPI) Model, which benchmarks Medicare reimbursement for Part B drugs to an international reference price.⁶³ We believe models that blend international reference prices into the ASP are worth examining. They have a chance to reduce costs for beneficiaries and taxpayers significantly while still ensuring access to critical medications.

Medicare Part D

The Medicare Part D program was designed with financial incentives to encourage plan and beneficiary participation to ensure its success. About 44 million of the 60 million people with Medicare have prescription drug coverage under Medicare Part D, and each beneficiary has, on average, 40 plan offerings.^{64,65}

Restructuring Part D to Improve Competitive Pricing

The financial structure that seemed necessary in 2006 is now creating incentives that waste taxpayer money. Here are a few examples. (1) *The Wall Street Journal* recently reported that plans generated over \$9.1 billion in profit since 2006 by overestimating their expected costs and capitalizing on the federal payment structure of Part D.⁶⁶ (2) Part D is required to cover all drugs in six classes, which undercuts plan ability to negotiate rebates. These drugs comprised about 20 percent of Part D spending in 2015, but only 14 percent of prescriptions.⁶⁷ CMS found that price trends for brand drugs are consistently higher for drugs in protected classes than such drugs in non-protected classes.⁶⁸ (3) The benefit structure encourages plans to prefer high cost drugs to move people into the catastrophic region where taxpayers pay 80 percent of the cost.⁶⁹ As mentioned previously, reinsurance payments (80 percent of which are financed by taxpayers) are growing rapidly. Medicare's reinsurance payments to plans are estimated to be seven times the amount they were in 2006, reaching \$43 billion in 2019.⁷⁰ There are over 3.6 million people in Medicare Part D who had drug spending above the catastrophic coverage threshold. Of the 3.6 million, 1.1 million did not receive a low-income subsidy, which is nearly triple the number of people who did not receive the LIS in 2010 (0.4 million).⁷¹

MedPAC has recommended a set of policies that restructure Medicare Part D to give plans greater financial incentives and stronger tools to manage the benefit.⁷² Both recent Republican and Democratic administrations have proposed similar policies.^{73, 74} Taken together, the following proposals would reduce the amount that taxpayers pay to provide the Part D drug benefit to its 44 million beneficiaries. However, the proposals would also expose some beneficiaries to higher cost sharing. In turn, some consideration could be given to using some of the savings to help people with higher out-of-pocket costs.

Benefit Structure

1. Transition Medicare's individual reinsurance subsidy from 80 percent to 20 percent while maintaining Medicare's overall 74.5 percent subsidy of basic benefits.
2. Exclude manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending.
3. Eliminate enrollee cost sharing above the out-of-pocket threshold.
4. Modify copayments for Medicare beneficiaries with incomes at or below 135 percent of the federal poverty level to encourage the use of generic drugs, preferred multisource drugs, or biosimilars when available in selected therapeutic classes (see detailed discussion below).

Plan Flexibility

5. Provide plans with additional leverage to lower prices paid for drugs by removing at least the antidepressant and immunosuppressant drug classes from protected status and by considering recent administrative proposals that give plans additional tools to manage the six protected classes.⁷⁵ To protect the beneficiary, these policies must be coupled with expeditious, well-functioning exceptions and appeals processes.
6. Streamline the process for formulary changes.
7. Require prescribers to provide supporting justifications with more clinical rigor when applying for exceptions.
8. Permit plan sponsors to use selected tools to manage specialty drug benefits while maintaining appropriate access to needed medications.

Penalize Excessive Price Growth

Drugs are launching at higher prices each year, particularly for specialty products, which are becoming a larger percentage of the pipeline and, in turn, drug spending. Once launched, drug prices continue to escalate year-over-year, while clinical efficacy stays the same. In order to address this issue, manufacturers should be required to pay a rebate to the HHS Secretary for drugs purchased by Medicare Part D if the drug's average manufacturer price rises faster than inflation. Manufacturers are required to pay this type of rebate to the Medicaid program. It is a key reason brand-name drugs are significantly less expensive in Medicaid when compared with Medicare Part D.⁷⁶ The savings generated from this policy could be used to provide greater protections to Part D beneficiaries by lowering the burden of their out-of-pocket costs in some capacity.

Require Deeper Discounts for Drugs Provided to the Elderly and Disabled with Limited Incomes

Prior to the Medicare Part D program, Medicaid provided drug coverage to low income individuals enrolled in both Medicare and Medicaid (dual eligibles). Medicaid requires manufacturers to pay a large statutory rebate that is not required under Part D. In turn, manufacturers saved a lot of money when dual eligibles transitioned from Medicaid into Medicare Part D. An additional way for Congress to contain Part D program costs would be to require manufacturers to pay an additional rebate to the

federal government for brand-name drugs sold to low-income enrollees. The rebate would be tied to the Medicaid statutory rebate, which for brand-name drugs is usually 23.1 percent of the drug's average manufacturer price plus an additional, inflation-based amount. A variant of this idea is to apply the rebate calculation described to a selected set of high cost drugs (e.g., drugs that under normal use would result in the beneficiary exceeding the catastrophic limit) that do not have a competitor or have a brand competitor(s) but prices remain high.

Bringing Rebate and Price Concession Transparency to Part D

In addition to the issues with Part D benefit design and plan flexibility, there are transactions such as rebates, pharmacy fees, and other forms of compensation that occur in the supply chain that pose several issues.

Although rebates put downward pressure on premiums, they give plans incentives to steer beneficiaries to drugs with the highest rebates, which also tend to have high list prices. This leads to higher cost sharing for beneficiaries and could accelerate the rate at which a beneficiary reaches the catastrophic portion of the benefit, where taxpayers pick up 80 percent of the cost.

There are several points for consideration. First, we may need to revisit how Part D's financing structure allocates rebates to the taxpayer versus the plan and fix any misalignments. Second, there are other forms of compensation that may not be shared with the program currently. We should ask whether plans should be permitted to profit from these types of compensations without the taxpayer directly benefiting. Third, if rebates are creating so many perverse incentives we should closely reexamine their role and determine the best way to restructure the system to be more transparent and benefit both the patient and the taxpayer.

Even if the benefit structure is reformed, plans are given more flexibility and rebate incentives are improved, Part D still has a problem. As mentioned earlier, specialty drugs are filling the pipeline and they tend to face little or no competition. Brand-name specialty drugs accounted for just 1 percent of prescriptions and about 30 percent of drug spending after rebates in both Medicare Part D and Medicaid in 2015.⁷⁷ Between 2010 and 2015:⁷⁸

- Spending per Medicare Part D beneficiary who used a brand-name specialty drug tripled, reaching \$33,460 after rebates;
- Overall spending on specialty drugs in Medicare Part D, after rebates, more than tripled, rising from \$8.7 billion to \$32.8 billion; and
- The average net price per prescription of a brand-name specialty drug grew at an average annual rate of 22 percent in Medicare Part D and 12 percent in Medicaid.

In 2017, high cost specialty drugs accounted for nearly a third of the pharmacy industry's prescription dispensing revenues. This is projected to reach 47% in 2022.⁷⁹

Addressing Part D's Limitations

Part D was constructed to rely on PBMs managing the benefit on behalf of taxpayers and beneficiaries. It assumes that the PBMs can effectively use various tools to leverage significant price concessions from manufacturers. However, as discussed, these tools only lower prices when drugs have competition. PBMs cannot do their jobs and extract price concessions from manufacturers of high cost specialty drugs that do not have competition. We need to think through creative solutions to address this issue to ensure the program's fiscal sustainability.

There are two sets of policies that could address this issue:

1. *Reference pricing.* The program could use the following external prices when setting reimbursement rates for certain high cost drugs:
 - a. Prices paid by a subset of foreign countries similar to the idea proposed by the Administration in its Part B demonstration.
 - b. Prices based on the clinical value of the drug to the patient.
 - c. Prices based on independently developed research and development costs for a given therapeutic class.
 - d. Prices paid for similar drugs with competition or other drugs within a similar therapeutic class.

2. *Introducing Negotiation.* Before Medicare covers certain high cost drugs, the Secretary of Health and Human Services and pharmaceutical manufacturers would negotiate a price. We recognize that there are a number of complex design issues that need to be worked through. As mentioned, this would be restricted to a small subset of high cost drugs with limited competition so it is administratively feasible. This concept of program-level negotiation may be foreign to Medicare, but it is important to keep in mind that the Department of Veterans Affairs engages in negotiation for drugs it purchases on behalf of their patients.

You can combine these two ideas and have reference prices built into the negotiation process in order to guide the bids that are offered.

In both of these policies, once there are a sufficient number of competitors on the market, price negotiation would return to Part D's standard negotiation process.

Bringing Beneficiary Accessibility and Price Transparency to the Drug Market

The Committee requested testimony on several legislative initiatives under consideration, which include eliminating generic cost-sharing for low-income Part D beneficiaries and increased transparency.

Eliminating Generic Cost-Sharing for Low-Income Part D Beneficiaries. Part D plans have limited tools available to them to encourage lower cost drug use by individuals enrolled in the Low-Income Subsidy (LIS) program. Currently, most LIS enrollees pay no more than \$3.40 for generic drugs (and brand drugs with generic equivalents) and \$8.50 for brand drugs without generic equivalents.⁸⁰ These co-payment amounts are set in statute and plans have limited flexibility to modify their structure to ensure the use of the most effective, least costly drugs.

Both the CLAY Act and the President's FY 2020 budget would eliminate LIS co-payments on generic drugs and biosimilars for LIS beneficiaries. We think this proposal would greatly improve access and adherence to prescription drugs for some of the most vulnerable Part D beneficiaries. However, the Congressional Budget Office estimated that this proposal would cost the taxpayer more than \$20 billion over 10 years.⁸¹ Given this significant increase in program costs, we would encourage the Subcommittee to consider the following alternative that modifies the LIS co-payment structure in a way that increases utilization of lower cost drugs while also reducing Part D costs.

Both MedPAC and the President's Budget in Fiscal Years 2016 and 2017 proposed reducing the LIS generic co-payment and increasing the brand co-payment amount.⁸² The Secretary would be able to (1) target particular classes where this structure would be most effective and (2) exclude brand drugs from the policy in classes where there are few lower cost generic alternatives. CBO estimated that this proposal would reduce Part D spending by over \$18 billion over 10 years.⁸³ This policy should include

requirements to ensure access to streamlined prior authorization and appeals processes in cases where therapeutic substitution was not clinically appropriate.⁸⁴

Transparency. Many policymakers and researchers point to a lack of transparency in drug pricing decisions and the business models of manufacturers and supply chain actors as a key blind spot for effective drug price legislation. While transparency efforts under consideration would not lead to lower drug prices, Congress should view these efforts as a way to provide better information and context for more comprehensive reform.

- Justification of Large Price Increases. Legislative efforts that would require manufacturers to report certain information in the event of a drug price increase can help taxpayers, patients, and payers understand more clearly why drug prices are increasing at rates well above inflation.

We think legislation that addresses this issue is most effective if it targets drugs that meet a minimum unit price threshold and those drugs experience a price increase that meet a minimum threshold calculated on both a percentage increase and dollar basis (calculated as a rolling average). This will ensure that reporting occurs for products for which a significant price change is most meaningful. Additionally, legislation should require manufacturers report, in a standardized way, the following types of information:

- Manufacturing and production costs;
- Research and development costs, including clinical trials;
- Tax credit amounts associated with research and development;
- Target Product Profiles;
- Marketing costs, including direct to consumer advertising and health care provider detailing.

The Chief Financial Officer of affected manufacturers should be required to sign an attestation form to ensure the information provided to the Secretary is accurate. The Secretary should have flexibility to add any additional data elements deemed necessary and there should be a penalty for manufacturer noncompliance. Non-proprietary summaries of this information should be available to the public.

- Sunshine Act Expansions. The Sunshine Act requires physicians to report to the federal government gifts from pharmaceutical and device companies that are greater than \$100 and has captured about \$33 billion in payments, similar donations made to non-providers are not required to be reported.⁸⁵ Other areas of concern that would benefit from expansions in the Sunshine Act are the distorting effects of manufacturer payments to patient groups and free drug samples given to prescribers and, in turn, to patients.

Patient groups can act as de-facto lobbyists for pharmaceutical companies. Patients testify at congressional hearings, meet with lawmakers, and provide grassroots influence for legislation.^{86,87} It is critical for Congress to know these groups' funding sources to understand potential biases when they advocate for particular policy changes.

Similarly, drug samples influence consumer demand for, and prescribing of higher cost brand medications, essentially acting as direct marketing by pharmaceutical manufacturers.⁸⁸ It was estimated that, in 2012, pharmaceutical companies spent nearly \$6 billion on free samples provided to physicians, making up over 20 percent of total marketing spend in that year.⁸⁹ The STAR Act, which was reported out of the Ways and Means Committee last month, takes an important step by expanding the Sunshine Act to require the disclosure of free drug samples. We

encourage Congress to expand its scope to ensure that all forms of distorting influence be reported publicly so that patients and lawmakers can better understand the scope of this market. At a minimum, this information should be reported to oversight agencies, researchers, payers, and health plans.

Conclusion

We believe that the system can deliver affordable treatments while also encouraging the development of the next generation of treatments. All of the ideas we offered you today involve trade-offs. We stand ready to support your work and your commitment to find the best policy approaches to achieve this important balance. Chairwoman Eshoo, Ranking Member Burgess, and Members of the Subcommittee, thank you for having Arnold Ventures testify on this important subject.

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¹⁹

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²⁶ Arnold Ventures' analysis using the Medicare Part D Prescription Drug Event Data and rebate information in the Medicare Trustees Report published June 2018 to derive the 2017 value and an analysis of Table 1.1 in the following CBO publication <https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/45552-PartD.pdf> for the 2007 value using Medpac's reporting of 24 million Part D enrollees in 2007.

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Ms. ESHOO. Thank you, Dr. Miller.

I was just sent a nice, handwritten note from my colleague, Mr. Long. And I should have done this at the outset of our hearing this morning. People are wondering what these yellow roses are all about. Well, today is the 100th anniversary of women's suffrage. And the suffragettes distinguished themselves as the vote was being taken, I think the final vote in the State of Tennessee. The suffragettes and their supporters wore yellow roses. Those that opposed them wore red. So, we are celebrating today, with the yellow roses, women gaining the right to vote in our country, the 100th anniversary. So, that is what the yellow roses are all about. We didn't attend an early-morning wedding.

[Laughter.]

But, nonetheless, this is a great celebration.

So now, I would like to recognize Dr. Holtz-Eakin. Welcome to you. You are an accomplished testifier.

[Laughter.]

And we look forward to your five minutes of testimony.

STATEMENT OF DOUGLAS HOLTZ-EAKIN, PH.D.

Dr. HOLTZ-EAKIN. Thank you, Chairwoman Eshoo, Ranking Member Burgess, and members of the committee, for the privilege of being at this important hearing.

Drug prices are a very important topic in the United States. And I want to say a couple of things about the debate in general, and then, a few remarks on the pieces of legislation under consideration today.

The first thing I would emphasize is that, at least to my eye, there is not a broad, general, widespread drug-pricing problem. Instead, it is important to recognize that we have some targeted areas with extreme drug-pricing issues, notably in specialty drugs, largely in oncology drugs right now, and in sole-source drugs that are off-patent. In thinking about solutions, it is often best to identify the problems first, and I would focus on those.

The second is that there is often relatively little clarity about which price people are trying to effect, and there are very different measures of price bandied about. There is the list price of manufacturers, probably the most important price. There is the net price post-rebate at which the drug is acquired. And then, there is also the price a beneficiary actually pays at the counter, including all the out-of-pockets, the one that is probably the most important to the American public. Thinking clearly about price allows you to avoid situations where you simply shift costs, but don't change the fundamental problem or address the issue itself.

And then, lastly, I think it is important to recognize that this is a difficult world of tradeoffs. There are no simple solutions because, in the end, there is a tradeoff between financial incentives like prices and the innovation that has made the United States the premier place for medical science on the globe. And being cognizant of that as you go forward is very important.

And secondly, for this hearing, the notion of transparency is not an unambiguously good thing. There are moments where transparency becomes quite costly and perhaps not worth it, and also situations where it interferes with the incentives to compete vigor-

ously and to have fierce negotiation, which we should want in our health markets, particularly our pharmaceutical markets.

So, in looking at the bills under consideration today, I think some concerns do arise. For example, the SPIKE Act, which looks at backward-looking triggers for price increases or an absolute value of \$26,000 for a drug, that is not independently the value of that drug, as Ranking Member Burgess mentioned in his remarks. It does trigger a set of disclosures and documentation that is quite intrusive and costly to produce. And when combined with the potential for the Secretary to offer a variety of different triggers backward-looking in launch prices, it could be a quite costly measure or transparency, with no particular accountability measure included that would guarantee any effort on drug prices. And so, I would be concerned about that.

The FAIR Act is similar in character. It has some, in my view, virtues of targeting. It is forward-looking as opposed to backward-looking, and I think that is an advantage in this setting. It excludes rare disease and vaccines, focuses on those drugs by physicians and hospitals, but has the same sort of potentially costly structure. And so, I worry about the transparency that generates no end result in those situations.

With regard to the samples, which has come up a couple of times already, samples are very important to beneficiaries. I think that has been documented. And so, you don't want to damage this valuable source of drugs. I think it makes sense to build on the existing reporting, rather than inventing new reporting; provide the information to the FDA, and provide this information to oversight and to professional researchers, so that the information about the influence of samples on the competition in the market is learned, but the damaging public disclosure is avoided. And I think that is something that the committee should think a little bit about.

Finally, with regard to providing public documentation of drug rebates negotiated by PBMs, I really have two sets of concerns. I understand why this committee should care deeply about how well the Part D program is functioning. I am a long-time fan of the Part D program, having been present at its birth, and I think it is our best entitlement program. I occasionally say I like it more than my children. I won't repeat that today. Oops, it is too late.

But I don't think the same sort of information should be provided for commercial transactions. These are in the end private contracts, and I don't think they should be publicly disclosed. So, collecting the information on Part D, making sure that for Part D there is vigorous competition that is effective is appropriate and should be done. Again, that means proprietary information provided to oversight and to researchers, not necessarily disclosed into the public domain.

So, I really do appreciate the chance to be here today. These are in the end difficult issues on one of the most important topics facing the American public. And I look forward to the chance to answer your questions.

[The prepared statement of Dr. Holtz-Eakin follows:]

Testimony Regarding:
“Improving Drug Pricing Transparency and Lowering Prices for American Consumers”

U.S. House
Committee on Energy and Commerce
Subcommittee on Health

Douglas Holtz-Eakin, President*
American Action Forum

May 21, 2019

*The views expressed here are my own and not those of the American Action Forum. I thank Christopher Holt and Tara O’Neill Hayes for their assistance.

Chairwoman Eshoo, Ranking Member Burgess, and members of the committee, thank you for the opportunity to testify today regarding H.R. 2113, the Prescription Drug STAR Act—which includes in part or in total: H.R. 2069, the SPIKE Act; H.R. 2064, requiring manufacturers to report certain kinds of product samples provided to health care providers; H.R. 2115, the Public Disclosure of Drug Discounts Act; and H.R. 2087, the Drug Price Transparency Act—as well as H.R. 2296, the FAIR Drug Pricing Act of 2019, H.R. 2376, the Prescription Pricing for the People Act, and the CLAY Act. These pieces of legislation are, as the two main themes alluded to in this hearing’s title suggest, best viewed from the perspective of lowering the prices of prescription drugs and increasing transparency in the pharmaceutical industry. These seemingly straightforward concepts are, unfortunately, not as simple as one might hope.

1. Lowering the prices paid by Americans for drugs is, in itself, a good idea. But the objective presumes that Americans are currently paying “too much” for pharmacological treatments. In fact, the conceptual arguments and evidence are riddled with ambiguity. Prices need to be high enough to sustain innovation, but no more. And measures such as list prices, net prices, out-of-pocket prices, development costs, and total spending on drugs have displayed very different patterns over time.
2. Transparency is a healthy safeguard against abuse, especially in the case of government programs. Transparency taken to an extreme, however, can have negative effects, particularly in the private sector in the context of healthy market-driven competition.

Let me discuss each of these points further.

Identifying the Problem: Patterns in Drug Prices and Costs

The first step in identifying whether there is a drug pricing problem is to differentiate between prices, costs, and spending, which are related but not identical concepts. Concerns about increasing drug prices might refer to a narrow definition focused on the sales prices (or “list price”) set by drug manufacturers. Alternatively, the problem might not be with all drugs, but instead with the high prices of particular drugs. Or the problem may be the increasing prescription drug prices paid by patients at the pharmacy counter, which has resulted—at least in part—from an increase in high-deductible health plans and increasing use of co-insurance (as opposed to co-pays).

We could consider increasing drug costs in the context of overall prescription drug expenditures, whether in dollar figures or as a percentage of National Health Expenditures. Because spending is a function of both price and quantity, this could result from increased utilization due to rising national reliance on prescription drugs or broader access to them. History has proven the best way to reduce the price of a good for which there is growing demand is to increase its supply through competition. For drug pricing, that means bringing generics and biosimilars to market to compete with brand-name drugs.

From my perspective, there is no broad prescription-drug pricing crisis. Indeed, in most instances, things are working just fine. Rather what we face are more targeted challenges. Among them is the price of specialty drugs and biologics, which are expensive to develop and manufacture and frequently treat a limited population. In these instances, particularly with oncology drugs, it is important to make sure that the price of the treatments correlate to the value they provide patients and society as a whole. Is the policy objective ultimately low prices or is it to acquire high-value treatments? It is easy to have low-priced drugs; they, however, may not do much good. Conversely, it might make sense to spend more for a drug if its therapeutic benefits are high enough.

Transparency's Positive and Negative Implications

Many of the bills before this committee today address the issue of transparency. Transparency can bring honesty and integrity to decision-making processes. Transparent pricing information allows consumers to easily differentiate between their cost for products and services, and market competition is enhanced.

Further, when the government has clear information on what is happening within federal programs it can help the government better manage those programs. Several of the policies being considered today seek to provide the government with just such insight. In some cases, however, these policies go beyond that objective in ways that are concerning.

Transparency requirements can have unintended consequences. For example, H.R. 2264—which admirably seeks to expose potential conflicts of interest—might result in fewer medication samples being made available to providers, ultimately harming those patients with constrained ability to pay who benefit most from sample treatments. Caution and a considered examination of the potential side effects of transparency requirements is advisable.

Other proposals under consideration advocate transparency for internal proprietary information of private companies engaged in business transactions with other private entities, as in the case of H.R. 2115. This seems to me an inappropriate overreach. On the other hand, the federal government might well have reason to know some of the information sought in H.R. 2115 in the context of the Medicare Part D program. That information, however, should be held in confidence rather than shared publicly so as to preserve the competitive nature of the program. The government should not, except in exceptional circumstances, expose the details of private contracts between private parties, disclose the proprietary information of private entities, or unnecessarily disrupt the competitive advantages of private actors.

Let me now turn to the specific proposals before the committee today.

H.R. 2069, the SPIKE Act

The Stopping the Pharmaceutical Industry from Keeping drugs Expensive (SPIKE) Act (H.R. 2069) requires the Secretary of Health and Human Services (HHS), at least once a year, to

determine if the price of a drug has increased by a given minimum amount over a specified lookback period, and if so, to require the manufacturer of the drug to submit documentation justifying that price increase.

I have a number of concerns with this legislation. First, the triggers specified in legislation, particularly the last one for newly available drugs with an expected cost or spending per user of \$26,000 or more per year, are arbitrary and will place a significant burden on the manufacturers of new and innovative drugs. This burden could discourage development of new drugs, or at the very least divert important, valuable resources from productive activities.

I am also troubled by the requirement that the Secretary post online alternative percentages, dollar amounts, and lookback periods that, if applied, would increase the number of drugs for which a SPIKE increase would have been triggered, and the number of drugs that would be subject to the triggers, if those benchmarks were applied. Further, I find the information required as part of a company's justification to be overly intrusive. No other industry has such requirements.

Finally, I am not convinced that these requirements will actually do anything to bring down prices, and there are no enforcement measures being granted to make prices come down if Congress learns something it finds objectionable from these reports.

I understand an amendment has been introduced to provide exemptions for new drugs if they treat a rare disease or condition, are the first drug approved to a certain indication, or are designated by the Food and Drug Administration (FDA) as a fast-track product. Such an amendment may mitigate the deterrent effect for much-needed new treatment options. Over 95 percent of the 7,000 known rare diseases still have no treatment option, and drugs now cost more than \$3 billion on average to develop.^{1,2} The chances that a new rare disease treatment would not meet the threshold here are close to zero. Congress should carefully consider these implications.

H.R. 2296, the FAIR Drug Pricing Act of 2019

The Fair Accountability and Innovation Research (FAIR) Drug Pricing Act (H.R. 2296) requires drug manufacturers to publicly report and provide justification for any pending price increases for certain drugs provided to Medicare and Medicaid beneficiaries 30 days prior to the increase. This legislation is similar to the SPIKE Act except that it requires advance notification rather than a post-hoc explanation and is more limited in terms of the scope of the drugs to which these requirements will apply. The FAIR Act focuses on physician- and hospital-administered drugs, and excludes vaccines and drugs used to treat rare diseases or conditions.

Between the two bills, the FAIR Act seems to be more narrowly focused on the drugs which are likely to be the most expensive and may therefore result in less of a regulatory burden for the industry overall. Further, because the legislation does not have a launch-price

trigger and provides exemptions for rare disease drugs, it is less likely to deter the development of new and innovative products.

H.R. 2064, Product Sample Reporting Requirements

The next section of the STAR Act mirrors H.R. 2064, which would require manufacturers of certain drugs, devices, biologicals, and medical supplies to report on product samples provided to certain health care providers. This reporting would be in addition to existing requirements imposed by the Affordable Care Act to report financial interests to the Centers for Medicare and Medicaid Services. Manufacturers providing payments or product samples would now also be required to submit electronically to HHS a form detailing the total quantity and value of all payments or other transfers of value provided to all covered recipients and the name of the drug, device, or supply provided, as well as any other information the Secretary may request. Much of this information is already required to be provided to FDA. This information would also be required to be included in a tax return filed by the company.

This transparency can be very valuable. Taxpayers and consumer deserve to know what factors might be influencing their providers' prescribing decisions. But it is unclear what this reporting requirement will accomplish besides increased regulatory burden and the potential to discourage the provision of samples.

Product samples provide significant patient benefit, particularly when a patient is unsure which product might be best for him or her. The patient can try a product, which might be quite expensive, without worrying about potential sunk cost if it turns out to be ineffective. Free samples are also quite beneficial when an insurance plan requires prior authorization. The free product sample allows the patient to begin treatment right away, at no cost until insurance coverage kicks in. It may be worth monitoring for this possibility and reevaluating the usefulness of this requirement in the future.

There is an important difference, however, between publishing such data and using the reported data to improve understanding of the industry. The Medicare Payment Advisory Commission (MedPAC) has recommended that product sample information be made available to oversight authorities and researchers "to study their impact on prescribing patterns, overall drug spending, and patients' adherence to treatment regimens."³

MedPAC also notes findings from several studies which suggest limiting samples might be beneficial. A 2008 study found that wealthy and insured patients were more likely to receive free samples than poor and uninsured individuals.⁴ Physicians who receive free samples of a new drug are more likely to prescribe it.⁵ Patients who receive free samples have higher out-of-pocket spending on drugs than patients who do not receive samples (presumably because they are reluctant to switch off the brand-name drug for which they've received a free sample once the sample runs out).⁶ And physicians are more likely to prescribe generic medicines to uninsured patients when they no longer have access to samples.⁷

For these reasons, the Committee may want to focus on collecting the data and giving the agencies the authority to permit access to those data to study more thoroughly the potential impacts on patients, both positive and negative.

Analysis and Report on Inpatient Hospital Drug Costs

This section of the STAR Act requires the Secretary of HHS to analyze drugs furnished in inpatient settings, assessing drug costs, Medicare spending, volume, and spending per admission, as well as the trends of each of these variables by hospital size, whether the hospital is in an urban or rural area, whether it is a teaching hospital or not, and the impact of drug shortages on services furnished in an inpatient setting. The Secretary is then required to report the findings to Senate Finance and House Ways and Means Committees. In order to pay for this study, \$3 million would be transferred from the Medicare Hospital Insurance (HI) Trust Fund.

I have no doubt this will be useful information for policymakers, but shifting money from the HI Trust Fund, which is already scheduled to be depleted in just seven short years, may not be the best use of those funds. Three million dollars is enough money to pay the hospital costs of 539 Medicare beneficiaries in 2020, according to the latest Medicare Trustees Report.⁸

H.R. 2115, the Public Disclosure of Drug Discounts Act

This section of the legislation, H.R. 2115, the Public Disclosure of Drug Discounts Act, requires the Secretary to make information regarding pharmacy benefit manager (PBM) and drug manufacturer rebates, discounts, and price concessions, as well as generic dispensing rates publicly available, and requires this information to be provided separately for each PBM. The language does stipulate that the data should be displayed in a manner that prevents the disclosure of information on rebates, discounts, and price concessions, at the individual drug or plan level. In order to ensure confidentiality of proprietary information, the information would be required to be aggregated by drug class, but only if the Secretary determines the number of drugs in a class is sufficient to meet the confidentiality requirement. Further, one year's data must only be made available after two years have passed.

In thinking about this proposal, a number of issues arise. First, while I appreciate the importance of understanding the effectiveness of the Part D and other programs, I do not see a reason for a federal role in commercial market negotiations.

Second, with regard to government programs, it is important to distinguish between those data needed to understand how well programs are working, and data in general. The former could be made available to MedPAC and other researchers, but not disclosed in general.

If information is made public, it is important to not provide so much data that competition is damaged. While this may seem counterintuitive, many economists agree that there is the

potential for price transparency to backfire and lead to higher prices, rather than lower prices. For publicly available data, it is worth considering the appropriate number of drugs in a given class. A manufacturer could easily figure out the price and rebate amounts of their competitor if there are just two drugs, for example. This could violate the intent to protect proprietary information and could illustrate for a company how much it could raise its price and still be the cheaper option.

H.R. 2087, the Drug Price Transparency Act

H.R. 2087, would require drug manufacturers without a rebate agreement in effect for the Medicaid Drug Rebate Program to report ASP pricing information for the purpose of determining the appropriate Medicare Part B payment rate for such a drug. The information provided would be subject to audit by the HHS Office of the Inspector General (OIG) and subject to verifying surveys of wholesalers and manufacturers conducted by HHS. Further, the OIG will be required to submit a report to Congress on the accuracy of ASP data and any recommendations on how to improve it.

This has been recommended by MedPAC and it seems reasonable that HHS have the information needed to ensure correct payment for products and services.

H.R. 2376, the Prescription Pricing for the People Act

The Prescription Pricing for the People Act, H.R. 2376, requires the Federal Trade Commission (FTC) to study the role of intermediaries, such as PBMs, in the pharmaceutical supply chain and whether industry stakeholders engage in anti-competitive and non-consumer-friendly behaviors. If so, the FTC should make recommendations to Congress as to how to make the market more competitive and transparent. The FTC should also make recommendations that would help ensure consumers benefit from the discounts and rebates provided to the various industry stakeholders.

It seems clear that there is a role for the FTC to take action where there are obvious abuses of monopoly power and anti-competitive behavior.

The Creating Lower Cost Alternatives for Your Prescription Drugs Act

This legislation would reduce the co-payment amounts for drugs provided to low-income subsidy (LIS) Medicare Part D beneficiaries. Specifically, the co-pay amount for generic drugs would be reduced to \$0 by 2021 and a middle tier with a co-pay of \$1 would be added for single-source drugs. Multiple-source brand-name drugs would be on the third tier with a co-pay of \$3. These amounts would apply to both full and partial dual-eligible individuals, eliminating the current discrepancy in co-pay amounts between the two groups.

MedPAC has long recommended that co-pay amounts for LIS beneficiaries be reduced for generic drugs.⁹ In 2016, 71 percent of high-cost enrollees (beneficiaries reaching the catastrophic coverage threshold) were LIS beneficiaries.¹⁰ Part of the reason for this is that

LIS enrollees take more medicines and are more likely to use brand-name drugs, rather than simply needing more expensive medicines. MedPAC has noted that high-cost LIS beneficiaries took 18 more prescriptions, on average, than non-LIS high-cost enrollees in 2015,¹¹ and the generic dispensing rate has consistently been 4-5 percentage points lower for LIS enrollees than non-LIS enrollees.¹² This is likely because of the minimal price difference they face between generic and brand-name medicines. Reducing the generic co-pay amount to \$0 will provide a strong financial incentive for individuals with limited income to use generics rather than higher-cost brand-name drugs. Further, providing a middle tier for brand-name drugs which still have rights to exclusive market access (rather than placing these drugs on the higher co-pay tier with other brand-name multiple-source drugs) helps to not burden low-income individuals with a higher co-pay when there is no other option.

Notes

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- ¹ <https://www.iqvia.com/institute/reports/orphan-drugs-in-the-united-states-growth-trends-in-rare-disease-treatments>
- ² <https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291>
- ³ http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf (page 197)
- ⁴ Cutrona, S.L., S. Woolhandler, K.E. Lasser, et al. 2008. Characteristics of recipients of free prescription drug samples: A nationally representative analysis. *American Journal of Public Health* 98, no. 2 (February): 284-289.
- ⁵ Peay, M.Y., and E.R. Peay. 1988. The role of commercial sources in the adoption of a new drug. *Social Science & Medicine* 26, no. 12: 1183-1189.
- ⁶ Alexander, G.C., J. Zhang, and A. Basu. 2008. Characteristics of patients receiving pharmaceutical samples and association between sample receipt and out-of-pocket prescription costs. *Medical Care* 46, no. 4 (April): 394-402.
- ⁷ Miller, D. P., R. J. Mansfield, J.B. Woods, et al. 2008. The impact of drug samples on prescribing to the uninsured. *Southern Medical Journal* 101, no. 9 (September): 888-893.
- ⁸ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/downloads/tr2018.pdf>
- ⁹ <http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report.pdf>
- ¹⁰ http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf (page 422)
- ¹¹ http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf (page 425)
- ¹² <http://www.medpac.gov/docs/default-source/reports/chapter-13-status-report-on-part-d-march-2016-report.pdf> (page 393)

Ms. ESHOO. Thank you very much, Dr. Holtz-Eakin.

And again, we all want to thank our witnesses for being here today and the testimony that you have given.

We have now concluded those opening statements and we are going to move to members' questions. Every member I think knows that they have five minutes to ask questions of our witnesses. And I will start by recognizing myself for five minutes.

Dr. Feldman, you said that PBMs have pushed you to prescribe higher-priced drugs, is that right?

Dr. FELDMAN. Thank you.

What I have found is there are some drugs that have come to market with lower list prices that have been unable to get onto the formulary because their list price was too low. And what I mean by that is, the price concession, for example, the rebate would be the list price times the discount times the market share.

Ms. ESHOO. So, the one on the list—

Dr. FELDMAN. Yes. So, yes, the lower list price—

Ms. ESHOO. You put on the table that PBMs pushed you to prescribe a higher-cost prescription drug.

So, I want to go to Ms. Bass and say to you, what is the answer to that?

Ms. BASS. Our companies always negotiate to the lowest net cost.

Ms. ESHOO. So, why was she pushed to a higher-priced drug?

Ms. BASS. Because the lowest net cost of that drug was lower than the drug with the lower list price.

Ms. ESHOO. So, the higher was lower, and the lower is higher? I mean, I don't quite get this.

Ms. BASS. But, yes, it—

Ms. ESHOO. Maybe you can rephrase it?

Dr. FELDMAN. Yes. So, competition can raise prices or lower prices. Because the price concession is the highest price concession, which ultimately, they are calling the lowest cost, sometimes to get at the highest price concession you need the highest list price. And therefore, a drug with a lower list price can't offer as big of a percent rebate. But I think that shouldn't be how it is. I think the lowest list price should get preferred status.

Ms. BASS. So, the way the math works on that, let me just quickly say—

Ms. ESHOO. Quickly.

Ms. BASS [continuing]. If both drugs had different pricing, but they came in at the same low net cost, that would be great, but—

Ms. ESHOO. If they came in or you negotiated lower?

Ms. BASS. Our companies negotiate to the lowest net cost. And if it is a lower list price drug that has the lowest net cost, that is the preferred drug.

Ms. ESHOO. Well, there doesn't seem to be an agreement here. Dr. Feldman is shaking her head in the negative.

Dr. Feldman, why do you think that drug manufacturers will not give samples to doctors if there is a public reporting requirement? I wasn't so clear on why you—

Dr. FELDMAN. Why I feel that way?

Ms. ESHOO. Yes.

Dr. FELDMAN. So, for example, it goes back to the list price of the drug.

Ms. ESHOO. Well, I mean, because the FDA already requires drug samples to be reporting. So, the reporting burden, at least on the surface to me, I don't think would be a deterrent.

Dr. FELDMAN. I can tell you, if it actually worked to the opposite—I mean, some of the samples that are given, the list prices of those are \$6,000 a month. And you usually get three months at a time.

Ms. ESHOO. So, you are saying that it is better that people don't know what it is and that, in turn, motivates samples being contributed?

Dr. FELDMAN. What I fear is that, when it looks like the pharmaceutical manufacturers are giving this much money to the doctor, that it may make them not do that. However, if it had just the opposite effect where everyone thought, oh, look how generous pharma is, and it actually didn't affect the ability—I just want to do whatever will keep the samples coming for our patients.

Ms. ESHOO. I understand. I understand. I don't think that the case has been definitely made on the point that you raise. Maybe it will be, but I am not so—

Dr. FELDMAN. I understand.

Ms. ESHOO. I am not convinced.

We are looking for money. We are looking for savings across the entire system, so that at the end of this chain, this pipeline—and you heard members on both sides of the aisle say this—so that the patient captures the savings, so that the price at the counter goes down.

Now there are some things that are real market influencers, and I want to examine this. I have thought for many years that research and development is the top cost. But, as it turns out, the marketing of drugs exceeds that; it outstrips it. And we only, I think, actively study and market drugs that are on patent. Is there any major drug company that advertises generics? Anyone know the answer to that? I think I know the answer. I stay up late at night. I haven't seen one, but I am missing them; I don't know have the TV on at the right time.

I think that that kind of stands the system on its head because it is a huge cost. And I understand costs. There are many costs to bring a drug to market. But you know what? When it exceeds research and development, which is absolutely essential, I think that we have an issue here.

There is marketing to physicians and other healthcare professionals. Is there anyone here that can put a price tag on that? Do you know, Dr. Holtz-Eakin or Dr. Miller? No? Mr. Isasi?

Mr. ISASI. What we know, this is very hard information to get at, in part, because the pricing and the payments in industry are so obfuscated. But we know that they are spending maybe 20 to 25 percent of their revenue on—

Ms. ESHOO. Well, we know that marketing to physicians and other healthcare professionals by companies increased from \$15.5 billion in 1997 to \$20.3 billion in 2016. That is about a 30 percent increase.

Mr. ISASI. And it is much more than they are spending on R&D; on innovating.

Ms. ESHOO. Does PhRMA want to weigh-in on this—wish to weigh-in on it?

Ms. JOLDERSMA. Yes, I do. Thank you, Chairwoman.

I would say at the outset that I think it is important to check our facts. We do hear regularly that the pharmaceutical industry spends more on advertising and marketing than we do on R&D. And at least speaking for my membership, that is patently false. Frequently, comparisons over State marketing expenditures, because those expenditures are pulled from the sales and general administration figures which includes a whole host of things other than marketing—

Ms. ESHOO. Why don't you get us some definitive information from your viewpoint?

Ms. JOLDERSMA. Sure. I would be happy to do that, absolutely.

Ms. ESHOO. That would be helpful to make part of the mix.

I have gone over my time. I now would like to recognize the ranking member of the subcommittee, Dr. Burgess from Texas, for five minutes for his questioning.

Mr. BURGESS. Thank you.

And, Dr. Feldman, as I look online, you reference that you have been practicing rheumatology for 35 years. I am a little older than you are. So, I actually remember not only that there wasn't much with which to treat rheumatoid arthritis, some of the treatments we had were probably as hazardous as having the disease itself. I mean, colloidal gold shots? Does anybody do that anymore?

Dr. FELDMAN. Very rarely.

Mr. BURGESS. And, of course, aspirin to toxicity, you raise the dose until the ear-ringing became so loud that people couldn't hear.

So, I, for one, am grateful that, as I look online, there are—what?—eight or nine biologics that are available? I mean, these are relatively-new medicines that really are game-changers as far as providing not just relief for your patients, but preservation of function, which previously wasn't available. I mean, that is a good thing, right? We have got nine agents that now are available to you.

I will confess, when I watch some of the ads on TV—and I play a little game. I have one of the pharmacy pricing apps on my phone. So, I type in the name of the drug. I, for one, would like to see—I think Secretary Azar is onto something when he says we ought to disclose what the cost to the patient would be. I mean, look, when I see all those ads, and if I were having to make a decision which drug to start, do I want the one that Phil Mickelson is on or do I want the one Cyndi Lauper likes to take? I don't know, I mean, as a patient, I don't know how to judge that.

But I think that information could be helpful. It might even be helpful to a physician to know that as well. Just going down this list of medicines, they are all fairly expensive, but some are more expensive than others. And if it is something you are going to be on over the long term—but you correctly said it would be wrong for a formulary or an insurance company, anyone else, to change your patient's medication. That is the practice of medicine, and we should not let that happen other than by a physician.

Now, on the issue of advertising generics, look at my State, and I assume most states are the same. I write a prescription, and the

pharmacist can actually substitute a generic. Even if I write, "Dispense as written," I don't know whether they always agree with that. So, no, generics may not be advertised, but at the same time the pharmacist has the ability to substitute the generic equivalent for the patient at the pharmacy counter, is that not correct?

Dr. FELDMAN. Yes.

Mr. BURGESS. So, I mean, if I am in the business of selling a generic, why would I advertise? I have got the good people at Crestor already doing the ads for me. I don't need to spend my money doing that.

I think that the thing is that you have got eight or nine medicines that are now advanced treatments for rheumatoid arthritis. And in your professional lifetime, certainly my professional lifetime, at the beginning of our professional careers those things were not available. So, it is a great thing that they are available now.

I do not know how many trials there were that didn't work out. I suspect there were. I don't know how you go back and price that in. I suspect that that is difficult to do. You gave a figure of what, 12 percent success rate? I mean, that is a lot of dry holes that you are drilling in order to get the home run. I want you to drill those dry holes. I think that is important. I want you to have eight or nine medicines that not just treat a patient's symptoms now, but preservation of function.

And that was the whole purpose in doing cures. We are getting to a place where things that were just unthinkable a few years ago are now within our grasp. A single-shot therapy to cure a disease that otherwise not just would bankrupt an individual, but a family; perhaps even a health plan, and now a single shot that can cure it. I don't know how you price that in. We are going to have to figure that out, and that is why these discussions are so important; because we do have to figure that out for the future.

Sickle cell disease, which was featured on "CBS 60 Minutes" a couple of months ago, the cost for this therapy that Dr. Collins referenced as a cure for sickle cell - I mean, that is a big deal.

We heard in this very room at this very table in 2016 the witness for the Sickle Cell Disease Association said there has been no new sickle cell FDA-approved treatment in 40 years. So, when we look at the cost of this new sickle cell therapy, when we look at that cost, I think we have to look at it in light of the fact that for 40 years we didn't improve at all. And what was the cost over those 40 years where we didn't improve? And we have got to somehow find a way to amortize that going 40 years into the future.

It is a good time to be in the business that you all are in.

Ms. ESHOO. The gentleman yields back.

Mr. BURGESS. And we appreciate so much you being here today. We have got some tough decisions to make and we are anxious to get on about making them, apparently.

Ms. ESHOO. Thank you, Dr. Burgess.

Mr. BURGESS. I will yield back.

Ms. ESHOO. And the gentleman yields back. It is a pleasure to recognize the gentleman from North Carolina, Mr. Butterfield, for his five minutes of questioning.

Mr. BUTTERFIELD. Thank you very much, Madam Chair.

Let me just begin with Ms. Joldersma. I am sure I got that wrong. I have a little trouble with names.

Ms. JOLDERSMA. Joldersma.

Mr. BUTTERFIELD. OK.

Ms. JOLDERSMA. Yes, not to worry.

Mr. BUTTERFIELD. I will just call you Lisa. How about that?

Ms. JOLDERSMA. You can call me Lisa. I prefer it.

Mr. BUTTERFIELD. Yes.

Ms. JOLDERSMA. Lisa J., if you will.

Mr. BUTTERFIELD. Yes. Thank you.

I am very pleased to hear that your member companies support the whole notion of transparency. That is a very important word now. It means sunlight. And thank you so much for making that acknowledgment today, especially with respect to prescription drug pricing.

I guess my question is sort of a reversed-type question. What information would you consider to be inappropriate for transparency?

Ms. JOLDERSMA. That is a very good question.

Mr. BUTTERFIELD. Yes.

Ms. JOLDERSMA. I think as many on the committee and other witnesses have noticed, we do need to be concerned about very commercially-sensitive information, proprietary information; that if released publicly, could cause conduct distortions in the market that we may not love. That is why I think both of the transparency approaches on the table today do attempt to protect proprietary and confidential information; and that is a very, very good thing.

Mr. BUTTERFIELD. And I suppose you are struggling every day to try to find a balance between those two interests?

Ms. JOLDERSMA. Absolutely.

Mr. BUTTERFIELD. Would that be correct?

Ms. JOLDERSMA. Absolutely.

Mr. BUTTERFIELD. What circumstances would require you to significantly raise drug prices? I mean, what would be the circumstances that would precipitate an increase in drug prices, other than corporate profit?

Ms. JOLDERSMA. Well, sure, there are many, many circumstances.

Mr. BUTTERFIELD. Just give me two or three examples, yes.

Ms. JOLDERSMA. Two or three examples? Increased costs, increased supply chain, expanded indications, expanded value. Maybe we learn that a drug is more effective than we previously thought it was.

Mr. BUTTERFIELD. Wouldn't that be corporate profit?

Ms. JOLDERSMA. No.

Mr. BUTTERFIELD. Yes, that would be separate from corporate profit?

Ms. JOLDERSMA. Yes. And I do want to talk about corporate profit briefly. A lot of people say that this industry's profits are far out of whack with other industries. And the truth is, that is because traditional accounting measures are not recognizing the high level of risk that this industry takes on.

And when you are talking about a 90 percent failure rate, the fact of the matter is, that 10 percent of the time when we don't fail, yes, it is true that the investors, the private entities that invest

and that help us fund this very difficult scientific search for cures—

Mr. BUTTERFIELD. Let me switch over to Ms. Bass. My time is clicking away. Ms. Bass, in your testimony you discuss the need to increase transparency in order to lower cost and improve the overall quality of care. Do you acknowledge that rebate practices are driving increased drug costs or do you dispute that?

Ms. BASS. We would dispute that.

Mr. BUTTERFIELD. Are you suggesting that the PBMs are sufficiently transparent or is there room for improvement?

Ms. BASS. As I testified, we are happy to report aggregate rebates. We have the same concerns that others on the panel have with respect to putting out information publicly that would allow for tacit collusion. Often, when one competitor learns that he or she has discounted more deeply than another competitor, what happens is that competitor doesn't discount as deeply the next time. And that is our big concern.

Mr. BUTTERFIELD. You are a nonprofit entity, if I am not mistaken, a 501(c)(6)?

Ms. BASS. We are the trade association for the industry, yes.

Mr. BUTTERFIELD. Which means that you are not in the business to make a profit. You are in the business to, according your 990 submission, you are in the business to lower prescription drug cost and increase access.

Ms. BASS. Our trade association represents the companies who are in the business to lower prescription drug costs and increase access, yes.

Mr. BUTTERFIELD. But you have told the Internal Revenue Service that your mission is to lower prescription drug costs. That is on your Form 990 that you submitted.

Ms. BASS. It sounds like we need to amend our form to say we represent the companies whose mission it is to lower prescription drug costs and increase access.

Mr. BUTTERFIELD. Take a look at that, if you would, please.

Ms. BASS. I will. Thank you.

Mr. BUTTERFIELD. Dr. Miller let me switch over to you, if I can. In your testimony, you discuss the importance of transparency and the consequence of Congress' inability to act to increase it. Why is transparency so important to implementing effective reforms? And you will have 15 seconds. I am sorry.

Dr. MILLER. What I would say is I think transparency can compel the issue forward. It may produce useful information for the Congress and other policy actors to act. I don't think transparency, in and of itself, will be enough to affect the drug price issues that you are facing now.

Mr. BUTTERFIELD. Thank you.

I yield back. Thank you.

Ms. ESHOO. I thank the gentleman and he yields back. I now have the pleasure of recognizing the ranking member of the full committee, the gentleman from Oregon, Mr. Walden, for five minutes.

Mr. WALDEN. Thank you, Madam Chair.

And I have got a question to Ms. Joldersma and Dr. Holtz-Eakin and Dr. Feldman.

H.R. 2064 is an attempt to provide transparency, but I am worried that the bill will have unintended consequences for patients. Manufacturers of drugs and devices often provide samples to providers that help low-income patients who may have trouble accessing a therapy, either because they lack insurance or an insurer does not provide robust coverage for a drug or a device. Yet, this bill places new reporting requirements on manufacturers. And my question is, doesn't this bill create a perverse incentive for manufacturers to simply not provide samples to physician offices? And can you describe how low-income patients benefit from samples provided by drug and device manufacturers, and any other unintended consequences? And I would just throw that out to the three of you.

Ms. JOLDERSMA. Thank you for that question.

Very briefly, I think there is a real question as to whether this could cause the lessening of provision of samples. I would also note that a significant amount of information is already reported to the FDA with regard to samples. So, in some respects, this is kind of creating a duplicate bureaucracy, if you will, and a duplicate reporting. So, our preference would be to work with what FDA already has.

Mr. WALDEN. To me, it also seems like a real convenience when you're with your physician, and they say, "Here, why don't you take these, and then, go get this?", and whatever. Dr. Feldman, what is your view?

Dr. FELDMAN. Yes. You know, we agree with MedPAC's recommendation under drug use confidential agreements. I mean, it can be something as simple as mandated mail orders for patients will deliver refrigerated drugs on the front porch in New Orleans in the middle of the summer.

Mr. WALDEN. That would seem to be a problem.

Dr. FELDMAN. And the medication is destroyed. So, then, of course, we can offer them samples.

Mr. WALDEN. OK. Dr. Holtz-Eakin?

Dr. HOLTZ-EAKIN. Yes, I don't know that it would eliminate the samples, but I think that is a risk you don't have to take. I mean, there are ways to collect the data you are interested in, have them available to researchers and oversight without the public disclosure the people are worried about. I would recommend that.

I guess the other thing I would mention is, there is existing reporting for drugs, but this expands that to include the devices. And I would think it would be worth the committee asking itself whether it is worth doing that. That is a costly new set of reporting, and I am not sure samples are all that typical in the device world.

Mr. WALDEN. OK. That is a good point. And I think I don't have too many people rushing me at town halls saying, "Please add more reporting requirements, more regulations, more rules." Yet, we know there is a place for that, but I think we have to be really judicious when we go down that path because we don't want to create more bureaucracy, more time away from caring for patients, and, also, I want to put the patient first.

I know a lot of States have been passing legislation to get to the bottom of why drug prices are increasing through price increase

disclosure legislation. But the bills we are talking about today go beyond any State law currently on the books, I believe.

So, my question would be, do you worry about the burden of companies complying with a patchwork of 50 different State laws plus a Federal law? And should Congress, if we go down this path, consider preemption language? Ms. Joldersma, would you like to comment on that?

Ms. JOLDERSMA. Absolutely. I think we have seen transparency legislation enacted now in seven or eight states.

Mr. WALDEN. Right.

Ms. JOLDERSMA. Obviously, today we have two different approaches before us.

Mr. WALDEN. Right.

Ms. JOLDERSMA. There were competing approaches in the Senate as well. So, certainly, harmonization of these reporting requirements is a high priority, and preemption would be one way to achieve that.

Mr. WALDEN. All right. Dr. Holtz-Eakin, do you want to comment on this?

Dr. HOLTZ-EAKIN. Drugs are nationally-traded commodities. There should be a single set of rules that prevail across all 50 States. I think preemption makes a lot of sense.

Mr. WALDEN. OK. And on transparency and PBM reporting, my question is, can you detail concerns of where too much disclosure could be anticompetitive? I have heard this from people. I am into disclosure. I am into public right to know. I think the more out there, the better. But I also recognize there comes a point where too much disclosure could actually have an unintended and reverse consequence; if a consolidated market was able to back in competitors' rebates, for example. So, Dr. Holtz-Eakin, can you comment on that?

Dr. HOLTZ-EAKIN. I think that is a real concern. If you can identify the deal that your competitor is getting, that is information that allows you the ability to perhaps negotiate less vigorously and get a higher price. We never want to let that happen. And so, all of these desirable attempts to ensure that these markets are competitive and work on behalf of beneficiaries, especially in Part D, I applaud. But disclosing those individual contracts and deals is a step in the wrong direction.

Mr. WALDEN. All right. Ms. Bass, could you comment on that as well?

Ms. BASS. Sure. It sounded like you wanted specifics. And what we would recommend would be making sure—the bill calls for reporting by class—you would need to make sure that every class had at least three drugs; otherwise, there wouldn't be reporting because you could back into rebates.

We would want to make sure that the reporting was lagged, preferably three years, again, to give a little bit of time between contracts. And we would want to make sure it wasn't PBM-specific, but across PBMs, for the same reason.

Mr. WALDEN. All right. I thank you all.

And I know the Chair has been quite generous with giving me extra time, I guess in recognition of the Blazers' defeat. So, we appreciate that generosity this morning.

Ms. ESHOO. All around nice man. All around good guy.

Mr. WALDEN. I yield back.

Ms. ESHOO. The gentleman yields back.

I just want to add something here. I believe that this particular legislation, that it is referencing a class of drugs. So, it is not one at a time. It is a class of drugs. And I think that we have to, all Members are going to have to do a deep dive on the actual wording and that is our job to do. But I thought I would throw that in the mix.

Now it is a pleasure to recognize a real gentlewoman from California, Ms. Matsui, for her five minutes of questioning.

Ms. MATSUI. Thank you very much, Madam Chair.

And I want to thank all the witnesses for appearing before us today.

We have been discussing in this committee that there is a need for greater transparency—that is really a word that we keep throwing around—but an entire drug supply chain that really gives us clear insight into the formulary and negotiations, price concessions, and market dynamics, that ultimately drive up the price consumers pay for the medications at the pharmacy counter.

Now drug price list increases have outpaced general inflation, medical inflation, and overall wage growth for many years. Lacking transparency, these price increases often seem arbitrary, indiscriminate, and very confusing. I am particularly interested today in discussing the trend of list price increases for drugs that are already on the market. A recent analysis found that prescription drug costs are primarily attributable to year-over-year price increases for drugs already on the market, not the introduction of new, innovative therapies or improvements to existing medications. And MedPAC has determined that, for high-cost Part D enrollees, the growth in drug spending was largely due to increases in average price per prescription filled.

Ms. Isasi, you mentioned in your testimony that increases in invoice prices for current drugs under exclusivity have generated \$108 billion in revenues, and that without these price increases, revenues would have been flat over the last decade for brand pharmaceutical companies, and overall spending on drugs would have fallen due to increased utilization of generic drugs. That is a staggering statistic and speaks to the motivations some manufacturers may have to raise prices for drugs already on the market. Mr. Isasi, from your perspective, what are the reasons that prices are increasing for drugs already on the market?

Mr. ISASI. Thank you very much for the terrific question.

I think it is really important. You know, we, all of us, want what is best for America's family, and we want to incentive innovation in the development of new drugs. That is a really important goal. But what we know is the current system is not doing that. As you point out, what has happened is so much of the pharmaceutical market share has migrated from patented, name-brand drugs to generics. And the drug companies are not developing the innovations that we need. So, instead, they are just raising the prices on the remaining patented drugs as fast and as quickly as they can.

And there are terrible examples of this. I mean, I will give you one example. Just last year, Catalyst Pharma acquired rights to

Firdapse. It is a 20-year-old drug used to treat neuromuscular disease. And the price increased to \$375,000. The drug was previously available from Jacob's Pharmaceutical and could be purchased for free through an FDA program, right? Those are the kind of abuses we are talking about.

Ms. MATSUI. OK. Dr. Miller, do you agree?

Dr. MILLER. Yes, I agree. I agree with the direction of your conversation. The attention or where I would direct your attention is, both in Part B and in Part D, you could consider inflation rebates which would penalize back part of the revenue that a manufacturer gets through its price increase. And you could devote that money to giving greater patient protections.

Ms. MATSUI. OK. So, Dr. Miller, it seems the rising prices for a product that has been long on the market kind of represents a market failure. Is this a typical market response for products outside the pharmaceutical marketplace?

Dr. MILLER. Well, as a general proposition, and what I understand about how broad your question is, no, it is not a typical. And insulin is, in particular—

Ms. MATSUI. Right.

Dr. MILLER [continuing]. A poster child for the problem.

Ms. MATSUI. So, both Mr. Isasi and Dr. Miller, from your perspectives, do you believe that research and development cost significantly account for the drug price increases? And I think I know the answer to that.

Dr. MILLER. No.

Ms. MATSUI. OK. What about high launch prices?

Mr. ISASI. No. And let me give you the example. Sovaldi is a great example.

Ms. MATSUI. Yes.

Mr. ISASI. Sovaldi was purchased by Gilead. They did not develop the drug. Their Wall Street analyst said, charge "X" amount, and then, they almost quadrupled it. Right?

Ms. MATSUI. Right. OK.

I have a PBM question. As I understand it, one way of PBM to keep costs down for plans is by keeping patients' out-of-pocket costs high. Simply put, what the plan pays as a net cost for a drug is calculated as a list price minus the rebate, minus the patient out-of-pocket share.

Dr. Miller, you mentioned some of the embedded incentives in your testimony. From your perspective, how are drug supply chain rebates preventing patients' cost-sharing from coming down?

Dr. MILLER. So, I mean, I want to be clear when I answer. I do think there is a role for negotiation and there is a role for a net price analysis and thinking through it, because those savings can be spread more generally through the benefit. But, given the current State of play, in particular, in Part D, there are drugs being placed on preferred formularies because of the rebate, and that is driving the out-of-pocket for the beneficiary and making it hard for the patient to afford it at the counter.

Ms. MATSUI. OK.

Mr. ISASI. Yes, and to the chairwoman's earlier question, when you were told, Chairwoman Eshoo, that the net cost was lower, the question is, to whom? The net cost to whom?

Ms. MATSUI. OK.

Mr. ISASI. Right? Not the beneficiary sitting in the pharmacy.

Ms. MATSUI. Right. OK.

I think I ran out of time. I yield back. Thank you.

Ms. ESHOO. Excellent.

The gentlewoman yields back. It is a pleasure to recognize the gentleman from Michigan, Mr. Upton, the former chairman of the full committee. Your time, five minutes.

Mr. UPTON. Thank you, Madam Chair. It is a delight to be here.

And I just have got a couple of questions. When we worked on 21st Century Cures, we spent a whole lot of time about thinking about policies that advanced new treatments for patients who had no therapies available, sort of like what former Chairman Walden said about sickle cell. But one of our main goals was to reduce the burden of discovery and development for small companies to ensure that new therapies got to patients who literally had no hope.

So, I am a little bit worried about the SPIKE Act, which is one of the bills that we are looking at today, looking at perhaps an opposite approach. The bill sets an arbitrary launch price level that triggers burdensome price reporting for companies. Many of the drugs produced for the orphan diseases are often developed by small companies. So, the price threshold doesn't always account for rebates and discounts provided by the manufacturers. If we are going to consider Federal price reporting, shouldn't we keep the focus on price increases, what was said a little bit earlier, rather than launch prices of orphan drugs produced by smaller companies advancing cures? Dr. Holtz-Eakin, what is your reaction to that?

Dr. HOLTZ-EAKIN. A couple of thoughts. I mean, in the end, I think it is important to focus on what the beneficiary ends up paying, and often, there is a big gap between list and what they pay. Often, they pay the list, and that is through the rebate structure. So, I think thinking through that carefully is important.

I do think that the kind of documentation that is envisioned by the SPIKE Act is unprecedented. I have never seen any kind of a request anywhere else in the economy; and for smaller manufacturers, it is going to be quite burdensome. I would be concerned about that.

And I don't see that this produces any particular pressure on pricing. And so, it is a pretty expensive piece of transparency that may or may not be effective.

Mr. UPTON. So, my next question is concerned about the H.R. 2064, the Sunshine for Samples Act of 2019. It impacts both drugs as well as devices. So, in 2017, MedPAC recommended that Congress expand the Physician Sunshine Act and require drug companies only. It didn't include medical device companies. So, as you look at device companies, they often provide, I guess, some free devices that are used, like prosthetics and others, to measure, but really a device is a one-time deal. And what are your reactions to including devices as well onto this bill versus just pharmaceuticals?

Dr. HOLTZ-EAKIN. I think it would make sense to not include the devices, see how effective the bill would be, if it goes forward on the drug front. And then, you could always revisit that issue going forward. But devices are very different than the drugs in terms of

the one-time aspect. And there is no existing reporting. So, that is the most costly part of what would be envisioned on this.

And I would just again say, I think building on what is in place as opposed to creating a new reporting channel makes a lot of sense; and that you can have oversight and you can have the FDA be required to provide the data to professional researchers to make sure that samples are used for the therapeutically-appropriate functions, and not to distort physician decisions. That is really what you want to know. All that can be done without putting this on a public website.

Mr. UPTON. Thank you. I yield back.

Ms. ESHOO. The gentleman yields back. I now recognize the gentleman from New Mexico, Mr. Luján, for five minutes of questioning.

Mr. LUJÁN. Thank you, Madam Chair.

Dr. Miller, you noted in your testimony that more and more drugs are saving people's lives or vastly improving their health outcomes and quality of life, are launching unsustainable prices that are simply unaffordable. What tools are currently available to control launch prices for the first-in-class, sole-source, novel therapies, and are there any mechanisms currently in place that constrain the price for these drugs?

Dr. MILLER. As a general proposition. I would say, no, that the mechanisms are not in place. I think it goes back to some comments earlier. When you grant a patent, you are granting a monopoly and the company can come first to class and charge any price.

I think the tools that I am trying to direct your attention to in the testimony and some of my comments is, in Part D, you might think of additional tools in the instances where you don't have a competitor. Part D was created to exploit competition and have the PBMs negotiate, but you are still going to have drugs that don't have competition. And you might want to think about things like pricing to the clinical value of the drug or some kind of negotiations strategy.

Mr. LUJÁN. How should we better ensure manufacturers are accountable to the public when setting prices for newly-launched drug products?

Dr. MILLER. Well, I think if you were to pursue the mechanisms that I just mentioned to you, that would bring a greater accountability at least a better price, to the Medicare beneficiary and to the taxpayer, if that is what you meant.

Mr. LUJÁN. The question that we had last week at hearings as well was the notion that there is a system that has been established such that you post your launch price, which I regard it as the highest price. And then, you have a lot of negotiations. There are discounts. There are rebates. There are other pieces that get to different lowest prices, if you will, that you have for each partner. And I just have a hard time understanding why we just don't get to that lowest price to begin with. They know how low they are willing to go. They know where they are going to be. So, if this is truly going to take into consideration the impacts to the patient and lowering costs, then that is where we should start.

Mr. ISASI. Is it Isasi?

Mr. ISASI. Isasi.

Mr. LUJÁN. Isasi.

Mr. ISASI. Yes.

Mr. LUJÁN. You noted in your testimony that the threshold to trigger reporting requirements for newly-launched products should be reduced from the current amount included in H.R. 2069 of \$26,000, the median income of average Medicare beneficiaries. Can you explain why Families USA would like to see this threshold price reduced for reporting purposes?

Mr. ISASI. Yes, absolutely. Thank you for the question.

It is critically important that we understand that, as these changes take place, industry is going to adapt, right? And so, what we will find is all the launch prices will come in just under whatever threshold is set. So, we have got to lower the threshold to a threshold that is based on the actual realities of the families who are in the benefit.

And to your earlier question, I also want to mention that a lot of folks don't realize this, but from the industry's perspective, even companies that aren't American, they start here in the U.S. launching first here, because we are willing to pay the highest price, twice, three times, four times more than the rest of the world, right? They start here. They set an incredibly high price. Then, they go out in the rest of the world and negotiate because we don't negotiate.

Mr. LUJÁN. I still want to talk a little bit more about the average Medicare beneficiary. One, I agree with your response to the first question. That is a concern that I have as well. How do we address that? And how do we set up a better environment when it comes to fairness?

To the question that I asked Dr. Miller, the number of people that are going to go without these therapies because they can't afford them—

Mr. ISASI. That is right.

Mr. LUJÁN [continuing]. Which is growing in the United States.

The advocacy that you are bringing forward in your testimony about lowering the amount that is listed in H.R. 2069, the \$26,000—and in your case, it would be a lower number—but \$26,000 is how much a family would make, would earn in a year. And all that this is saying is, if you are going to list your drug price higher than a Medicare beneficiary makes in an entire year, you should say why. Does that sound fair?

Mr. ISASI. Very fair.

Mr. LUJÁN. Madam Chair, I think that, as we talk about pricing care and the notion that, if you just leave it alone, and if Congress walks away and no one wants to be a part of this, that it will fix itself, it has not worked yet. And too many people out there are suffering and they are getting hit every day. And we should be reminded that we made a commitment, when we went to the American people over the last two years, that we would pass legislation to lower the cost of prescription drug prices for the American people, and we had better deliver on it.

And with that, I yield back.

Ms. ESHOO. Amen.

The gentleman yields back. I now would like to recognize the gentleman from Virginia, Mr. Griffith, five minutes for questioning, sir.

Mr. GRIFFITH. Thank you very much, Madam Chair.

Let me say, so that everybody is clear, my Democratic colleague just said that, you know, taking no action isn't working. He is right. And we are going to have to take action. And so, we will have to sort out what is the best action that we can take. But I think both sides of the aisle are dedicated to figuring out how we fix this. And there are all kinds of different ways to do it and all kinds of issues.

Dr. Feldman, in your oral testimony, I was very taken with what you were saying. You indicated you had a patient who had gotten a call to change their drug. I believe it was for rheumatoid arthritis, is that correct? And I want to know who called them, not the individual's name, but was it the PBM? Was it the insurance company? Who called them and said, "Hey, let's switch you over to this new drug"?

Dr. FELDMAN. It was the PBM, and they received a notification in the mail.

Mr. GRIFFITH. So, they received a notification in the mail from the PBM. And were you ever consulted about that?

Dr. FELDMAN. No. In fact, the patient brought it to me and said, "I've been asked to switch to this drug, a lower-cost alternative." And it is not necessarily a lower list price. This happens all the time when you have midyear formulary changes. Patients just get dropped. They won't even pay for it anymore. So, this at least was slightly less egregious than the complete exclusion of a drug from preferred formulary.

Mr. GRIFFITH. But you also indicated that this drug was not similar. It was not really an alternative for that patient. Can you explain that to me?

Dr. FELDMAN. It treats rheumatoid arthritis, but it was not a therapeutic equivalent drug. You know, there are different mechanisms of action in the immune system. And the drug that this patient finally ended up on affected T cells in a certain way. This one was something, a different drug entirely that did not affect the same part of the immune system. So, it would be ridiculous for me to change it.

Mr. GRIFFITH. So, let me try to break this down into more simple terms that I can understand, and hopefully, the folks back home who will be watching this later or watching it now will be able to understand. So, antacids, I take Zantac because I have lots of food allergies, and a lot of times a stomach upset is caused by my allergies. That being said, Tums doesn't do much for me, as a result of that, and Zantac has an antihistamine in it. Are you saying that what they did was they took him off the Zantac that had something that could help him and moved him onto something like the Tums, which might be a very good product for some people, but doesn't work for me? Is that what you are trying to say?

Dr. FELDMAN. Scientifically, it is not the same—

Mr. GRIFFITH. OK.

Dr. FELDMAN [continuing]. But, conceptually, yes.

Mr. GRIFFITH. Conceptually? OK.

[Laughter.]

At least I got the concept.

Ms. Bass, all right, shouldn't PBMs at least be trying to contact doctors? Look, my stomach upset is not a big deal. But somebody that has got rheumatoid arthritis, that is a big deal. Shouldn't the PBMs be contacting the doctor to say, for this patient, does this switch make sense because we are trying to save some money? Now I don't mind anybody trying to save some money, but let's make sure it works for the patient.

Ms. BASS. So, in those kinds of situations, there are definitely appeals rights for everybody in Medicare and every private sector plan. And PBMs absolutely work with doctors to figure out in that instance what the right thing is.

Mr. GRIFFITH. But most patients don't understand the appeals rights. They don't understand the appeals process. They just know they have gotten this. And what about the cases like Dr. Feldman said? In some cases, they don't even give you a choice; it is a matter of "We are no longer paying for the drug that you have been on for the last four years or five years that has been effective for you, and we are switching you over to this drug. And you can pay for that other drug, if you want to, but we are not paying for it." That really can be disruptive, wouldn't you agree?

Ms. BASS. It sounds terribly disruptive, I agree.

Mr. GRIFFITH. So, what can we do about that?

Ms. BASS. Again, there are exceptions in Medicare Part D, and there are processes to go through. And in that instance, the patient would have to go through that with his or her physician.

Mr. GRIFFITH. So, the physician and the patient are going to have to have a lawyer to help them figure out the process, is that what you are saying?

Dr. FELDMAN. And that is why we need the samples to continue the patient on the correct medication because it can take six to eight weeks to go through an appeals process.

Mr. GRIFFITH. Thank you. So, that way, you have more time to go through the appeals process. Well, that makes sense. Thank you, Dr. Feldman.

How many different PBMs are members of your association?

Ms. BASS. Right now, there are about 15.

Mr. GRIFFITH. About 15? So, across the country we have about 15? Or how many PBMs do we have? Some of them probably aren't members, I guess.

Ms. BASS. There are 66 full-service PBMs in the U.S., and there are more organizations that provide PBM services.

Mr. GRIFFITH. Does that seem like maybe we have got a little monopoly going in the PBM industry?

Dr. FELDMAN. Three PBMs control nearly 80 percent of the population.

Mr. GRIFFITH. Yes, that is why I was asking the question. And I understand you can't answer that because you have got an association to represent. But the point is that, when we hear testimony that the PBMs are asking our drug manufacturers to raise the list price, and then, many of them get a percentage of the cost of the drug for handling it, it looks like to me, We have got, the fox is in the henhouse and we are going to have to take some action.

I yield back, Madam Chair.

Ms. ESHOO. I thank the gentleman and he yields back. And now, I would like to recognize the gentleman from Oregon, Mr. Schrader, for five minutes of questioning.

Mr. SCHRADER. Thank you, Madam Chairman. I appreciate it very much.

Yes, I would associate myself with the remarks of the last two Members that talked because industry is, unfortunately, in a situation where there are a lot of changes. The pricing structure is completely opaque and very complex. I don't blame anyone in any of the industry sectors for that. It has just grown up that way. But, as a result, it calls for, unfortunately, our work here to make it a little more transparent. And everyone, apparently, loves transparency, but what that means is in the eye of the beholder; is what we are hearing now. So, that would be, unfortunately or fortunately, our judgment call, hopefully based on hearings we have had. We have had a number of hearings, and hopefully, will give the American people some assurance that we are on their side and trying to help, not stifle innovation, but at the same time make sure they get the best deal possible out there.

Ms. Joldersma, I appreciate you being here. I appreciate your discussion on the role that rebates may play and having a higher list price drug get a preferable placement on the formulary. Could you give any examples of medicines where you think that might be the case?

Ms. JOLDERSMA. Well, it is challenging for me, as a trade association, to speak to what would really be a very proprietary arrangement. But I can say that I noticed last week one of our member companies did testify here and talk about the difficulties it has had with formulary uptake after it did lower the list price of one of its blockbuster medicines really. So, there is that in the record.

I believe that other statements have been made on the record in the diabetes space, where we have seen companies who have launched authorized generics with the hope of being able to lower that list price, and they, too, have faced some challenges. So, there certainly are examples.

Mr. SCHRADER. All right. So, then, do you think public disclosure of the discounts, including administrative fees, would be helpful in preventing this?

Ms. JOLDERSMA. So, yes, we do agree that more disclosure is required in that, including administrative fees would be important. We have seen the fees that manufacturers paid to manufacturers increase enormously; really in the last several years. And at least my read of the current statute is that a whole swath of administrative fees are excluded from reporting under Section 1150(a) that was enacted by the ACA.

Mr. SCHRADER. It seems a little bit like PBMs almost double-dip. You have the rebate situation. The price negotiating goes on. Then, there is also this administrative fee, which seems a little inappropriate.

Ms. Bass, I appreciate the explanation of the role, at least in your testimony, of the P&T committees and evaluating all the clinical and medical evidence that is out there before making coverage

recommendations. Does cost and rebate amount play at all in these determinations?

Ms. BASS. The P&T committees work solely on the clinical efficacy of the drugs. And then, they give their recommendations to the PBMs, and the PBMs then go and negotiate to the lowest—

Mr. SCHRADER. So, if that is the case, then, how would you explain the higher list price drug with a greater drug rebate receiving a more favorable formulary placement oftentimes?

Ms. BASS. If the lower list cost drug came down as low on the net cost basis, it would be on the formulary.

Mr. SCHRADER. So, it does have an impact, apparently? Do you support increase in transparency in the fees, including administrative fees I just talked about that you'll receive from the pharmaceutical companies; and also, DIR payments that go on with the pharmacies?

Ms. BASS. All of the fees and pharmacy DIR are reported in Medicare Part D to CMS.

Mr. SCHRADER. So, you wouldn't object to them being public?

Ms. BASS. So, again, we have issues around public reporting when it is very clear and would get at, would allow for tacit collusion. But, in the aggregate, no.

Mr. SCHRADER. OK. A question for Dr. Feldman on the samples. I listened to Dr. Burgess talk about his lack of attention to the samples from the standpoint of what he is going to prescribe. He knows what he thinks that patient needs best. I would assume Dr. Bucshon would feel much the same way. The samples, to your testimony—I was a veterinarian for many, many years—do provide an opportunity for a patient to get much-needed care they couldn't get otherwise in the interim. So to me, the sample issue seems much to do about nothing. Is there really a reason to collect all of this data and go down that road, in your opinion?

Dr. FELDMAN. As long as it keeps the samples coming for the patients that need them, I am happy. And I do have specific examples of the question about a lower-price drug not getting on the formulary, if anyone wants to know.

Mr. SCHRADER. Well, maybe we could get that to my office after the hearing is finished.

Following up a little bit, would utilizing existing frameworks for evaluating the quality of a physician and their conduct, how they do things, be a suitable metric for lifting prior authorization? You have testified about how that really makes it difficult; ergo, these samples become important. We are trying to find ways to lessen the requirements for prior authorization. Are there some policies, either that a physician's office, a hospital, whatever, follows that might give us some guidance to help us help you?

Dr. FELDMAN. Yes. With specific guidelines and pathways developed by certain physician groups, we can bypass PAs on things from MRIs to certain drugs. And I think that is a valuable way to make it easier for the patient to get the proper medication.

Mr. SCHRADER. If we could get some of that, that would be outstanding.

And I yield back. I am sorry.

Ms. ESHOO. The gentleman yields back. I now recognize the gentleman from Indiana, Mr. Bucshon.

Mr. BUCSHON. Thank you, Madam Chairwoman.

I was a surgeon before I was in Congress.

Ms. ESHOO. Dr. Bucshon, I am sorry.

Mr. BUCSHON. Yes, thank you.

I would agree, Mr. Schrader, that the sample issue is a red herring. I mean, I will just say, as a physician, the basic premise that we practice medicine based on this type of thing as a group is false. I would decide what type of medication that a patient is on and, then, ask my staff, "Hey, do we have any samples of this?", not the other way around.

The other thing is, from a PBM perspective, I don't like restricted formularies, and I particularly don't like it when non-medical people don't allow access to medications for patients based on profit. And we have heard a lot of testimony, and that may not be pervasive across the industry, but there clearly is substantial evidence that that is happening.

And I don't believe it when people say that drug companies aren't being called literally daily and talking about their list prices and the margins and other things like that. That is happening, and the incentives are just not aligned.

The last thing I will say, and then, I have a couple of questions, is we have been going after providers now since the last 1980s, cutting reimbursement to the people that actually are in the arena taking care of patients. And it has solved all our problems, right? It is the providers' fault. They make too much money. They are doing too many procedures. They are prescribing too many drugs. Well, the reason we haven't been able to make a dent in medical prices—in fact, it is worse not only in this, but other areas of medicine—is because that is not the problem. And now, we have got shortages of physicians nationwide as a result, including particularly in primary care.

Ms. JOLDERSMA, as part of H.R. 2087, the Drug Price Transparency Act, all drug manufacturers will be required to submit information to the Secretary on the average sales price, ASP, for physician-administered drugs coming under Medicare Part B. However, it is my understanding that certain medical devices that are reimbursed under the drug benefit could be excluded from this requirement. In keeping with the spirit of transparency and market-based pricing, is there opposition to including a policy change to ensure all such devices reimbursed as drug products also would be subject to ASP reporting?

Ms. JOLDERSMA. From the perspective of PhRMA, no, there is no opposition.

Mr. BUCSHON. OK. Well, Chairwoman Eshoo, I hope we can work together to address this issue and the legislation as it moves forward.

And so, I just want to again, on the samples, Dr. Feldman, you raised the issue, and again, is there any evidence in your view anywhere that samples that are given to physician offices have any effect on overall practice of medicine? And also, doing this type of reporting, do you feel like it would do anything to lower drug prices?

Dr. FELDMAN. I don't think it will do anything to lower drug prices. And, no, they have absolutely no bearing on my prescribing habits whatsoever.

Mr. BUCSHON. Mr. Holtz-Eakin, do you think particularly that the sample issue is a big enough issue that it would have any substantial impact on lowering drug prices? As you pointed out, the key here is out-of-pocket costs. That is what we are trying to get down.

Dr. HOLTZ-EAKIN. I don't think the sample issue drives much.

Mr. BUCSHON. Yes. So, there is just really, really no evidence that that would be the case.

And I guess, Ms. Bass, what do you think of the administration's proposed rule on rebates?

Ms. BASS. We don't think that the administration's proposed rule on rebates will do anything to lower list prices.

Mr. BUCSHON. How come?

Ms. BASS. Because the manufacturers set the list prices, and the PBMs negotiate lower net costs, but PBMs are not involved in list prices.

Mr. BUCSHON. Don't get me wrong, I know that PBMs have a value-added role in this whole thing. My personal view is that the proposed rule, although the devil is in the details, is something that is going to lower, going to take away the upper pressure on list price. I mean, I know the PBMs all say that it won't make any difference at all, but I would argue that it does. I mean, what is your view on that?

Ms. BASS. We would respectfully have to agree to disagree. We do think that there is a conversation to be had around the use of the price concessions PBMs negotiate.

Mr. BUCSHON. OK. Fair enough.

Ms. BASS. But, right now, they are used for premium in Part D. And what the Secretary is trying to get at, I believe, in part, aside from lower list, is to help people at the pharmacy counter.

Mr. BUCSHON. OK. With your indulgence, Madam Chairwoman, Mr. Holtz-Eakin, you had a little comment on that?

Dr. HOLTZ-EAKIN. Just from the economics of it, if you have the ability to negotiate rebates, you ought to have the ability to negotiate prices, and it is the same negotiation. It will be more effective if the rule covered not just Part D, but the commercial market as well. I mean, that would make a difference.

Mr. BUCSHON. I agree with that. Thank you.

I yield back.

Ms. ESHOO. The gentleman yields back.

Did you want to add something to that, Dr. Miller? You looked like you were just ready to turn your microphone on.

Mr. BUCSHON. Excuse me. I didn't recognize him to respond to my question.

Ms. ESHOO. I am recognizing him. I am recognizing him.

Mr. BUCSHON. OK. Fair enough.

Dr. MILLER. I mean, we think the most credible analysis is that it ends up in the Part D program, adding to the cost of the taxpayer, and that it doesn't have a significant effect on list prices.

Ms. ESHOO. Thank you.

I recognize the gentleman from California, Mr. Cárdenas.

Mr. CÁRDENAS. Thank you very much, Madam Chair, and thank you for recognizing as the chair, as you have the right to do so.

Also, I would like to thank the ranking member for having this committee as well, to both of you.

I am very proud to serve on the Energy and Commerce Committee and proud to say that we take the time to consider many perspectives, so that we can move forward with meaningful legislation. And the bottom line is that, right now, Americans across the country are hurting. It is our job to tackle these big problems like drug pricing to help all Americans, to give them real choices that don't involve choosing between keeping their families fed and keeping them healthy.

With that in mind, we have had several hearings now on prescription drug pricing. One thing we have been hearing about is how efforts to cut costs are just not making it to the everyday American citizen.

Ms. Bass, thank you for being here today.

I am interested in discussing how price concessions and rebates directly impact consumers and whether insurance plans or their beneficiaries are more likely to benefit from these negotiated prices. You mentioned that plan sponsors can determine how PBM-negotiated price concessions are used. Can you explain some ways that health plans, and specifically prescription drug plans, will use the rebates and other price concessions that PBMs acquire?

Ms. BASS. Sure. Thank you for the question.

In Part D, the rebates are used, essentially, to buy down the premium or to lower the premium and to keep it affordable across all beneficiaries. In the commercial market, plan sponsors use rebates across their health plan sometimes to help offset hospital costs. In other instances, they think about the rebates when they are setting their enrollees' cost-sharing. So, your \$10 generic copay and your, say, \$30 preferred brand copay, your health plan is probably taking into account the rebates it gets when it determines that level of cost-sharing. So, it goes sometimes toward premium, sometimes toward cost-sharing. It depends on the plan. In Part D, it is almost always for premium.

Mr. CÁRDENAS. So, what you just described is, it could be that, the biggest beneficiary of the system that we have today might actually be favoring the decision making of an insurance provider, not necessarily directly to the end-user, the citizen?

Ms. BASS. I guess the way I would characterize it is, if whoever the plan sponsor is decides to use it for premium, it benefits all enrollees with a lower premium. If the plan sponsor decides to put it toward cost-sharing, then it helps the people who are using drugs that have rebates, and 61 percent of brand drugs do.

Mr. CÁRDENAS. OK. All right. Are plan sponsors required to disclose how they utilize price concessions?

Ms. BASS. In Medicare, every plan sponsor reports its rebates, its fees, which we talked about earlier, to CMS; and CMS is aware of how those are used. In the commercial market, the PBM discloses to the plan sponsor what its rebates are; but plan sponsors are not required to publicly disclose, or even really—to the Secretary how they use the rebates.

Mr. CÁRDENAS. OK. I would like to point out that, on H.R. 2376, the Prescription Pricing for the People Act would require the Federal Trade Commission to study the role of PBMs in the supply

chain and report to Congress on recommendations. Do you have any recommendations on how we can best ensure consumers are directly benefitting from the cost savings generated by price concessions and rebates negotiated by PBMs? Ms. Bass?

Ms. BASS. So, first of all, we welcome the FTC review. And our recommendations are that, in Part D, you, as policymakers—and, in fact, you are overseeing the plan sponsors—have a conversation about should that money be used for reducing premium, holding down the premium, or should it be used for reducing cost-sharing? And that is a conversation you, as policymakers, should have, and we welcome that conversation as well.

Mr. CÁRDENAS. Again, Madam Chair, I really appreciate the opportunity for us to cover this very important issue. And healthcare is complicated.

Earlier today I was able to meet with a young woman in my office who actually grew up in my ZIP code. Very few people in my ZIP code actually make it to four-year institutions. She went beyond that and she is currently studying to be a doctor. She is in her third year. And I asked her what motivated her. And what motivated her was her little brother who passed away from a non-diagnosed illness that he had since he was born. He was a little boy when he died. And then, when her father got very ill, she urged him to go to the doctor and he said, “I never want to see another medical bill again.” And shortly thereafter, he died from a heart attack.

My point is, here we have a young person as an example of an American citizen who decided that is how I am going to try to make the world a better place, by becoming a doctor. I hope that we have that same urgency, as Members of Congress, to try to get down to the bottom of these issues and to make the world a better place for American citizens, and for everybody in this country, by doing what we can in the way that we have been appointed to do so or elected to do so.

So, again, thank you to the witnesses.

And thank you, Madam Chair. I yield back.

Ms. ESHOO. The gentleman yields back. Thank you for your beautiful words.

I now have the pleasure of recognizing the gentleman from Florida, Mr. Bilirakis, who has an important bill with Mr. Cunningham, the Creating Lower Cost Alternatives for Your Prescription Drugs Act. The gentleman is recognized for five minutes of questioning.

Mr. BILIRAKIS. Thank you. Thank you, Madam Chair. I appreciate it. Thank you for holding this very important hearing.

We have had a couple of hearings on this issue, and we should be focusing on this issue because this is what a lot of our constituents care about. I have a lot of seniors in my district and a large veterans population; and lowering prescription drug prices is an utmost priority for me.

To that end, I want to ask a question of Dr. Holtz-Eakin. To that end, the bill that I recently introduced, as Madam Chair pointed to, alluded to, with Congressman Cunningham, the Creating Lower Cost Alternatives for Your Prescription Drugs, or CLAY, the CLAY Act, is a great first step, in my opinion, modernizing Part D to

lower prescription drug costs. However, it is a first step, and I believe that modern Part D has been an outstanding program, one of the greatest programs we have had. And it has been below budget, like 40 percent below budget, and it has helped out our seniors. But we must upgrade it and modernize it.

I understand that AAF has a comprehensive proposal for modernizing Part D. Would you please share your input with the committee, Doctor, please?

Dr. HOLTZ-EAKIN. Well, certainly we would be happy to provide a copy of the paper that Tara O'Neill Hayes wrote, who is here with me today.

It is similar in spirit to what Dr. Miller discussed in his remarks, which is what we see in Part D is the most rapidly-growing Government cost, taxpayer cost, is in the reinsurance area. So, it is above the catastrophic maximum. And so, the proposal, in essence, says: "Why don't we have the prescription drug plans and the pharmaceutical industry be responsible for their share of the costs above that catastrophic maximum, so that the incentives to have high-priced drugs are diminished? Why don't we fully protect taxpayers against their out-of-pocket by having a catastrophic maximum where they don't owe any more past that? And then, have a sort of typical 80/20 split for the remainder of the drugs, so that PDPs have a real strong incentive to get PBMs to negotiate on their behalf for the remainder of the drugs."

Where typically they are not sole-sourced there is more competition, and the possibility of vigorous competition is much more likely. So, it is a good program. It is not broken. It has been very successful. But we can sharpen the basic negotiating incentives that were built into the program, make it better going forward.

Mr. BILIRAKIS. Very good.

Again, Doctor, Congress developed incentives to encourage development of rare disease therapies—and I work on that issue—where innovation was previously almost nonexistent. How might the SPIKE Act in its current form have an outsized impact on future innovation for rare disease drug development? And how can we best address this concern?

Dr. HOLTZ-EAKIN. I guess I would say a couple of things. You know I have my reservations about the SPIKE Act. I mentioned them in my written testimony and in my opening remarks. There is nothing about it, I think, that guarantees lower drug prices. It is most likely to impact those startups specializing in those kinds of drugs and where launch prices are typically very high. And so, you will be above this arbitrary threshold with that very high-value drug. And I worry about diminishing those incentives.

Having said that, I just want to echo something Dr. Miller said, which is I don't think transparency in the end is going to deal with the places where we have high drug costs in the United States. And the things under consideration today have merit, but they are not ultimately the solution. It is fundamental reforms of the type you talked about in Part D. I think those are important in Part B, where there is no particular reason to give 6 percent of the ASP to delivery of a drug. That is uncorrelated with the cost of actually treating a patient. So, reimburse for that instead. Those are the reforms that I think will be more effective than just transparency.

Mr. BILIRAKIS. Thank you.

One other question. Often when discussing high drug prices, we tend to focus on what is wrong without mentioning what is going right to ensure we achieve the desired result in a way that does not undermine the progress that has already been made or produce other negative, unintended consequences. Can you share with us what is currently working and how we might double-down on these efforts?

Dr. HOLTZ-EAKIN. As I noted at the outset, there is a tradeoff between financial incentives like prices and innovation. We are literally in an era with unprecedented innovation in the capacity to treat illnesses that were not previously deemed to be treatable. And all that is evidence of the power of that incentive, and I think it is important to hold onto that.

I also think it is very important to think “price for who?” That has come up several times. And keep focusing on the fact that in some cases—so, for example, with the rebate rule, if, in fact, list prices don’t go down, then there is a chance that premiums will go up for everybody. But the people who are going to be protected are those who have the biggest drug costs and the most severe conditions. That is exactly what an insurance program should do. And so, let’s keep track of whose price is being affected as much as prices in general.

Mr. BILIRAKIS. All right. Thank you very much.

I yield back, Madam Chair.

Ms. ESHOO. The gentleman yields back. I now would like to recognize the gentleman from Vermont, Mr. Welch, five minutes.

Mr. WELCH. Thank you.

Just starting to acknowledge something that Dr. Holtz-Eakin said, we have made a lot of progress in pharma. Unfortunately, the price is starting to kill us.

And I want to go to you, Ms. Joldersma. You mentioned that R&D is a big deal; there are 9 failures for every one success. And you said you spend a lot on R&D. My question is this: would you, on behalf of your member organizations and companies, provide to the committee specific and concrete information as to how much each company claims it has spent on R&D, how much it has spent on advertising, how much it has spent on stock buybacks, and how much it has spent on the top five paid compensation executives? Would you do that?

Ms. JOLDERSMA. I would have to consult with my counsel to know if—

Mr. WELCH. This is not a mystery here. I mean, what is the big deal? Pharma is claiming that it spends all its money on R&D, but it won’t show us the books. So, at a certain point, count me as skeptical.

Now, Dr. Miller, I think your research shows that what pharma claims it needs to spend is about 176 percent higher than what actually is required in order for them to get the return.

Dr. MILLER. I just want to be clear that the research I am citing is by other people. It was summarized in my testimony. There were a couple of things that were said. The amount of revenue that comes out of the United States alone exceeds worldwide R&D investments by something like 70 percent. And there have been stud-

ies that Arnold Ventures supported that show that the costs of producing the drugs are less than being claimed by the industry.

Mr. WELCH. Suggesting it is an inflated claim by pharma?

Dr. MILLER. Suggesting that.

Mr. WELCH. I mean, Madam Chair, all of us, R's and D's, whatever side we are on, we want to know what the facts are.

So, you won't answer me now. You have to go back to your quote, "counsel". Go back to your counsel and, then, answer me, and tell us whether we are going to get that information. But, while I am at it—

Ms. JOLDERSMA. Sir, I would be happy to provide the wealth of information that is already filed by our companies annually.

Mr. WELCH. I do not want a "wealth of information". I want four issues. One, R&D spending; 2, stock buybacks; 3, advertising; 4, executive compensation. That is all I want, not a "wealth of information".

Ms. JOLDERSMA. I believe that is all available, and I would be happy to provide it.

Mr. WELCH. All right. While I am at it, I want to ask this question: there is the justification of R&D. Sanofi increased the price of its drug Lantus by 171 percent from \$99 in 2010 to \$270 in 2018. That drug had been on the market since 2001. Presumably, the R&D that was done to put that drug on the market was done before 2001. How much R&D was part of the justification for that explosion in the price between 2010 and 2018?

Ms. JOLDERSMA. I am not sure of the answer, but I suspect that it would be R&D for treatments and cures that we are still waiting for, not for that product.

Mr. WELCH. Give us the facts, all right?

Now, Dr. Holtz-Eakin, you have made some criticisms that I actually think have merit about nibbling on the edges with transparency. I want transparency when there is a claim that it justifies the price increases. In some of the reporting, that is a big hassle. In the heart of this, you have nibbled around the edges, but what it reflects is the frustration that states and payers are having to try to get some grip on how they are getting hammered every year.

And my question is whether some of the suggestions Dr. Miller makes you agree with, where we have to really bite the bullet and have the Government play a role. Our Government is the only one in the Western industrialized democracies where we stand aside and let the consumer get hammered. Price negotiation, would you be supportive of some of the price negotiation suggestions that Dr. Miller is making to apply to commercial as well as the PBMs and the rebates?

Dr. HOLTZ-EAKIN. Let me disappoint you. I mean, when I was CBO Director, we wrote any number of studies that said that negotiation wouldn't lower spending. CBO just recently issued a response to, I believe it was Senator—

Mr. WELCH. Without a formulary. It is with or without a formulary.

Dr. Miller, why don't you—

Dr. HOLTZ-EAKIN. That is a key part of it, yes.

Mr. WELCH. That is right.

Dr. HOLTZ-EAKIN. It is a key part of it.

Mr. WELCH. And you get savings with a formulary. The formularies we have now are not done on behalf of the public. They are done for the benefit of the PBMs.

Dr. Miller, give me your top three steps we have to take in order to start bringing to heal these outrageous drug prices.

Dr. MILLER. The first thing is, in Medicare Part D, adopt the changes that have been recommended that bring more pressure on the PBMs and change the risk structure, which both of us agree on. There is a whole set of patent, anticompetitive behaviors, legislation, that you are moving on; you need to move on; you need to move further.

The last one-this is where we disagree potentially-on the drugs where there is not competition, that is where we are recommending that you think about things like negotiation and/or reference pricing. And we think it can be done without formulary exclusion; and I am happy to talk to you and your staff about that.

Mr. WELCH. Thank you.

I yield back. I thank the witnesses. I thank the Chair.

Ms. ESHOO. The gentleman yields back. I now recognize the gentleman from Oklahoma, Mr. Mullin, for five minutes of questioning.

Mr. MULLIN. Thank you, Madam Chair.

And thank you for the witnesses to be here.

I am going to focus on the FAIR Act, and there is going to be a little bit of a difference of approach. This is the difference between the gentleman from Vermont and myself. We both agree that drug pricing is too high, 100 percent. We 100 percent agree with that. We do agree there has to be something done. The approach is what is different.

See, I believe in private industry. I believe that, when the Government gets in things, the entry to the industry only gets more difficult and the less competition is there at that point. The more regulation that you put on the industry, the less people are going to enter into that industry. It is just matter of fact.

When you start looking at the FAIR Act, you start looking at what it is wanting the companies to do. What that is, it is just one step closer to what I think the ultimate goal is to some Members in Congress, and that is to take over the industry and be Government-run. That is the quickest way you can possibly kill an industry.

I mean, when you look at the FAIR Act and it says they want the total revenue and net profit generated from the qualifying drug for each calendar year since the FDA approved it, the total cost associated with marketing and advertising for the drug, the total revenue and net profit of the manufacturer, not the drug, for the manufacturer for 12 to 36 months, what does that have to do with anything? The compensation for the executives, what does that have to do with the Federal Government? Since when does the Federal Government get into the fact that they can limit the compensation for a non-Federal employee? But that is exactly what the FAIR Act is going to.

What we want to do is figure out how Congress can make it more competitive. See, Congress is not in the business of creating businesses. We should not be in the business of creating jobs. What we should be in the business of is creating an environment for entre-

preneurs to create jobs. When you allow competition in the market, then you are going to start seeing the competitive prices move downward.

Now, Dr. Miller, what you said a while ago, I think there might be something that we can work on there. When you said where Congress should maybe look at is when there is no one else in the market, when it is a specialty drug. I could see that. I could see where there could be a way for us to possibly find an area to where we could help come up with a rebate or come up where you kind of look at it with the insurance, with someone with preexisting conditions, where we can help offset maybe some of that cost. There could be some areas for us to work on there.

And I agree there is plenty of bad actors here. I think everybody has some stake to blame in this. And what I don't want to happen is that Congress overreacts. And I believe that is where we are moving, especially when you start looking at the FAIR Act.

So, I am going to ask, ma'am, and I am going to do my best with your name—Joldersma?

Ms. JOLDERSMA. That will work.

Mr. MULLIN. That will work? How do you actually pronounce it?

Ms. JOLDERSMA. Well, "Yeldersma" is how they would say it in the homeland. So, you are exactly right. But we say "Joldersma" here in the U.S.

Mr. MULLIN. Joldersma?

Ms. JOLDERSMA. Yes.

Mr. MULLIN. I am going to say "ma'am."

[Laughter.]

So, let me get into some questions, first of all, for you. Is PhRMA opposed to reporting price increasing to the Secretary?

Ms. JOLDERSMA. No, in fact, it is already publicly disclosed.

Mr. MULLIN. OK. What kind of problems do you see with the Fairness Act then?

Ms. JOLDERSMA. With the FAIR Act?

Mr. MULLIN. FAIR Act. Sorry. Yes, it is not Fairness Act. That is another bill I am working on.

Ms. JOLDERSMA. One leading concern is it is somewhat ambiguous, but it appears that it could be applying retroactively. Because one of the triggers is a 3-year trigger, you know, you think about that. Taking, in fact, in 2019, we are concerned that that is effectively imposing the requirement going back to price increases that were taken three years ago. That retroactivity seems not ideal and not a great precedent, and it is certainly challenging to comply with the law in good faith when the law was not even on the books at the time the conduct occurred. So, that is probably our top issue.

Mr. MULLIN. The FAIR Act requires, I believe, a 30-day notice.

Ms. JOLDERSMA. Yes, sir.

Mr. MULLIN. Is that time acceptable or is there a better time-frame for you?

Ms. JOLDERSMA. So, it does require a notification of price increases 30 days in advance. It goes to the Secretary. We are concerned that that could lead to some negative behavior in the market, including potentially opportunistic buying at the lower price, stockpiling. That could lead to drug shortages, et cetera. So, in general, we are very concerned with advanced notice.

Mr. MULLIN. Thank you.

With that, I will yield back. Thank you, Madam Chair.

Ms. ESHOO. The gentleman yields back. And now, I have the pleasure of recognizing the gentlewoman from New Hampshire, Ms. Kuster.

Ms. KUSTER. Thank you, Madam Chair.

And thank you to all of you for your patience, bearing with us.

So far, we have had multiple hearings on the critical issue of our bipartisan efforts to lower prescription drug prices. And the bottom line is simple: drug spending is placing an undue burden on our constituents, patients across this country, and taxpayers who are footing the bill for our public programs.

Mr. Miller, you mentioned in your testimony, “whether we like to admit it or not, we are actually rationing drugs in our country. And in our current system, patients and payors are forced to make difficult tradeoffs and choices.”

I want to step into, I understand there is no silver bullet on bringing down the rising cost of drugs, but I do want to focus in on your testimony, if I could, Mr. Miller. You mentioned how transparency efforts under consideration would not necessarily lead to lower drug prices, though they might help us understand more clearly why drug prices are increasing at the rates that they are. Do you believe that requiring justification for launch prices and price increases will at least slow the rate of growth in drug prices or that pharmaceutical companies might reconsider price increases with transparency?

Dr. MILLER. I think you could have some small Sentinel Effect. I think, ultimately, it doesn't stop the wave.

Ms. KUSTER. So, your advice seems to be to go further than that and go toward the negotiation of volume discounts. And in particular, I am looking at the Medicare negotiation based on leveraging volume discounts. And you mention Part D negotiation. Can you elaborate on how Part D negotiation might look? Especially taking into consideration the high cost of drugs now with limited competition, it seems to me both the patient and the taxpayer are paying more than they should.

Dr. MILLER. OK. Yes, I will. But, very quickly, I just want to remind you part of our recommendations are start to rebuild the competition in the market. I don't want to forget that.

Ms. KUSTER. OK.

Dr. MILLER. That is a very important—

Ms. KUSTER. And that is important.

Dr. MILLER. Absolutely important.

Ms. KUSTER. I concur.

Dr. MILLER. We also think, in Part D, once again, bringing the pressure to the PBMs and the manufacturers in the catastrophic cap, to kind of force negotiations where, in fact, you do have competitors, is very important. And then, I am stepping into your question. OK?

Ms. KUSTER. OK.

Dr. MILLER. Sorry about that.

Ms. KUSTER. Got it.

Dr. MILLER. But, you know, you will still always be faced with very expensive drugs that don't have competition. And so, there are

a few ways we would suggest that you might think about that. One is you think about a reference price. So, we look at the clinical value of the drug and say that the Medicare program will cover this drug, but the price it will pay and the beneficiary's copayment will be tied to the clinical value.

Ms. KUSTER. And let me just stop you there. Clinical value maybe as compared to hospitalization or as compared to future surgery? How do you determine clinical value?

Dr. MILLER. Usually, what you are doing is talking about the performance of the drug in and of itself on the value it adds to the life of the patient. That is usually how that is done.

Ms. KUSTER. OK. Longevity or quality of life.

Dr. MILLER. You could engage in other studies like hospitalization watchful waiting, WAW, but mostly what we are talking about here are clinical and cost-effectiveness analysis that talk about extending the patient's life, that type of thing.

Let me just give you one other to your question. You could think of a negotiation process in which you set lanes for the bids, so that you are saying there is some range of negotiation between the manufacturer and the Government, but it is not completely wide open. And you might use some of the clinical effectiveness to set those ranges or international prices, some set of considerations.

Why I am making this point is it is a way to try and get a more rigorous process that CBO might give credit for.

Ms. KUSTER. So, let me ask you this: do you think that the Federal Government is taking maximum advantage of their volume purchasing power, if you will, in the negotiations? I am just wondering, for example, if we were to consolidate, say, for Medicare and Medicaid, veterans, Federal employees, DOD, all of these together, do you think that we could do better in the price negotiation for the drugs where there is an equivalent, where we are talking about competition?

Dr. MILLER. I see. So, in this instance, you are moving the conversation. You are not talking about the drugs that don't have competition? You are talking about the drugs that do have competition?

Ms. KUSTER. Right.

Dr. MILLER I haven't thought about it, and I just want to say one thing. There are certain tradeoffs you would have to contemplate in how you do that. For example, in Medicaid, there are very large discounts. And so, if you move to a different system, you have to ask yourself, do you lose those discounts?

Ms. KUSTER. Right. Can you do better than that discount?

Dr. MILLER. Yes, can you do better? And then, VA, which I am very uninformed on, the same question. But a very—

Ms. KUSTER. Just as a theoretical concept, would you agree that the larger the volume share—

Dr. MILLER. Yes, and that is exactly where I was going. Just a straight economics, bigger volume, bigger ability to extract discounts because it is harder to walk away.

Ms. KUSTER. Thank you. I yield back.

Ms. ESHOO. The gentlewoman yields back. I now would like to recognize the gentleman from North Carolina, Mr. Hudson, for five minutes of questioning.

Mr. HUDSON. Thank you to the Chair.

And thank you to our panel for being here today. This is very informative.

Every time I go home, I hear from my constituents about high drug prices. I will never forget the constituent I met years ago who told me that she literally some months had to choose between picking up her prescription and paying for groceries. This is a problem.

And in this committee, we have a long history of bipartisan work to address the most serious problems facing Americans. I believe we should continue that work, but I am having a tough time seeing what some of the policies that were proposed here will accomplish for American patients.

Doing some rough, back-of-the-envelope math, I took one of the most recent examples of a drug failure, Biogen's Alzheimer drug, and looked at what it would take to recoup their investment. Biogen spent \$950 billion seeking a cure for Alzheimer's that ultimately failed. It was disheartening for me and many others, particularly those who have relatives with Alzheimer's, but also illuminated what it takes to bring a drug to market.

So, back-of-the-envelope math, let's say Biogen was successful with the latest attempt. There are 5.8 million people in the United States with Alzheimer's. So, assuming every single one of them was able to access this drug, Biogen would have to charge, roughly, \$164,000 to break even on all their research. This is, arguably, a bargain compared to not only the roughly \$350,000 of cost to care for an Alzheimer's patient over a lifetime of the illness, but also the emotional cost that families endure watching a loved one deteriorate right before their eyes, as my family has experienced.

Under the SPIKE Act, this price or anything higher would have triggered a naming-and-shaming exercise. What benefit does this have for patients? Ideally, patients would be taken out of the middle of this conversation.

And this brings me to my questions, which the first one I will open to the entire panel. The FAIR Act includes high penalties for noncompliance. Where should those penalties, where should that revenue go to? As it is currently written, do you see them going to benefit patients or is it going back to the Treasury to be spent by politicians? Shouldn't they be explicitly designated to help those who need it most and not just go to the Treasury for Congress to spend? I would just open it up to the panel, if anyone would like to talk on that.

Ms. JOLDERSMA. We would agree. We would note that the fees are quite high. And, yes, it would be ideal to have those fees going to help patients.

Mr. HUDSON. Anybody else? I see some nods. OK.

Dr. FELDMAN. It is kind of a no-brainer, back to the patients.

Mr. HUDSON. OK. I will assume everybody agrees.

Ms. Bass, in your testimony, you mentioned the real-time benefit tools to help physicians and patients know what drugs are on formulary and what the cost-sharing would be. How could your industry, the PBM industry, facilitate making this a reality?

Ms. BASS. So, those tools are already in use. And I think one of the issues, everybody understands that it needs to be as streamlined as possible for physician workflow. And so, hopefully, the interoperability exercise that the administration is currently under-

going will help make sure that every physician has access and it works really quickly. But all of our PBMs, most of our PBMs are making that product available already in the marketplace.

Mr. HUDSON. Great.

And, Ms. Joldersma. I hope I am not butchering your name. I know lots of states have been passing legislation to get to the bottom of why drug prices are increasing. But the bills we are talking about today go beyond any State law currently on the books. Do you worry about the burden of companies complying with a patchwork of 50 State laws plus this Federal law? Because if there ever was a time for preemption, it seems to me like this would be it. What are your feelings?

Ms. JOLDERSMA. Absolutely. There are, I think, seven or eight different approaches already on the books in states. There are additional states who are probably today considering different approaches. We have different approaches that are coming to light here in the Congress as well. And all of that is just added cost that is not going to research and it is not going to help patients. So, absolutely, harmonization/preemption are high priorities.

Mr. HUDSON. Great. Well, I appreciate that.

And, Madam Chair, I look forward to continuing to work with you to focus on patients, and we have a long track record of working together in a bipartisan way on this committee. I think as long as we continue to focus on the patients and use common sense, I think we can get there.

So, with that, I will yield back.

Ms. ESHOO. The gentleman yields back. And now, the gentlewoman from California, Ms. Barragán, is recognized for five minutes for her questioning.

Ms. BARRAGÁN. Thank you.

I want to follow up on that. You know, while we are here in Congress drafting legislation and debating what to do, we have seen States taking up legislation that shines light on manufacturers' drug pricing. Part of that is attributed to the fact that Congress isn't moving and Congress isn't doing anything; that States are acting to help consumers and to help people who are rationing their drugs.

In my own State of California, they passed a drug transparency law in 2017. It requires drug companies to notify health insurers and Government plans at least 60 days in advance if they plan to increase a drug price by more than 16 percent in a 2-year period. Now the law also requires the companies to explain the reason behind the increase in price, with all of the information provided to the State made public online for citizens to review.

Now PhRMA sued to block the California law. This may be because the law was effective in shining a light on upcoming price increases. For example, it showed that Valeant was going to raise the price of a generic glaucoma medication by 63 percent and that Teva Pharmaceuticals planned a 49 percent price increase for an inhaled solution to prevent asthma attacks.

Ms. Joldersma, you testified that PhRMA supports transparency. In this case, PhRMA sued to block this California law that would have transparency. Did PhRMA sue to block the California law be-

cause you are concerned about the unfair drug-pricing policies of drug manufacturers?

Ms. JOLDERSMA. No, we sued to block the California law because we believe it is unconstitutional in at least two ways, the Dormant Commerce Clause and, also, First Amendment compelled speech. And we are also concerned about the impact that that 60-day advance notification could have on the market; given the opportunity it creates for bulk purchasing, stockpiling, and—

Ms. BARRAGÁN. OK. Let me ask you another question. So, if Congress passed that same law, you would have the same concerns, is that correct?

Ms. JOLDERSMA. Well, the Federal Government, obviously, has different authority to regulate interstate commerce.

Ms. BARRAGÁN. I am just asking, if Congress passed the same law, would you have the same concerns?

Ms. JOLDERSMA. First Amendment compelled speech remains a concern.

Ms. BARRAGÁN. OK. I am just going to take that as a yes, because it is just a yes or no.

Ms. JOLDERSMA. Yes.

Ms. BARRAGÁN. I have other questions I want to get to.

Ms. JOLDERSMA. The answer to that is yes.

Ms. BARRAGÁN. Thank you very much.

Ms. JOLDERSMA. Yes.

Ms. BARRAGÁN. So, during the drug supply chain hearing a week ago, Amgen raised the issue of lowering the list price of their cholesterol drug by 60 percent. However, PBMs have not shifted this drug from high-cost formulary tiers to lower-cost tiers which carry lower copayments.

Ms. Bass, you testified that the mission of the association you represent, the PBMs, is to help control cost. So, do you support patients having access to these lower-price drugs? It seems that when you have a specific instance like in this one, we are not seeing the movement.

Ms. BASS. So, I testified that the mission of our companies is to provide access to lower-cost drugs. I can't speak to specific company decisions with respect to these drugs, but our companies negotiate to the lowest net cost and make their decisions accordingly.

Ms. BARRAGÁN. OK. Well, thank you.

So, Mr. Isasi, I am dead-focused on trying to find meaningful solutions to the drug-pricing problem. My constituents continue to demand that we find a way to significantly lower the price of medications. In your testimony, you discuss that, while you are supportive of these transparency bills, that transparency legislation alone will not significantly affect the price of prescription drugs. You go on to state that Medicare Part D negotiation should be enacted as a meaningful step to lower prices. While you discuss one specific negotiation bill in your testimony, I would like you to focus on the policy generally. Do you have any projections on the impact on drug pricing if we enact Medicare Part D negotiation? And then, beyond Medicare negotiation, what other policies should Congress pass to meaningfully lower prices?

Mr. ISASI. Sure. Thank you very much for the question.

So, this question of the projected savings is very difficult, in large part because industry has done a very good job of veiling what the actual price is that we are paying, how the monies are flowing; and so, it is a very, very difficult thing to model.

But what we know for sure is that, in order for it to work, something as simple as just saying “the Government can negotiate” won’t work. We need to have a serious way to put teeth in negotiations to make sure that industry shows up and in good faith negotiates. So, there are lots of policies. One of them would be something like allowing others to produce a drug if the pharmaceutical industry isn’t willing to negotiate a fair price. Another one is imposing a tax on excess profits, things like that. So, there is a lot of different methods; but you have to real teeth in negotiations or it won’t work.

But what we do know is, just common sense, as I mentioned earlier, the pharmaceutical industry starts in the U.S. when they launch prices most often because they know we don’t negotiate. So, they get a very, very high price in the United States, and then, they go around the rest of the world and they start negotiating.

And so, for example, we know that we spend maybe 50 percent or 100 times more than other countries on drugs, not all drugs, but many drugs. For example, in Norway, Humira is almost twice as much as what we are paying; Crestor is four times more in Australia and in France. So, we know in those cases, Government negotiation results in fourfold decrease in price.

And then, another thing we know is that, as I mentioned, manufacturers start in the U.S. The last thing to say is, I think there are three really important policies to think about beyond negotiation. The first is to think carefully about those increases in price year over year, because it is not just the launch prices. We have heard that industry has had a really hard time because so many of the drugs go to generic. So, they just increase prices far above inflation year over year. So, the idea of thinking about how price should be tied to inflation year over year is really important.

Two, as Dr. Miller mentioned, we need to understand the value of the benefit.

Ms. ESHOO. Excuse me to interrupt because it is over the time, but there is also a 1:30 classified briefing for all Members of the House. And I think that it is important that everyone be able to get there.

So, the gentlewoman yields back. And I now would like to recognize the gentleman from Georgia, Mr. Carter.

Mr. CARTER. Thank you, Madam Chair, and thank you for having this hearing. This is extremely important.

Thank you to each and every one of you for being here.

Dr. Feldman, earlier you had a conversation about list price. And my colleague before me just mentioned about list price, and we were taking about it.

Ms. Bass, you mentioned that your concern was net price. Let me ask you, a copayment to a patient, is it based on list price or net price?

Ms. BASS. Copayments are a set price.

Mr. CARTER. Copayments are a set price? They could be a percentage. Is that percentage based on a list—

Ms. BASS. Oh, sure.

Mr. CARTER. Is that percentage based on the list price or the net price?

Ms. BASS. Co-insurance is typically based—it depends on the plan, but in Medicare, say, co-insurance is based on the list price.

Mr. CARTER. On the list price. So, if the list price is higher, then the copay to the patient could be higher? Yes?

Ms. BASS. That math works.

Mr. CARTER. That math works. Good. That is new math, but it still works. Great.

Let me ask you, in Medicare Part D, also, patients go from deductible to the donut hole, and then, into the catastrophic. Is that based on list price or is that based on net price? It is based on list price.

Ms. BASS. The deductible, yes.

Mr. CARTER. So, the higher the list price, the quicker they get into the donut hole; the quicker they get into catastrophic. And if they get into catastrophic, then the taxpayer is the one who is on the hook because they are paying the majority of it, not the plan sponsor, not the insurance company, correct? That is correct.

Let me ask you, Dr. Feldman, you mentioned, correctly, that when Ms. Bass was asked about how many members or how many PBMs there were in the nation, there were 66, I believe you said. However, you mentioned that there were three PBMs that control 80 percent of the market, and that is correct. Not only that, but also those three PBMs that control 80 percent of the market also have an insurance company that they own and also have pharmacies they own. In fact, that vertical integration carries over into that.

You mentioned that you had some patients who came in and had a letter that said that they had to change a particular drug to something else that was on the formulary. Just out of curiosity, any of those, the insurance or the pharmacy is owned by that PBM, or would you know that?

Dr. FELDMAN. This was a particular PBM that is now owned by an insurance company.

Mr. CARTER. Exactly. So, in other words, the PBM is directing that patient to use a drug on the formulary through their mail order pharmacy or through their pharmacy. It may not be a mail order. Because we know that Aetna owns Caremark, owns CVS. We know that Express Scripts owns Cigna, owns Express Scripts mail order. We know that Optum is owned by United and has their own mail order as well.

So, what we are essentially talking about here is taking money out of one pocket and putting it in the other pocket. Because if you ask the PBMs where are these discounts, as the chairlady likes to say, or rebates going, they say, “well, they are going to the plan sponsor to decrease the premium.” Well, who is setting that premium? The insurance company that they own in many cases. So, that vertical integration is something that is very concerning.

Let me change gears here for just a second and ask Dr. Miller and Dr. Holtz-Eakin: Earlier Ms. Joldersma was asked about one of the parts of this bill that says that drug companies would have to give notification before they went up on a price. And there was

concern about stockpiling. Are you familiar with spread pricing and how that works, either one of you?

Dr. MILLER. Yes.

Mr. CARTER. OK. And do you agree in her assessment that, you know, if we know that if a pharmacy or a wholesaler knows that a price is going to be going up, that there is a possibility that they would stockpile those drugs in order to buy them at a lower cost and, then, also to be able to keep them, so that they can sell them at the higher price?

Dr. MILLER. My own comments are—and I just want to preface by saying I still don't think that the transparency has a huge effect, but—

Mr. CARTER. Did I ask you that? What I asked you about was this fair pricing.

Dr. MILLER. To the question that you are asking—

Mr. CARTER. Thank you very much.

Dr. MILLER [continuing]. I think I would say that I would not do a prior notice.

Mr. CARTER. You would not do a prior notice?

Dr. MILLER. For the reasons that you are raising.

Mr. CARTER. Thank you.

Dr. HOLTZ-EAKIN. I would be concerned about that as well.

Mr. CARTER. Absolutely. And I can tell you from firsthand experience, and from having been in business and owning a pharmacy for 30 years before I became a Member of Congress, that was something we did all the time. If we knew the price was going up, of course, we are going to buy it at the lower price and stockpile it. So, there is a danger there, and I would warn you very carefully in this legislation to be careful of that. That is something that could happen.

Madam Chair, I want to thank you again for holding this hearing.

And also, the Prescription Pricing for the People Act that has the FTC, an investigation into potential anticompetitive business practices and the PBM-pharmacy relationship, that is an issue that our committee has asked the FTC to investigate. And I hope, Madam Chair, that will come to us and that we will have access to that report, so that this committee can look at it.

Thank you, Madam Chair, and I yield back.

Ms. ESHOO. I thank the gentleman. He yields back. Recognize the gentleman from Maryland, Mr. Sarbanes, for five minutes of questioning.

Mr. SARBANES. Thank you. Thank you, Madam Chair.

Thanks to the panel.

Mr. Isasi, I assume you are familiar generally with how, for example, state-level insurance commissioners regulate the premium hikes that health insurance companies bring on an annual basis, where they ask for information to justify those proposed increases. And then, as well, we see the example of, say, electric utilities—sorry, I have a cold—who have to justify any rate increases that they propose and provide a good deal of information.

Do you have a sense of how the kind of information that we have available to us from the pharmaceutical companies or the PBMs compares to the kind of information that is available to the public

or to the commissions that operate in those other arenas that I mentioned?

Mr. ISASI. It is a much poorer quality, because it is not being collected to understand how the rates are being built. It is just being collected.

Mr. SARBANES. Yes. And I am increasingly intrigued by using that example as a kind of reference point for the kind of insight that we should be getting into the drug pricing. Because, frankly, I think if you look at the impact on the public of drug prices, it is hard to argue that it isn't as extensive and permeating as those other things are, where we bring a different kind of approach.

I wanted to ask Ms.—I can't see your name all the way down there at the end—

Ms. JOLDERSMA. Lisa.

Mr. SARBANES [continuing]. Ms. Joldersma—

Ms. JOLDERSMA. Call me Lisa.

Mr. SARBANES [continuing]. And Ms. Bass, talk to me a little bit about the excuse/explanation for resisting some of the transparency measures that we have suggested, based on the concern about proprietary information. What is the argument there exactly?

Ms. BASS. I will start. So, I will cite OACT, the Office of the Actuary, and CBO as well, in suggesting that if pricing becomes public, which it would under the Secretary's rebate rule, prices go up, OACT and CBO think, by about 15 percent. In other words, competitors are not willing to discount as deeply when they know the competition's less deep discount. And so, prices, the net cost, the way we talk about it, float upward. And probably there would be about, according to OACT and CBO—and we think that is about right—a 15 percent loss, in effect, of savings, or a 15 percent increase.

Mr. SARBANES. Do you buy that, Mr. Isasi? And if you do buy it, do you think the approach I was just discussing a moment ago could be an antidote to the result that was just being described; i.e., if that kind of transparency creates some pressures in the direction Ms. Bass just suggested, then the counter-pressure could be authority residing within some Governmental entity to come in and push back on that? So, maybe you could speak to that.

Mr. ISASI. That is right. So, that is the fundamental question here: is it just transparency or is it transparency with teeth? And I think it is really important to note that we need to have transparency with teeth. We have to have an ability for the Government to come in and say—and this is what, again, 80 percent of Republicans, 90 percent of Democrats, are asking for, right?—the Government to come in and say, "That's not a fair price. We will not pay it." You have to combine both things together.

Mr. SARBANES. Yes. Well, I am for transparency with teeth, just for the record.

And maybe, Dr. Holtz-Eakin is for transparency with teeth. He did wonder or worry about, or at least observe, that transparency alone might not achieve the goals that we seek. And I share some of that, those misgivings. But I think transparency in combination with other measures we could take would get us to a place that we want to get to on behalf of Americans who are paying too much for their drugs.

With that, I yield back my time. Thank you.

Ms. ESHOO. The gentleman yields back. Now I would like to recognize the gentleman from Montana, Mr. Gianforte.

Mr. GIANFORTE. Thank you, Madam Chair.

And thank you for the panel for being with us today.

I continue to hear from Montanans about the cost of their prescription drug medications and the difficulties they face in trying to pay for their drugs. During our first hearing on drug prices this Congress, I spoke about a constituent in Great Falls whose lupus medication had increased by hundreds of dollars in recent years. The price increase put her and her family, made them financially unstable. Unfortunately, her story is not uncommon.

We need to find common-sense solutions, and I look forward to finding those with my colleagues across the aisle, to make drugs less expensive, increase transparency where it is needed, and put patients first.

Although I appreciate the FAIR Act and understand what it is trying to accomplish, as a business owner, when I look at the list of reporting requirements in the bill, I do have some concerns. It seems that there are requirements that manufacturers might not be able to provide answers for.

Dr. Holtz-Eakin, can you speak to the challenges of gathering the required information regarding research and development and manufacturing costs?

Dr. HOLTZ-EAKIN. Well, certainly I think the reporting requirements are extraordinarily extensive. I have never seen anything like it. And if you started today and had to go back, you might not have the records in place to do it, especially the smaller firms. Going forward, you would have to put in place the sort of mechanisms to collect that on a regular basis.

Mr. GIANFORTE. So, do you believe, based on the complexity, that it might be the situation that certain firms would not be able to comply with these new rules?

Dr. HOLTZ-EAKIN. I would suspect that at the outset, yes.

Mr. GIANFORTE. OK. I am also concerned that the FAIR Act gives the Secretary very broad authority to include other information that the Secretary considers appropriate. Typically, I would say, I am all in favor of flexibility for the Secretary, but the list of regulations in the bill is already incredibly robust. To me, it seems that if something was left out or needs to be added, it should be done legislatively as opposed to through the Secretary.

So, I just want to follow on, if I could, Dr. Holtz-Eakin. Can you speak briefly to the estimated cost to consumers of these regulations?

Dr. HOLTZ-EAKIN. I don't have an estimate of the cost. But I just want to echo something you just said. You can imagine putting in place systems to collect the data because you want to comply with the law, assuming it was passed. And then, the Secretary changes the nature of the information that you have to provide. You now are back at the starting situation where you haven't collected it and you have to go back. So, it could get progressively more costly if that is how it transpired.

Mr. GIANFORTE. OK. So, if you can't comment specifically on cost, if all these new reporting requirements were signed into law, and

the Secretary decided there was more information that he needed, how do you think that would affect new drugs coming to market?

Dr. HOLTZ-EAKIN. I think they would be more costly to provide and they would be more expensive.

Mr. GIANFORTE. OK. Which is not the objective that we are shooting for.

Dr. HOLTZ-EAKIN. Yes.

Mr. GIANFORTE. A question, if I could, for the whole panel. I support transparency across healthcare. I think that consumers need to know exactly what they are paying for. It is my understanding that the rationale behind these bills is that the Federal Government is a large payor in the system today; therefore, we need to know about price increases. That makes sense.

I support the idea of flagging large increases in price, but looking at the whole picture, pharmaceutical spending accounts for less than 20 percent of what the Government spends on healthcare. Are there other aspects of healthcare in the 80 percent that need to report price or fee increases as well to the Federal Government? For example, do hospitals have to report increases in surgical supplies or procedures that Medicare is going to cover?

Dr. MILLER. One thing to keep in mind is that hospitals on the Medicare side do report a cost report and they do lay out what their cost structures are. However, you have a very similar situation in the hospital industry where you have high degrees of consolidation and high prices escalating. So, there is certainly a question that could be brought to bear in there.

Mr. GIANFORTE. OK. Other comments?

Dr. FELDMAN. From the physician's point of view, we are told every year how much we are paid. So, that information is already out there.

Mr. GIANFORTE. So, we should be arguing for, we should be working for transparency in all areas? Anybody else who would like to add anything?

Mr. ISASI. We strongly agree with that. And the problem of price in healthcare is not just a pharmaceutical issue, but it is a big pharmaceutical issue.

Mr. GIANFORTE. And I think our constituents expect us to look at all of healthcare costs, certainly drugs—that is the topic today—but more broadly.

Comments?

Ms. JOLDERSMA. I would like to just follow up quickly on something that Representative Sarbanes raised. He did mention the rate review framework put into place for health insurers and the fact that they have to give advance notice of increases—

Mr. GIANFORTE. Unfortunately, my time is up, and I yield back, Madam Chair.

Ms. JOLDERSMA. It is only one year, not three.

Ms. ESHOO. The gentleman yields back. I now would like to recognize the gentleman from Kentucky, Mr. Guthrie, for five minutes.

Mr. GUTHRIE. Thank you very much. Sorry, I was in another hearing on a committee that I am the ranking member of the subcommittee. So, I wasn't here for a lot of discussion. So, I will just

ask a couple of questions. I know we are pushing against a deadline here.

So, for Dr. Feldman and Dr. Holtz-Eakin, MedPAC recommended that the information provided to the Secretary regarding samples be shared with specific other entities. How might this information be helpful to oversight agencies, researchers, payers, and health plans? And how is selectively sharing this information different from publicly posting it?

Dr. FELDMAN. Public posting it leaves it open to anyone with any opinion to create a campaign on Twitter and various social media, which can lead to really false impressions of what the samples really do accomplish for patients.

Mr. GUTHRIE. OK.

Dr. HOLTZ-EAKIN. I think that is the chief concern. And professional analysis of the data should be welcomed.

Mr. GUTHRIE. OK. Thank you.

And everybody here wants transparency and lower drug prices, but we have to get this right. So, if you are looking at the SPIKE and the FAIR Act, the SPIKE and the FAIR Act use different definitions for a manufacturer. While the FAIR Act uses the proper Food, Drug, and Cosmetic Act definition, the SPIKE Act uses a definition for a manufacturer that is improper.

And, Ms. Joldersma, drafting concerns have been raised that, while the intent of the drafters was to provide discretion to the manufacturer on which materials would justify their SPIKE disclosure, the language is not clear or prohibitive that the Secretary cannot reject such a justification or ask for additional disclosures from the manufacturer. The question is, do you agree that this is an issue, and if we pursue this bill, the language needs to be clarified?

Ms. JOLDERSMA. I do.

Mr. GUTHRIE. What are the issues that would happen if you didn't clarify it?

Ms. JOLDERSMA. I am sorry?

Mr. GUTHRIE. So, the issues, if it wasn't clarified, then it would open up to—

Ms. JOLDERSMA. If it wasn't clarified, I think that, given the certification requirement in that bill, I think manufacturers would believe they have to provide every single thing listed as illustrative in the bill, regardless of whether it was applicable to the actual increase or not.

Mr. GUTHRIE. So, as our colleague here defined, manufacturer in the FAIR Act is the better route?

Ms. JOLDERSMA. They both have issues that we would like to work with the committee on.

Mr. GUTHRIE. OK. Thanks. Fair.

And one final question, Dr. Holtz-Eakin. You note in your testimony that there are elements of transparency that can have inverse market impacts. Can you explain this issue more and how Congress can ensure helpful transparency is done while not driving unwanted behavior?

Dr. HOLTZ-EAKIN. You simply don't want to disclose the outcome of other people's negotiations, so that competitors can take advan-

tage of it. So, that kind of transparency is actually counter-productive.

Mr. GUTHRIE. What would be an example of that?

Dr. HOLTZ-EAKIN. Well, if, for example, Mark cut a deal on a big rebate for his drug and I found out about it, I would be like, well, geez, I didn't get that rebate. And that would lead that negotiation to have less vigor the next time around; they may not give such a big rebate.

Mr. GUTHRIE. Well, thank you. I appreciate that.

And I will yield back.

Ms. ESHOO. The gentleman yields back. I will recognize the gentlewoman from Illinois, who is the sponsor of the FAIR Drug Pricing Act, Ms. Schakowsky, for five minutes. And I think because Ms. Schakowsky is waved onto the subcommittee, that she will be the last Member that is questioning. So, hold on, testifiers; you are just about through.

Ms. SCHAKOWSKY. I thank the chairwoman for allowing me. I will be as quick as possible.

This is what people with multiple sclerosis are facing, for example, showing the increases over just three years in the cost of their drugs. Betaseron went from \$65,000 to \$92,000 in those three months. Avonex went from \$62,000 to \$88,000 in these two months—in those three years. I am sorry.

You know, the whining that is going on about having to talk about some transparency is really irritating to me. The drug companies tell us all the time that it is about research and development; it costs so much. How much? That is the question in the FAIR Act, which is my bill. How much? If you are going to use that as the excuse for raising the prices, then I think we have an absolute right to know how much is being spent.

The ten top drugs that are advertised on television - and we are going to see, because of the cooperation with the President of the United States, those list prices next to the drug on television - the ten top ones, every month it is either between \$500 per drug up to \$17,000 per drug per month. And so, we want to know how much are you really spending on marketing and advertising.

Believe me, these are not extraneous questions. These are what consumers want to know. They want to know the manufacturing cost. They want to know how much money are you making. "I can't afford your medication," they say. And so, I am going to get sick. And so, I want to know, how much are you making off of me when I can actually pay for this?

So, really, the idea that transparency is going to cause all these problems, and problems for consumers, I wonder if my friend Mr. Isasi, whatever, could answer that.

Mr. ISASI. Isasi. No problem.

Ms. SCHAKOWSKY. Isasi? No Isis, OK.

Mr. ISASI. No, not Isis; Isasi.

I would say that we share your skepticism about this concern, very much share this skepticism. And it is the very least, as you say, when people's lives are hanging in the balance and they are making decisions that in some cases end up in their death because they can't afford their drugs. At the very least, there could be more transparency about the way these funds are flowing.

And I want to point out that the makers of the top 12 best-selling drugs in the United States have filed, on average, 125 patents per drug; for an industry filing, 125 patents per drug. It seems like a little transparency about how they are spending their money isn't much of a burden.

Ms. SCHAKOWSKY. I really appreciate that.

We do have to go to a classified briefing.

I just want to say I think, at the very least, consumers deserve transparency. But I also want to agree with you, it has to be with teeth. We are going to do more than this getting transparency. We are going to have to lower the cost of prescription drugs. People are dying. They can't afford it. So, this is just the beginning.

Thank you very much, and I yield back.

Ms. ESHOO. The gentlewoman yields back.

Pursuant to committee rules, Members have 10 business days to submit additional questions for the record, to be answered by the witnesses who have appeared. And I ask each witness to respond as promptly and as fully to the questions that you receive.

I ask unanimous consent to enter into the record the following documents:

A letter from the American Society of Clinical Oncology regarding H.R. 2296, 2087, and 2064.

A letter from the Campaign for Sustainable Prescription Pricing in support of H.R. 2296, 2069, 2087, 2064, 2757.

A letter from the AARP in support of H.R. 2296, 2069, 2087, 2115, and 2064.

A letter from the National Multiple Sclerosis Society.

And a letter from the Alliance of Specialty Medicine regarding H.R. 2113.

There aren't any objections. So, without objections, these documents will be placed into the record.

Ms. ESHOO. I want to thank all of the witnesses once again. You have been here for three hours. You have worked hard, and I think that the hearing has been more than worthwhile, recognizing that we have a great deal to do.

I also think that we need to really scrub your written testimony because many of you really put forward worthwhile ideas that we didn't get to ask questions, and they are worthwhile and deserve the full attention of committee members.

So, with that, the House subcommittee will now adjourn.

[Whereupon, at 1:36 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. ELIOT L. ENGEL

Madame Chairwoman Eshoo, thank you for holding today's important hearing on drug supply chain transparency.

U.S. prescription drug spending rose by 41 percent between 2007 and 2017. While some of this growth was due to innovation—such as CAR—T therapies and hepatitis C cures—much of it can be attributed to price spikes. The price of insulin, a century old drug, for instance, has doubled since 2012 without much change to the underlying formula.

Due to the lack of transparency, my constituents often get a pricing surprise when they arrive at their pharmacy. This can blindside consumers, putting them in situations where they have to choose between filling a life-saving prescription or purchasing other necessities.

The shroud of secrecy that veils the drug supply chain can make it challenging even for experienced health care professionals to determine the cost of a medication, let alone average-day Americans. As with buying groceries, my constituents deserve to know the cost of their prescription drugs ahead of time.

I look forward to working with my colleagues on efforts to shine light on this murky segment of our healthcare system.



116TH CONGRESS
1ST SESSION

H. R. 2064

To amend title XI of the Social Security Act to require manufacturers of certain drugs, devices, biologicals, and medical supplies to report on product samples provided to certain health care providers, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 3, 2019

Ms. JUDY CHU of California (for herself and Mr. NUNES) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XI of the Social Security Act to require manufacturers of certain drugs, devices, biologicals, and medical supplies to report on product samples provided to certain health care providers, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. REQUIREMENT FOR MANUFACTURERS OF CER-**
2 **TAIN DRUGS, DEVICES, BIOLOGICALS, AND**
3 **MEDICAL SUPPLIES TO REPORT ON PROD-**
4 **UCT SAMPLES PROVIDED TO CERTAIN**
5 **HEALTH CARE PROVIDERS.**

6 (a) IN GENERAL.—Section 1128G(a) of the Social
7 Security Act (42 U.S.C. 1320a–7h(a)) is amended by add-
8 ing at the end the following new paragraph:

9 “(3) CERTAIN PRODUCT SAMPLES.—

10 “(A) IN GENERAL.—In addition to the re-
11 quirements under paragraphs (1)(A) and (2),
12 on the 90th day of each calendar year (begin-
13 ning with 2023), any applicable manufacturer
14 that provides a payment or other transfer of
15 value that is a product sample described in sub-
16 paragraph (B) to any covered recipient (or to
17 an entity or individual at the request of, or des-
18 ignated on behalf of, such a covered recipient)
19 shall submit to the Secretary, in such electronic
20 form as the Secretary shall require, the fol-
21 lowing information with respect to the pre-
22 ceding calendar year:

23 “(i) The total quantity of all such
24 payments or other transfers of value pro-
25 vided to covered recipients.

1 “(ii) The total value of all such pay-
2 ments or other transfers of value provided
3 to covered recipients.

4 “(iii) If applicable, information de-
5 scribed in clauses (vii) and (viii) of para-
6 graph (1)(A) with respect to such a pay-
7 ment or other transfer of value.

8 “(B) PRODUCT SAMPLE DESCRIBED.—For
9 purposes of subparagraph (A), a product sam-
10 ple described in this subparagraph is a product
11 sample that is not intended to be sold and is in-
12 tended for patient use.”.

13 (b) PUBLIC AVAILABILITY OF INFORMATION.—Sec-
14 tion 1128G(c)(1)(C) of the Social Security Act (42 U.S.C.
15 1320a-7h(c)(1)(C)) is amended—

16 (1) in clause (ii)—

17 (A) by striking “(ii) contains” and insert-
18 ing “(ii)(I) with respect to information that is
19 not information submitted under paragraph (3)
20 of subsection (a), contains”;

21 (B) by striking “, as applicable;” and in-
22 serting “, as applicable; and”;

23 (C) by adding at the end the following new
24 subclause:

1 “(II) with respect to information sub-
2 mitted under paragraph (3) of subsection
3 (a), contains information that is presented
4 by the name of the applicable manufac-
5 turer, the total amount of all payments or
6 other transfers of value described in such
7 paragraph provided to covered recipients,
8 the total value of all such payments or
9 other transfers of value provided to covered
10 recipients, and the name of the covered
11 drug, device, biological, or medical supply,
12 as applicable;”;

13 (2) in clause (viii), by striking “, and” at the
14 end and inserting a semicolon;

15 (3) in clause (ix), by striking the period at the
16 end and inserting “; and”; and

17 (4) by adding at the end the following new
18 clause:

19 “(x) in the case of information sub-
20 mitted under paragraph (3) of subsection
21 (a), lists such information separately from
22 the other information submitted under
23 subsection (a) and presents such informa-
24 tion by the name of the applicable manu-
25 facturer, the total quantity of all payments

1 or other transfers of value described in
2 such paragraph provided to covered recipi-
3 ents, the total value of all such payments
4 or other transfers of value provided to cov-
5 ered recipients, and the name of the cov-
6 ered drug, device, biological, or medical
7 supply, as applicable.”.

8 (e) CONFORMING AMENDMENT.—Section
9 1128G(e)(10)(B)(ii) of the Social Security Act (42 U.S.C.
10 1320a–7h(e)(10)(B)(ii)) is amended by striking “Product
11 samples” and inserting “Except for purposes of paragraph
12 (3) of subsection (a), product samples”.

○



116TH CONGRESS
1ST SESSION

H. R. 2069

To amend title XI of the Social Security Act to provide for drug manufacturer price transparency.

IN THE HOUSE OF REPRESENTATIVES

APRIL 3, 2019

Mr. HORSFORD (for himself and Mr. REED) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XI of the Social Security Act to provide for drug manufacturer price transparency.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Stopping the Pharma-
5 ceutical Industry from Keeping drugs Expensive Act” or
6 the “SPIKE Act”.

1 **SEC. 2. DRUG MANUFACTURER PRICE TRANSPARENCY.**

2 Title XI of the Social Security Act (42 U.S.C. 1301
3 et seq.) is amended by inserting after section 1128K the
4 following new section:

5 **“SEC. 1128L. DRUG MANUFACTURER PRICE TRANS-**
6 **PARENCY.**

7 “(a) IN GENERAL.—With respect to each year, begin-
8 ning with 2021, the Secretary shall, at least once during
9 such year, determine if there is a triggered SPIKE in-
10 crease (in accordance with subsection (b)) with respect to
11 an applicable drug (as defined in subsection (f)(1)). If the
12 Secretary determines, with respect to a year, there is such
13 an increase with respect to an applicable drug, the manu-
14 facturer of the applicable drug shall submit to the Sec-
15 retary the justification described in subsection (c), subject
16 to subsection (b)(3), for each such triggered SPIKE in-
17 crease in accordance with the timing described in sub-
18 section (d).

19 “(b) TRIGGERED SPIKE INCREASE.—

20 “(1) IN GENERAL.—A triggered SPIKE in-
21 crease occurs, with respect to an applicable drug and
22 year (beginning with 2021), in any of the following
23 cases:

24 “(A) If there is a 10 percent (or \$10,000)
25 increase with respect to the wholesale acquisi-
26 tion cost (or alternative cost measure specified

1 by the Secretary under paragraph (2)) of such
2 drug during any 12-month period beginning
3 and ending within the lookback period that is
4 the 5-year period preceding 2021 or 2022, re-
5 spectively.

6 “(B) If there is a 25 percent (or \$25,000)
7 increase with respect to the wholesale acquisi-
8 tion cost (or such alternative cost measure) of
9 such drug during any 36-month period begin-
10 ning and ending within such respective lookback
11 period.

12 “(C) In the case of such a drug that is
13 first covered under title XVIII with respect to
14 such year, if the estimated cost or spending
15 under such title per individual or per user of
16 such drug (as estimated by the Secretary) for
17 such year (or per course of treatment, as de-
18 fined by the Secretary) is at least \$26,000.

19 “(2) ALTERNATIVE TO WAC.—The Secretary
20 may, for purposes of making determinations under
21 paragraph (1), in addition to using the wholesale ac-
22 quisition cost for an applicable drug, use alternative
23 cost measures of such drug.

24 “(3) EXCEPTION.—A justification under sub-
25 section (c) shall not be required for a triggered

1 SPIKE increase described in paragraph (1) of an
2 applicable drug of a manufacturer if there is any
3 portion of the lookback period described in the re-
4 spective subparagraph of such paragraph for such
5 increase that is included within the lookback period
6 for another triggered SPIKE increase (or combina-
7 tion of such increases) for which a justification is
8 made under this section for such drug by such man-
9 ufacturer.

10 “(4) UNIT DETERMINATION.—For purposes of
11 determining the wholesale acquisition cost in car-
12 rying out this section, the Secretary shall determine
13 a unit (such as a unit size) to apply.

14 “(5) PUBLIC POSTING.—Beginning with respect
15 to 2021, the Secretary shall publicly post on the
16 Internet website of the Department of Health and
17 Human Services—

18 “(A) alternative percentages, dollar
19 amounts, and lookback periods that, if applied
20 under paragraph (1), would be projected to in-
21 crease the number of applicable drugs for which
22 a triggered SPIKE increase would occur for
23 such year; and

24 “(B) the number of applicable drugs for
25 which a triggered SPIKE increase would occur

1 for such year of such an alternative percentage,
2 dollar amount, or period were applied for such
3 year.

4 “(e) JUSTIFICATION DESCRIBED.—

5 “(1) IN GENERAL.—The justification described
6 in this subsection, with respect to a triggered
7 SPIKE increase described in subsection (b)(1) of an
8 applicable drug of a manufacturer, is—

9 “(A) all of the information described in
10 paragraph (2);

11 “(B) all of the information and supporting
12 documentation described in paragraph (3), as
13 applicable to the increase and drug; and

14 “(C) a certification described in paragraph
15 (4).

16 “(2) REQUIRED INFORMATION.—For purposes
17 of paragraph (1), the information described in this
18 paragraph is the following:

19 “(A) The individual factors that have con-
20 tributed to the increase in the wholesale acqui-
21 sition cost.

22 “(B) An explanation of the role of each
23 factor in contributing to such increase.

24 “(3) INFORMATION AS APPLICABLE.—For pur-
25 poses of paragraph (1), the information and sup-

1 porting documentation described in this paragraph is
2 the following:

3 “(A) Total expenditures of the manufac-
4 turer on—

5 “(i) materials and manufacturing for
6 such drug;

7 “(ii) acquiring patents and licensing
8 for each drug of the manufacturer; and

9 “(iii) costs to purchase or acquire the
10 drug from another company, if applicable.

11 “(B) The percentage of total expenditures
12 of the manufacturer on research and develop-
13 ment for such drug that was derived from Fed-
14 eral funds.

15 “(C) The total expenditures of the manu-
16 facturer on research and development for such
17 drug.

18 “(D) The total revenue and net profit gen-
19 erated from the applicable drug for each cal-
20 endar year since drug approval.

21 “(E) The total costs associated with mar-
22 keting and advertising for the applicable drug.

23 “(F) Additional information specific to the
24 manufacturer of the applicable drug, such as—

1 “(i) the total revenue and net profit of
2 the manufacturer for the period of such in-
3 crease, as determined by the Secretary;

4 “(ii) metrics used to determine execu-
5 tive compensation;

6 “(iii) total expenditures on—

7 “(I) drug research and develop-
8 ment; or

9 “(II) clinical trials on drugs that
10 failed to receive approval by the Food
11 and Drug Administration; and

12 “(iv) any additional information re-
13 lated to drug pricing decisions of the man-
14 ufacturer.

15 “(G) Any other relevant information and
16 supporting documentation necessary to justify
17 the triggering SPIKE increase.

18 “(H) Any other relevant information and
19 supporting documentation, as specified by the
20 Secretary.

21 “(4) CERTIFICATION.—For purposes of para-
22 graph (1), the certification described in this para-
23 graph is a certification, that all such information
24 and documentation is accurate and complete, by one
25 of the following:

1 “(A) The chief executive officer of the
2 manufacturer.

3 “(B) The chief financial officer of the
4 manufacturer.

5 “(C) An individual who has delegated au-
6 thority to sign for, and who reports directly to,
7 such chief executive officer or chief financial of-
8 ficer.

9 “(d) TIMING.—

10 “(1) NOTIFICATION.—Not later than 60 days
11 after the date on which the Secretary makes the de-
12 termination that there is a triggering SPIKE in-
13 crease with respect to an applicable drug, the Sec-
14 retary shall notify the manufacturer of the applica-
15 ble drug of such determination.

16 “(2) SUBMISSION OF JUSTIFICATION.—Not
17 later than 90 days after the date on which a manu-
18 facturer receives a notification under paragraph (1),
19 subject to subsection (b)(3), the manufacturer shall
20 submit to the Secretary the justification required
21 under subsection (a), including a summary of such
22 justification, in a form and manner specified by the
23 Secretary. In specifying such form, with respect to
24 the summary required under the previous sentence,
25 the Secretary shall provide that such summary shall

1 be in an easily understandable format, as specified
2 by the Secretary, and shall permit the manufacturer
3 to exclude proprietary information from such sum-
4 mary.

5 “(3) POSTING ON INTERNET WEBSITE.—Not
6 later than 30 days after receiving the complete jus-
7 tification under paragraph (2), the Secretary shall
8 post on the Internet website of the Centers for Medi-
9 care & Medicaid Services the summary included for
10 such justification.

11 “(e) PENALTIES.—

12 “(1) FAILURE TO SUBMIT TIMELY JUSTIFICA-
13 TION.—If the Secretary determines that a manufac-
14 turer has failed to submit a justification as required
15 under this section, including in accordance with the
16 timing and form required, with respect to an appli-
17 cable drug, the Secretary shall apply a civil mone-
18 tary penalty in an amount of \$10,000 for each day
19 the manufacturer has failed to submit such justifica-
20 tion as so required.

21 “(2) FALSE INFORMATION.—Any manufacturer
22 that submits a justification under this section that
23 knowingly provides false information in such jus-
24 tification is subject to a civil monetary penalty in an

1 amount not to exceed \$100,000 for each item of
2 false information.

3 “(3) APPLICATION OF PROCEDURES.—The provisions of section 1128A (other than subsections (a)
4 and (b)) shall apply to a civil monetary penalty
5 under this subsection in the same manner as such
6 provisions apply to a penalty or proceeding under
7 section 1128A(a). Civil monetary penalties imposed
8 under this subsection are in addition to other pen-
9 alties as may be prescribed by law.

10 “(f) DEFINITIONS.—In this section:

11 “(1) APPLICABLE DRUG.—

12 “(A) IN GENERAL.—Subject to paragraph
13 (2), the term ‘applicable drug’ means, with re-
14 spect to a lookback period described in para-
15 graph (2), a covered outpatient drug (as de-
16 fined in paragraph (2) of section 1927(k), with-
17 out application of paragraph (3) of such sec-
18 tion) that is covered under title XVIII and is
19 not a low cost drug.

20 “(B) EXCLUSION OF LOW COST DRUGS.—
21 For purposes of subparagraph (A)(iii), not later
22 than January 1, 2021, the Secretary shall
23 specify a threshold (such as a cost or spending
24 threshold) for identifying (and shall identify)
25

1 low cost drugs to be excluded from the defini-
2 tion of the term ‘applicable drug’, such as a
3 drug that has a wholesale acquisition cost of
4 less than \$10 per unit or less than \$100 in av-
5 erage estimated expenditures under title XVIII
6 per individual per year or per user of such drug
7 per year. For purposes of this section, a drug
8 shall not be considered specified as a low cost
9 drug for a lookback period described in para-
10 graph (2) with respect to a year unless such
11 drug is identified as being below the specified
12 threshold for the entirety of the lookback pe-
13 riod.

14 “(2) MANUFACTURER.—The term ‘manufac-
15 turer’ has the meaning given that term in section
16 1847A(c)(6)(A).

17 “(3) WHOLESAL ACQUISITION COST.—The
18 term ‘wholesale acquisition cost’ has the meaning
19 given that term in section 1847A(c)(6)(B).”

○



116TH CONGRESS
1ST SESSION

H. R. 2087

To amend title XVIII of the Social Security Act to require certain manufacturers to report drug pricing information with respect to drugs under the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 4, 2019

Mr. DOGGETT (for himself and Mr. BUCHANAN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to require certain manufacturers to report drug pricing information with respect to drugs under the Medicare program, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Drug Price Trans-
5 parency Act”.

1 **SEC. 2. REQUIRING CERTAIN MANUFACTURERS TO REPORT**
2 **DRUG PRICING INFORMATION WITH RE-**
3 **SPECT TO DRUGS UNDER THE MEDICARE**
4 **PROGRAM.**

5 (a) IN GENERAL.—Section 1847A of the Social Secu-
6 rity Act (42 U.S.C. 1395w-3a) is amended—

7 (1) in subsection (b)—

8 (A) in paragraph (2)(A), by inserting “or
9 subsection (f)(2), as applicable” before the pe-
10 riod at the end;

11 (B) in paragraph (3), in the matter pre-
12 ceding subparagraph (A), by inserting “or sub-
13 section (f)(2), as applicable,” before “deter-
14 mined by”; and

15 (C) in paragraph (6)(A), in the matter
16 preceding clause (i), by inserting “or subsection
17 (f)(2), as applicable,” before “determined by”;
18 and

19 (2) in subsection (f)—

20 (A) by striking “For requirements” and
21 inserting the following:

22 “(1) IN GENERAL.—For requirements”; and

23 (B) by adding at the end the following new
24 paragraph:

25 “(2) MANUFACTURERS WITHOUT A REBATE
26 AGREEMENT UNDER TITLE XIX.—

1 “(A) IN GENERAL.—In the case of a man-
2 ufacturer of a drug or biological described in
3 subparagraph (C), (E), or (G) of section
4 1842(o)(1) or in clause (ii) or (iii) of section
5 1881(b)(14)(B) that does not have a rebate
6 agreement in effect under section 1927, for cal-
7 endar quarters beginning on or after January
8 1, 2020, such manufacturer shall report to the
9 Secretary the information described in sub-
10 section (b)(3)(A)(iii) of such section 1927 with
11 respect to such drug or biological in a time and
12 manner specified by the Secretary.

13 “(B) AUDIT.—Information reported under
14 subparagraph (A) is subject to audit by the In-
15 spector General of the Department of Health
16 and Human Services.

17 “(C) VERIFICATION.—The Secretary may
18 survey wholesalers and manufacturers that di-
19 rectly distribute drugs described in subpara-
20 graph (A), when necessary, to verify manufac-
21 turer prices and manufacturer’s average sales
22 prices (including wholesale acquisition cost) if
23 required to make payment reported under sub-
24 paragraph (A). The Secretary may impose a
25 civil monetary penalty in an amount not to ex-

1 ceed \$100,000 on a wholesaler, manufacturer,
2 or direct seller, if the wholesaler, manufacturer,
3 or direct seller of such a drug refuses a request
4 for information about charges or prices by the
5 Secretary in connection with a survey under
6 this subparagraph or knowingly provides false
7 information. The provisions of section 1128A
8 (other than subsections (a) (with respect to
9 amounts of penalties or additional assessments)
10 and (b)) shall apply to a civil money penalty
11 under this subparagraph in the same manner as
12 such provisions apply to a penalty or proceeding
13 under section 1128A(a).

14 “(D) CONFIDENTIALITY.—Notwithstand-
15 ing any other provision of law, information dis-
16 closed by manufacturers or wholesalers under
17 this paragraph (other than the wholesale acqui-
18 sition cost for purposes of carrying out this sec-
19 tion) is confidential and shall not be disclosed
20 by the Secretary in a form which discloses the
21 identity of a specific manufacturer or whole-
22 saler or prices charged for drugs by such manu-
23 facturer or wholesaler, except—

24 “(i) as the Secretary determines to be
25 necessary to carry out this section (includ-

1 ing the determination and implementation
2 of the payment amount), or to carry out
3 section 1847B;

4 “(ii) to permit the Comptroller Gen-
5 eral to review the information provided;
6 and

7 “(iii) to permit the Director of the
8 Congressional Budget Office to review the
9 information provided.”.

10 (b) ENFORCEMENT.—

11 (1) IN GENERAL.—Section 1847A such Act (42
12 U.S.C. 1395w-3a) is further amended—

13 (A) in subsection (d)(4)—

14 (i) in subparagraph (A), by striking
15 “IN GENERAL” and inserting “MISREPRE-
16 SENTATION”;

17 (ii) in subparagraph (B), by striking
18 “subparagraph (B)” and inserting “sub-
19 paragraph (A), (B), or (C)”;

20 (iii) by redesignating subparagraph
21 (B) as subparagraph (D); and

22 (iv) by inserting after subparagraph
23 (A) the following new subparagraphs:

24 “(B) FAILURE TO PROVIDE TIMELY INFOR-
25 MATION.—If the Secretary determines that a

1 manufacturer described in subsection (f)(2) has
2 failed to report on information described in sec-
3 tion 1927(b)(3)(A)(iii) with respect to a drug or
4 biological in accordance with such subsection,
5 the Secretary shall apply a civil money penalty
6 in an amount of \$25,000 for each day the man-
7 ufacturer has failed to report such information
8 and such amount shall be paid to the Treasury.

9 “(C) FALSE INFORMATION.—Any manu-
10 facturer required to submit information under
11 subsection (f)(2) that knowingly provides false
12 information is subject to a civil money penalty
13 in an amount not to exceed \$100,000 for each
14 item of false information. Such civil money pen-
15 alties are in addition to other penalties as may
16 be prescribed by law.”; and

17 (B) in subsection (c)(6)(A), by striking the
18 period at the end and inserting “, except that,
19 for purposes of subsection (f)(2), the Secretary
20 may, if the Secretary determines appropriate,
21 exclude repackagers of a drug or biological from
22 such term.”.

23 (2) CONFORMING EXISTING MANUFACTURER
24 REPORTING PENALTIES.—Section 1927(b)(3)(C)(i)
25 of such Act (42 U.S.C. 1396r-8(b)(3)(C)(i)) is

1 amended by inserting “(or, for such failures occur-
2 ring on or after January 1, 2020, \$25,000)” after
3 “\$10,000”.

4 (c) REPORT.—Not later than January 1, 2021, the
5 Inspector General of the Department of Health and
6 Human Services shall assess and submit to Congress a
7 report on the accuracy of average sales price information
8 submitted by manufacturers under section 1847A of the
9 Social Security Act (42 U.S.C. 1395w–3a). Such report
10 shall include any recommendations on how to improve the
11 accuracy of such information.

○



116TH CONGRESS
1ST SESSION

H. R. 2115

To amend title XI of the Social Security Act to provide greater transparency of discounts provided by drug manufacturers.

IN THE HOUSE OF REPRESENTATIVES

APRIL 8, 2019

Ms. SPANBERGER (for herself, Mr. ARRINGTON, and Mr. BRENDAN F. BOYLE of Pennsylvania) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XI of the Social Security Act to provide greater transparency of discounts provided by drug manufacturers.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Public Disclosure of
5 Drug Discounts Act”.

6 **SEC. 2. PUBLIC DISCLOSURE OF DRUG DISCOUNTS.**

7 Section 1150A of the Social Security Act (42 U.S.C.
8 1320b–23) is amended—

1 (1) in subsection (c), in the matter preceding
2 paragraph (1), by inserting “(other than as per-
3 mitted under subsection (e))” after “disclosed by the
4 Secretary”; and

5 (2) by adding at the end the following new sub-
6 section:

7 “(e) PUBLIC AVAILABILITY OF CERTAIN INFORMA-
8 TION.—

9 “(1) IN GENERAL.—In order to allow the com-
10 parison of PBMs’ ability to negotiate rebates, dis-
11 counts, and price concessions and the amount of
12 such rebates, discounts, and price concessions that
13 are passed through to plan sponsors, beginning Jan-
14 uary 1, 2020, the Secretary shall make available on
15 the Internet website of the Department of Health
16 and Human Services the information with respect to
17 the second preceding calendar year provided to the
18 Secretary on generic dispensing rates (as described
19 in paragraph (1) of subsection (b)) and information
20 provided to the Secretary under paragraphs (2) and
21 (3) of such subsection that, as determined by the
22 Secretary, is with respect to each PBM.

23 “(2) AVAILABILITY OF DATA.—In carrying out
24 paragraph (1), the Secretary shall ensure the fol-
25 lowing:

1 “(A) CONFIDENTIALITY.—The information
2 described in such paragraph is displayed in a
3 manner that prevents the disclosure of informa-
4 tion on rebates, discounts, and price conces-
5 sions, with respect to an individual drug or an
6 individual plan.

7 “(B) CLASS OF DRUG.—The information
8 described in such paragraph is made available
9 by class of drug, using an existing classification
10 system, but only if the class contains such num-
11 ber of drugs, as specified by the Secretary, to
12 ensure confidentiality of proprietary informa-
13 tion or other information that is prevented to
14 be disclosed under subparagraph (A).”.

○



116TH CONGRESS
1ST SESSION

H. R. 2296

To require reporting regarding certain drug price increases, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 12, 2019

Ms. SCHAKOWSKY (for herself and Mr. ROONEY of Florida) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To require reporting regarding certain drug price increases, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Fair Accountability
5 and Innovative Research Drug Pricing Act of 2019” or
6 the “FAIR Drug Pricing Act of 2019”.

1 **SEC. 2. REPORTING ON JUSTIFICATION FOR DRUG PRICE**
2 **INCREASES.**

3 Title III of the Public Health Service Act (42 U.S.C.
4 241 et seq.) is amended by adding at the end the fol-
5 lowing:

6 **“PART W—DRUG PRICE REPORTING; DRUG**
7 **VALUE FUND**

8 **“SEC. 3990O. REPORTING ON JUSTIFICATION FOR DRUG**
9 **PRICE INCREASES.**

10 “(a) DEFINITIONS.—In this section:

11 “(1) MANUFACTURER.—The term ‘manufac-
12 turer’ means the person—

13 “(A) that holds the application for a drug
14 approved under section 505 of the Federal
15 Food, Drug, and Cosmetic Act or the license
16 issued under section 351 of the Public Health
17 Service Act; or

18 “(B) who is responsible for setting the
19 price for the drug.

20 “(2) QUALIFYING DRUG.—The term ‘qualifying
21 drug’ means any drug that is approved under sub-
22 section (e) or (j) of section 505 of the Federal Food,
23 Drug, and Cosmetic Act or licensed under subsection
24 (a) or (k) of section 351 of this Act—

25 “(A) that has a wholesale acquisition cost
26 of \$100 or more per month supply or per a

1 course of treatment that lasts less than a
2 month and is—

3 “(i)(I) subject to section 503(b)(1) of
4 the Federal Food, Drug, and Cosmetic
5 Act; or

6 “(II) commonly administered by hos-
7 pitals (as determined by the Secretary);

8 “(ii) not designated as a drug for a
9 rare disease or condition under section 526
10 of the Federal Food, Drug, and Cosmetic
11 Act; and

12 “(iii) not designated by the Secretary
13 as a vaccine; and

14 “(B) for which, during the previous cal-
15 endar year, at least 1 dollar of the total amount
16 of sales were for individuals enrolled under the
17 Medicare program under title XVIII of the So-
18 cial Security Act (42 U.S.C. 1395 et seq.) or
19 under a State Medicaid plan under title XIX of
20 such Act (42 U.S.C. 1396 et seq.) or under a
21 waiver of such plan.

22 “(3) WHOLESALE ACQUISITION COST.—The
23 term ‘wholesale acquisition cost’ has the meaning
24 given that term in section 1847A(c)(6)(B) of the So-
25 cial Security Act (42 U.S.C. 1395w-3a(c)(6)(B)).

1 “(b) REPORT.—

2 “(1) REPORT REQUIRED.—The manufacturer of
3 a qualifying drug shall submit a report to the Sec-
4 retary for each price increase of a qualifying drug
5 that will result in an increase in the wholesale acqui-
6 sition cost of that drug that is equal to—

7 “(A) 10 percent or more over a 12-month
8 period; or

9 “(B) 25 percent or more over a 36-month
10 period.

11 “(2) REPORT DEADLINE.—Each report de-
12 scribed in paragraph (1) shall be submitted to the
13 Secretary not later than 30 days prior to the
14 planned effective date of such price increase.

15 “(c) CONTENTS.—A report under subsection (b)
16 shall, at a minimum, include—

17 “(1) with respect to the qualifying drug—

18 “(A) the percentage by which the manufac-
19 turer will raise the wholesale acquisition cost of
20 the drug on the planned effective date of such
21 price increase;

22 “(B) a justification for, and description of,
23 each manufacturer’s price increase that will
24 occur during the 12-month period described in

1 subsection (b)(1)(A) or the 36-month period de-
2 scribed in subsection (b)(1)(B), as applicable;

3 “(C) the identity of the initial developer of
4 the drug;

5 “(D) a description of the history of the
6 manufacturer’s price increases for the drug
7 since the approval of the application for the
8 drug under section 505 of the Federal Food,
9 Drug, and Cosmetic Act or the issuance of the
10 license for the drug under section 351, or since
11 the manufacturer acquired such approved appli-
12 cation or license;

13 “(E) the current list price of the drug;

14 “(F) the total expenditures of the manu-
15 facturer on—

16 “(i) materials and manufacturing for
17 such drug; and

18 “(ii) acquiring patents and licensing
19 for such drug;

20 “(G) the percentage of total expenditures
21 of the manufacturer on research and develop-
22 ment for such drug that was derived from Fed-
23 eral funds;

1 “(H) the total expenditures of the manu-
2 facturer on research and development for such
3 drug that is used for—

4 “(i) basic and preclinical research;

5 “(ii) clinical research;

6 “(iii) new drug development;

7 “(iv) pursuing new or expanded indi-
8 cations for such drug through supple-
9 mental applications under section 505 of
10 the Federal Food, Drug, and Cosmetic Act
11 or section 351 of the Public Health Service
12 Act; and

13 “(v) carrying out postmarket require-
14 ments related to such drug, including those
15 under section 505(o)(3) of the Federal
16 Food, Drug, and Cosmetic Act;

17 “(I) the total revenue and the net profit
18 generated from the qualifying drug for each cal-
19 endar year since the approval of the application
20 for the drug under section 505 of the Federal
21 Food, Drug, and Cosmetic Act or the issuance
22 of the license for the drug under section 351,
23 or since the manufacturer acquired such ap-
24 proved application or license; and

1 “(J) the total costs associated with mar-
2 keting and advertising for the qualifying drug;

3 “(2) with respect to the manufacturer—

4 “(A) the total revenue and the net profit
5 of the manufacturer for each of the 12- and 36-
6 month periods preceding the submission of the
7 report;

8 “(B) all stock-based performance metrics
9 used by the manufacturer to determine execu-
10 tive compensation for each of the 12- and 36-
11 month periods preceding the submission of the
12 report; and

13 “(C) any additional information the manu-
14 facturer chooses to provide related to drug pric-
15 ing decisions, such as total expenditures on—

16 “(i) drug research and development;

17 or

18 “(ii) clinical trials on drugs that failed
19 to receive approval by the Food and Drug
20 Administration; and

21 “(3) such other related information as the Sec-
22 retary considers appropriate.

23 “(d) CIVIL PENALTY.—Any manufacturer of a quali-
24 fying drug that fails to submit a report for the drug as

1 required by this section shall be subject to a civil penalty
2 of \$100,000 for each day on which the violation continues.

3 “(e) PUBLIC POSTING.—

4 “(1) IN GENERAL.—Subject to paragraph (3),
5 not later than 30 days after the submission of a re-
6 port under subsection (b), the Secretary shall post
7 the report on the public website of the Department
8 of Health and Human Services.

9 “(2) FORMAT.—In developing the format of
10 such report for public posting, the Secretary shall
11 consult stakeholders, including beneficiary groups,
12 and shall seek feedback on the content and format
13 from consumer advocates and readability experts to
14 ensure such public reports are user-friendly to the
15 public and are written in plain language that con-
16 sumers can readily understand.

17 “(3) TRADE SECRETS AND CONFIDENTIAL IN-
18 FORMATION.—In carrying out this section, the Sec-
19 retary shall enforce applicable law concerning the
20 protection of confidential commercial information
21 and trade secrets.

22 **“SEC. 39900–1. USE OF CIVIL PENALTY AMOUNTS.**

23 “The Secretary shall, without further appropriation,
24 collect civil penalties under section 39900 and use the
25 funds derived from such civil penalties, in addition to any

1 other amounts available to the Secretary, to carry out ac-
2 tivities described in this part and to improve consumer and
3 provider information about drug value and drug price
4 transparency.

5 **“SEC. 3990O–2. ANNUAL REPORT TO CONGRESS.**

6 “(a) IN GENERAL.—Subject to subsection (b), the
7 Secretary shall submit to Congress, and post on the public
8 website of the Department of Health and Human Services
9 in a way that is easy to use and understand, an annual
10 report—

11 “(1) summarizing the information reported pur-
12 suant to section 3990O; and

13 “(2) including copies of the reports and sup-
14 porting detailed economic analyses submitted pursu-
15 ant to such section.

16 “(b) TRADE SECRETS AND CONFIDENTIAL INFORMA-
17 TION.—In carrying out this section, the Secretary shall
18 enforce applicable law concerning the protection of con-
19 fidential commercial information and trade secrets.”.

○



116TH CONGRESS
1ST SESSION

H. R. 2376

To require the Federal Trade Commission to study the role of intermediaries in the pharmaceutical supply chain and provide Congress with appropriate policy recommendations, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 29, 2019

Mr. COLLINS of Georgia (for himself and Mr. NADLER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To require the Federal Trade Commission to study the role of intermediaries in the pharmaceutical supply chain and provide Congress with appropriate policy recommendations, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Prescription Pricing
5 for the People Act of 2019”.

1 **SEC. 2. DEFINITIONS.**

2 In this Act:

3 (1) **APPROPRIATE COMMITTEES OF CON-**
4 **GRESS.**—The term “appropriate committees of Con-
5 gress” means—

6 (A) the Committee on the Judiciary of the
7 Senate; and

8 (B) the Committee on the Judiciary of the
9 House of Representatives.

10 (2) **COMMISSION.**—The term “Commission”
11 means the Federal Trade Commission.

12 **SEC. 3. STUDY OF PHARMACEUTICAL SUPPLY CHAIN**
13 **INTERMEDIARIES AND MERGER ACTIVITY.**

14 (a) **INITIAL REPORT.**—Not later than 1 year after
15 the date of enactment of this Act, the Commission shall
16 submit to the appropriate committees of Congress a report
17 that—

18 (1) addresses at minimum—

19 (A) whether pharmacy benefit managers—

20 (i) charge payers a higher price than
21 the reimbursement rate at which the phar-
22 macy benefit managers reimburse com-
23 peting pharmacies;

24 (ii) steer patients for anticompetitive
25 purposes to any pharmacies, including re-
26 tail, mail-order, or any other type of phar-

1 macy, in which the PBM has an ownership
2 interest;

3 (iii) audit or review proprietary data,
4 including acquisition costs, patient infor-
5 mation, or dispensing information, of com-
6 peting pharmacies that can be used for
7 anticompetitive purposes; or

8 (iv) use formulary designs to increase
9 the market share of higher cost prescrip-
10 tion drugs and depress the market share of
11 lower cost prescription drugs (each net of
12 rebates and discounts);

13 (B) whether there are any specific legal or
14 regulatory obstacles the Commission currently
15 faces in ensuring a competitive and transparent
16 marketplace in the pharmaceutical supply
17 chain, including the pharmacy benefit manager
18 marketplace and pharmacy services administra-
19 tive organizations;

20 (C) how companies and payers assess the
21 benefits, costs, and risks of contracting with
22 intermediaries, including pharmacy services ad-
23 ministrative organizations, and whether more
24 information about the roles of intermediaries

1 should be available to consumers and payers;
2 and

3 (D) whether there are any specific legal or
4 regulatory obstacles the Commission currently
5 faces in ensuring a competitive and transparent
6 marketplace in the pharmaceutical supply
7 chain, including the pharmacy benefit manager
8 marketplace and pharmacy services administra-
9 tive organizations; and
10 (2) provides—

11 (A) observations or conclusions drawn
12 from the November 2017 roundtable entitled
13 “Understanding Competition in Prescription
14 Drug Markets: Entry and Supply Chain Dy-
15 namics”, and any similar efforts;

16 (B) specific actions the Commission in-
17 tends to take as a result of the November 2017
18 roundtable, and any similar efforts, including a
19 detailed description of relevant forthcoming ac-
20 tions, additional research or roundtable discus-
21 sions, consumer education efforts, or enforce-
22 ment actions; and

23 (C) policy or legislative recommendations
24 to—

- 1 (i) improve transparency and competi-
2 tion in the pharmaceutical supply chain;
3 (ii) prevent and deter anticompetitive
4 behavior in the pharmaceutical supply
5 chain; and
6 (iii) best ensure that consumers ben-
7 efit from any cost savings or efficiencies
8 that may result from mergers and consoli-
9 dations.

10 (b) INTERIM REPORT.—Not later than 180 days
11 after the date of enactment of this Act, the Commission
12 shall submit to the appropriate committees of Congress
13 an interim report on the progress of the report required
14 by subsection (a), along with preliminary findings and
15 conclusions based on information collected to that date.

○



116TH CONGRESS
1ST SESSION

H. R. 2757

To amend title XVIII of the Social Security Act to provide for adjustments to the Medicare part D cost-sharing reductions for low-income individuals.

IN THE HOUSE OF REPRESENTATIVES

MAY 15, 2019

Mr. CUNNINGHAM (for himself, Mr. BILIRAKIS, and Mr. EVANS) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to provide for adjustments to the Medicare part D cost-sharing reductions for low-income individuals.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Creating Lower cost
5 Alternative for Your prescription drugs Act” or the
6 “CLAY Act”.

1 **SEC. 2. ADJUSTMENTS TO MEDICARE PART D COST-SHAR-**
2 **ING REDUCTIONS FOR LOW-INCOME INDIVID-**
3 **UALS.**

4 Section 1860D-14(a) of the Social Security Act (42
5 U.S.C. 1395w-114(a)) is amended—

6 (1) in paragraph (1)—

7 (A) in subparagraph (D)—

8 (i) in clause (ii)—

9 (I) by striking “that does not ex-
10 ceed \$1 for” and all that follows
11 through the period at the end and in-
12 serting “that does not exceed—

13 “(I) for plan years before plan
14 year 2021—

15 “(aa) for a generic drug or a
16 preferred drug that is a multiple
17 source drug (as defined in section
18 1927(k)(7)(A)(i)), \$1 or, if less,
19 the copayment amount applicable
20 to an individual under clause
21 (iii); and

22 “(bb) for any other drug, \$3
23 or, if less, the copayment amount
24 applicable to an individual under
25 clause (iii); and”;

3

1 (II) by adding at the end the fol-
2 lowing new subclauses:

3 “(II) for plan year 2021—

4 “(aa) for a generic drug, \$0;
5 and

6 “(bb) for any other drug,
7 the dollar amount applied under
8 this clause (after application of
9 paragraph (4)(A)) for plan year
10 2020 for a drug described in sub-
11 clause (I)(bb); and

12 “(III) for a subsequent year, the
13 dollar amount applied under this
14 clause for the previous year for the
15 drug, increased by the annual percent-
16 age increase in the consumer price
17 index (all items; U.S. city average) as
18 of September of such previous year.”;
19 and

20 (ii) in clause (iii)—

21 (I) by striking “does not exceed
22 the copayment amount specified
23 under” and inserting “does not ex-
24 ceed—

1 “(I) for plan years beginning be-
2 fore plan year 2021, the copayment
3 amount specified under”;

4 (II) by striking the period at the
5 end and inserting “; and”; and

6 (III) by adding at the end the
7 following new subclause:

8 “(II) for plan year 2021 and
9 each subsequent plan year the copay-
10 ment amount applied under clause (ii)
11 for the drug and year involved.”; and

12 (B) by adding at the end the following new
13 subparagraph:

14 “(F) ROUNDING.—Any amount established
15 under clause (ii) of subparagraph (D), including
16 as applied under clause (iii) of such subpara-
17 graph or paragraph (2)(E), that is based on an
18 increase of \$3, that is not a multiple of 5 cents
19 or 10 cents, respectively, shall be rounded to
20 the nearest multiple of 5 cents or 10 cents, re-
21 spectively.”;

22 (2) in paragraph (2)—

23 (A) in subparagraph (C), by inserting “and
24 subparagraph (E)” before the period;

25 (B) in subparagraph (D)—

1 (i) by striking “of coinsurance of” and
2 inserting “of—

3 “(I) for plan years before plan
4 year 2021, coinsurance of”;

5 (ii) by striking the period at the end
6 and inserting “; and”;

7 (iii) by adding at the end the fol-
8 lowing new subclause:

9 “(II) for plan year 2021 and
10 each subsequent plan year, a copay-
11 ment amount that does not exceed the
12 copayment amount applied under
13 paragraph (1)(D)(ii) for the drug and
14 year involved.”; and

15 (C) in subparagraph (E)—

16 (i) by striking “subsection (c), the
17 substitution for” and inserting “subsection
18 (e)—

19 “(i) for plan years before plan year
20 2021, the substitution for”;

21 (ii) by striking the period at the end
22 and inserting “; and”;

23 (iii) by adding at the end the fol-
24 lowing new clause:

1 “(ii) for plan year 2021 and each sub-
2 sequent plan year, the elimination of any
3 cost-sharing imposed under section
4 1860D-2(b)(4)(A).”; and
5 (3) in paragraph (4)(A)(ii), by inserting “(be-
6 fore 2021)” after “subsequent year”.

○



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FACP, FASCO

2318 Mill Road, Suite 800
Alexandria, VA 22314

May 21, 2019

The Honorable Frank Pallone
Chair, House Energy & Commerce Committee
U.S. House
Washington, DC 20515

The Honorable Greg Walden
Ranking Member, House Energy & Commerce Committee
U.S. House
Washington, DC 20515

Cc: Health Subcommittee Chairwoman Anna Eshoo, Ranking Member Michael Burgess,
and all members of the House Energy & Commerce Committee

Dear Chairman Pallone and Ranking Member Walden,

The American Society of Clinical Oncology (ASCO) appreciates the Committee's ongoing efforts to examine prescription drug pricing and consider solutions to lower costs for patients. Patients with cancer are twice as likely to file bankruptcy than those without the disease. ASCO shares your concern about the rising cost of prescription drugs and stands ready to work with you on real solutions that address the affordability of cancer drugs. We applaud the Committee's previous work to spur competition in the generic marketplace and prohibit actions which only have the goal of delaying generic entry in the name of profit.

As the Committee continues its work with today's hearing, "Improving Drug Pricing Transparency and Lowering Prices for American Consumers," we offer our strong support for policies that would increase transparency throughout the supply chain such as HR 2296 *the FAIR Drug Pricing Act* and HR 2087 *Drug Pricing Transparency Act* moving forward through the legislative process. Transparency allows payers and patients to make an informed comparison of the relationship between development costs and price for drug products and exert public pressure on companies where the two appear to be widely divergent. As you consider HR 2064 *the Sunshine for Samples Act*, it is critical that any required reporting in this area be accurate and not impede access for patients, such as those with cancer beginning a round of oral chemotherapy in a physician office.

Of critical importance to our members and their patients is a need for greater transparency around the actions of Pharmacy Benefit Managers (PBMs). ASCO offers for your review the [ASCO Position Statement: PBMs and Their Impact on Cancer Care](#). We hear serious concerns from our members about the negative effects of certain PBM practices on patients and the cancer care system. These include errors in filling prescriptions, treatment doses being altered in the absence of consultation with oncology care providers, duplicate patient copays because of incomplete dispensing, and drug waste resulting from incorrect doses or treatments sent directly to a patient's home. HR 2115 *Public Disclosure of Drug Discounts Act* and HR 2376 *Prescription Pricing for the People Act of 2019* will take important steps toward better understanding of practices by Pharmacy Benefit Managers.

We further support efforts to improve patient out of pocket costs such as HR 2757 *Creating Lower Cost Alternatives for Your Prescription Drugs Act*. In addition to cost, ASCO members also relay experiences of patient care delayed or denied because of utilization management techniques used by PBMs, especially prior authorization and step therapy. [ASCO's Policy Statement on the Impact of Utilization Management Policies for Cancer Drug Therapies](#) provides greater detail on ASCO's recommendations around prior authorization and step therapy.

If you have questions on any issue involving the care of individuals with cancer or would like additional information about ASCO's views on drug pricing issues, please contact Amanda Schwartz at Amanda.schwartz@asco.org.

Sincerely,



Monica M. Bertagnolli, MD, FACS, FASCO
President, American Society of Clinical Oncology

Testimony Submitted for the Record
U.S. House Committee on Energy and Commerce
Subcommittee on Health
Hearing: Improving Drug Pricing Transparency and Lowering Prices for American Consumers

Lauren Aronson
Executive Director
The Campaign for Sustainable Rx Pricing (CSRxP)

May 21, 2019

Chairwoman Eshoo, Ranking Member Burgess, and members of the U.S. House Committee on Energy and Commerce, the Campaign for Sustainable Rx Pricing (CSRxP) thanks you for the opportunity to submit testimony for the record on legislation under consideration to increase transparency and lower prescription drug prices. We very much appreciate your leadership in advancing these critically important issues, which will help make prescription drugs more affordable for all Americans.

CSRxP is a nonpartisan coalition of organizations committed to fostering an informed discussion on sustainable drug pricing and to developing bipartisan, market-based solutions that promote competition, transparency, and value to improve affordability while maintaining patient access to innovative prescription drugs that can improve health outcomes and save lives. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and insurance providers.

Prescription drug prices are out of control and continue to grow at unsustainable rates. Twenty-three cents of every health care dollar goes toward prescription drugs.¹ One in four Americans cannot afford their medications. Excessively high prices unfairly threaten the financial security, health and wellbeing of U.S. patients and their families every day, as well as strain Federal and state health budgets and the taxpayers who fund them. Too often patients are faced with the unfortunate and unfair choice of purchasing the medications they need to get well and stay healthy and paying their bills. Patients simply should never be presented with such a choice and deserve affordable access to prescription drugs.

Given the critical drug pricing crisis facing U.S. consumers and taxpayers today, CSRxP ardently believes it is imperative to rein in the out-of-control drug prices that put patient access to affordable life-saving drugs at risk. We share and applaud the Committee's commitment to lowering drug prices and very much appreciate your leadership in tackling this critically important issue that U.S. patients and taxpayers face every day.

CSRxP in particular wishes to applaud the Committee's efforts to increase transparency in prescription drug pricing. We ardently believe that improving transparency in prescription drug pricing is a critical component to making prescription drugs more affordable for consumers and taxpayers. Among other benefits, increased transparency will better enable transformation of the U.S. healthcare system toward

¹ AHIP. "[Where Does Your Healthcare Dollar Go?](#)" May 22, 2018.

one based on value; will better inform patients, prescribers, and dispensers of actual drug costs as they determine the most appropriate treatments to meet individual patient needs; and encourage drug makers to actually justify the high prices they unilaterally set for their products. To this end, as discussed below, CSRxP wishes to offer support for a number of bills the Committee is considering that will enhance transparency in prescription drug pricing and costs and lead to lower prices for consumers and taxpayers.

Support for the FAIR Drug Pricing Act: Drug companies unilaterally are responsible for setting high list prices and increasing them at excessively high rates. High drug prices unfortunately harm patients by putting access at risk to the affordable medications that improve their health outcomes and quality of life. Therefore, CSRxP supports the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act, which will require drug makers to justify unreasonably high price increases for their products to the U.S. Department of Health and Human Services (HHS). Mandating that drug companies justify their abusive and unfair price gouging practices will place pressure on them to reduce prices and increase prescription drug affordability for consumers and taxpayers.

Support for the SPIKE Act: CSRxP strongly believes that drug makers should be held accountable for their abusive price gouging practices that jeopardize patient access to the affordable prescription drugs they need to get well and stay healthy. As such, CSRxP supports the Stopping the Pharmaceutical Industry from Keeping drugs Expensive (SPIKE) Act, which will require drug makers to submit to HHS a written justification of their prices for drugs with significantly high launch prices and excessive price increases. As stated above, we believe that making drug makers justify their needlessly high prices will increase pressure on them to lower prices and cost for consumers and taxpayers.

Support for the Drug Price Transparency Act: CSRxP supports the Drug Price Transparency Act. This legislation will require all manufacturers to submit Part B drug pricing data to HHS. Submission of such data will ensure that Medicare has fully transparent, complete and accurate data on Part B drug prices, resulting in more accurate Medicare payments to providers for these prescription drugs whose costs are continuing to grow at rates far in excess of the rest of the Medicare program.

Support for the Sunshine for Samples Act: Free prescription drug samples can be helpful for patients, particularly for those on limited incomes that need to take expensive medications to get well and stay healthy. However, CSRxP is concerned that free samples also can serve as marketing tools that inappropriately could incentivize patients and providers to use and prescribe drugs, respectively, that may not be the most cost-effective treatment option for the patient's individual healthcare needs. Making publicly available the value of the free samples that drug makers provide will meaningfully improve transparency, better ensuring that prescribers and patients select the most cost efficient and medically appropriate therapy to treat the patient's condition and therefore CSRxP supports the Sunshine for Samples Act.

Support for the Creating Lower cost Alternatives for Your prescription drugs Act: The Creating Lower cost Alternatives for Your prescription drugs Act will reduce cost-sharing for Medicare Part D Low-Income Subsidy (LIS) beneficiaries to \$0 for generic drugs. As a result, this legislation importantly both will make prescription drugs more affordable for vulnerable low-income beneficiaries as well as increase the efficiency of the Medicare Part D program. As such, CSRxP supports the Creating Lower cost Alternatives for Your prescription drugs Act.

Conclusion

In conclusion, CSRxP again wishes to express appreciation for your leadership and the Committee's clear commitment to improving transparency and lowering prescription drug prices for all Americans. We thank the Committee for the opportunity to submit testimony for the record to support legislation that enhances transparency in prescription drug pricing and lowers prices for consumers. CSRxP firmly believes that without major actions by this Committee and others, the brand pharmaceutical industry will continue to excessively profit from their unfair and unsustainable pricing practices that increase drugs costs and risk access for the patients who need them. CSRxP looks forward to continue working with the Committee to develop bipartisan, market-based policies that promote transparency, foster competition, and incentivize value to improve affordability for consumers while at the same time maintaining access to the treatments that can improve health outcomes and save lives.



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May 21, 2019

The Honorable Frank Pallone, Jr.
 Chairman
 Committee on Energy and Commerce
 United States House of Representatives
 2125 Rayburn House Office Building
 Washington, D.C. 20515

The Honorable Greg Walden
 Ranking Member
 Committee on Energy and Commerce
 United States House of Representatives
 2322 Rayburn House Office Building
 Washington, D.C. 20515

The Honorable Anna Eshoo
 Chairwoman
 Subcommittee on Health
 Committee on Energy and Commerce
 United States House of Representatives
 2125 Rayburn House Office Building
 Washington, D.C. 20515

The Honorable Michael C. Burgess
 Ranking Member
 Subcommittee on Health
 Committee on Energy and Commerce
 United States House of Representatives
 2322 Rayburn House Office Building
 Washington, D.C. 20515

Dear Chairman Pallone, Ranking Member Walden, Chairwoman Eshoo, and Ranking Member Burgess:

On behalf of its nearly 38 million members and all older Americans, appreciates your focus on prescription drug prices and the challenges that high drug costs pose for seniors. Thank you for holding today's hearing on improving drug price transparency and for focusing on five bills that AARP has endorsed: H.R. 2296, the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act; H.R. 2069, Stopping the Pharmaceutical Industry from Keeping Drugs Expensive (SPIKE) Act; H.R. 2087, the Drug Price Transparency Act; H.R. 2115, the Public Disclosure of Drug Discounts Act; and H.R. 2064, the Sunshine for Samples Act.

Older adults cannot afford to pay higher and higher prices for the medications they need. The annual median income of Medicare beneficiaries is just over \$26,000, and, on average Medicare Part D enrollees take as many as five prescriptions per month often for chronic conditions. 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.

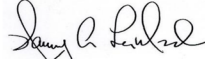
Alabama | Alaska | Arizona | Arkansas | California | Colorado | Connecticut | Delaware | District of Columbia | Florida | Georgia | Hawaii | Idaho | Illinois | Indiana | Iowa | Kansas | Kentucky | Louisiana | Maine | Maryland | Massachusetts | Michigan | Minnesota | Mississippi | Missouri | Montana | Nebraska | Nevada | New Hampshire | New Jersey | New Mexico | New York | North Carolina | North Dakota | Ohio | Oklahoma | Oregon | Pennsylvania | Puerto Rico | Rhode Island | South Carolina | South Dakota | Tennessee | Texas | Utah | Vermont | Virgin Islands | Virginia | Washington | West Virginia | Wisconsin | Wyoming

AARP strongly supports requiring drug manufacturers to justify price increases that make it difficult for older Americans to afford critical prescription medications. That is why we have endorsed these important bills. Both the FAIR Drug Pricing Act and the SPIKE ACT would require drug manufacturers to report and justify drastic price increases. This kind of price transparency is an important step toward holding drug companies accountable for pricing decisions. Americans are paying the highest prescription drugs prices in the world. Patients, providers, and policymakers deserve to know why the price of the drugs continue to increase - which could make it even more difficult for older Americans to afford the medications they need.

In addition, H.R. 2087 would require all drug manufacturers to provide timely reporting on the average sales prices (ASP) for their drugs, which will help to ensure that Part B reimbursement for those drugs is accurate. H.R. 2064 would require companies that manufacture drugs, devices, biologics, or medical supplies to report the aggregated value and quantity of drug samples they give to health care providers each year. While free samples can help patients to obtain the prescription drugs they need – particularly when those drugs are unaffordable – there are also reasonable questions about the impact that free samples have on prescribing behaviors. In addition, drug manufacturers are able to obtain large tax breaks by providing free samples. Finally, H.R. 2215 would require Pharmacy Benefit Managers (PBMs) to report the aggregated rebates and discounts on each class of drug that they receive, which will help the public to better understand the current rebate system.

We look forward to working with the Committee to enact these bills as well as other measures that will help lower prescription drug prices and reduce costs for older Americans. If you have any additional questions, feel free to contact me or have your staff contact Amy Kelbick on our Government Affairs staff at akelbick@aarpp.org or 202-434-2648.

Sincerely,



Nancy A. Leamond
Executive Vice President and
Chief Advocacy and Engagement Officer



May 21, 2019

The Honorable Jan Schakowsky
 United States House of Representative
 2367 Rayburn House Office Building
 Washington, DC 20515

Dear Representative Schakowsky,

On behalf of the National Multiple Sclerosis Society (Society), we write to share our experience and recommendations relating to high prescription drug costs and the real-life impact these prices have on people living with multiple sclerosis (MS). We hope these recommendations will be useful to you as you consider advancing legislation to tackle high prescription drug costs in the United States.

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. A new study funded by the National MS Society has confirmed that nearly one million people are living with MS in the United States, more than twice the original estimate from a previous study¹. 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 MS experience with high prescription drug and out-of-pocket costs:

The Society believes that the MS drug class clearly demonstrates areas where the reliance on simple forces of supply and demand, or the purported efficacy of a competitive market, is failing people with MS and other high cost chronic diseases and conditions.

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, and these medications have transformed the treatment of MS over the last 25 years. Fortunately, there are now over a dozen FDA-approved DMTs for different forms of MS. The full range of MS DMTs represent various mechanisms of action and routes of administration with varying efficacy, side effects and safety profiles. No single agent is 'best' for all people living with MS². As MS presents differently in each individual, every person's response to a DMT will vary. In fact, it is critically important that payers, payment models and delivery systems recognize that despite similarities in their indications and usage, these medications are not

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therapeutically interchangeable.

Unfortunately for people affected by MS, the cost of MS therapies has dramatically risen since the first DMT was approved in 1993. 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. When MS DMTs first came on the market in 1993, the price range was \$8,000 to \$11,000 for one year of treatment. Since that time, price increases occurring one or more times per year for almost all DMTs have become the norm. In 2013, the annual median price was less than \$60,000. In 2019, the median price for brand MS DMTs is \$88,853ⁱⁱⁱ and several pharmaceutical companies have already raised prices this year (see Appendix 1 and 2). 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.^{iv}

While we have seen prices of most MS DMTs rise in a similar trajectory, there has been, generally, no lowering of prices due to increased competition in the market as more therapies have come on market. This is true even with the generics now available as alternatives to one of the brand disease-modifying therapies. These generics are also very expensive- having entered the market with a list price of more than \$60,000 per year. One MS generic recently dropped its list price in half, yet this has had little impact on both overall costs within the class or on patients' out-of-pocket costs.

High costs create access challenges for people with MS

As the prices of MS DMTs increase, health plans and pharmacy benefit managers (PBMs) employ increasingly strict utilization management practices (prior authorization, step therapy and formulary restrictions) to minimize their use and cost liability for these therapies. This practice presents significant hurdles for prescribers and real barriers for people with MS. Utilization management tools can result in delays or disruptions in treatment as patients wait for their health plan to determine whether they will cover care as prescribed. Any delay or disruption in treatment is particularly problematic for people with MS as delays may result in disease progression that cannot be reversed. Many proposals offered to lower drug prices do so by restricting access or employing utilization management practices and we would urge Congress to evaluate the impact of any legislative proposals on patient access to therapies. We believe that any delivery system reform that aims to provide true patient-centered care for persons with MS must allow for timely access to the DMT most likely to produce optimal treatment outcomes for each person. Further, persons with MS who are stable on a DMT should be allowed to stay on that DMT without interruption until, or unless, changes in the patient's clinical status warrants a new treatment plan.

The Society has supported legislation in previous Congresses that would require health plans to provide a clear, easily-accessible, expedited process to seek an exception to step therapy protocols. In Rep. Wenstrup's Safe Step Act (H.R. 2279), a patient or provider could request an exception based on certain criteria outlined in the bill—for example, if the insurer's preferred treatment is likely to cause an adverse reaction, or likely to be ineffective. If those

criteria are met, the request would be granted in a timely manner. We would suggest that Congress look to policies like these as they are looking to advance legislation that lowers drug price so that patient's access to needed therapies are not negatively impacted.

Recommendations for drug pricing legislation

In 2016, the 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**⁴. We believe there is no single solution that can fully reverse the trend toward ever-increasing drug costs and payer policies that inhibit or delay access to medically necessary therapies. All stakeholders must engage in conversations to drive solutions. The Society's Recommendations call for increased transparency in all areas of the pharmaceutical supply chain, so that all stakeholders are operating from the same level of information. This includes transparency from the manufacturer on what factors are used to set prices, how price increases are determined (including frequency of increases), how prices and price increases both support the research and development of new therapies and the marketing of these to both physicians and the public, and money spent on patient assistance programs and the numbers of patients assisted with those programs.

Our recommendations also call for increased transparency from insurers and pharmacy benefit managers by encouraging them to provide easily accessible, understandable, and searchable information on formulary coverage determinations, including information about cost-sharing. Further, our recommendations call on Congress to limit price increases for medications on the market for a considerable time and to act so that prices can be reduced for medications which have drastically increased in price since first coming on the market. Many of the MS DMTs have been on the market since the early-mid 1990's and should be long past patent and market exclusivity protections, yet they are still increasing in price. We believe that Congress should increase HHS regulatory oversight of drug classes that do not fit the expectations of a competitive market, like the MS DMT class, and authorize HHS to act to help lower prices for products whose prices do not reflect normal economic forces of supply and demand.

As the Society supports transparency in all areas across the pharmaceutical supply chain, we acknowledge that we have financial and collaborative relationships with the manufacturers of MS therapies. The Society works with all ethical companies, organizations and individuals that share our mission to end MS forever. However, we do not accept pharmaceutical support for our advocacy work. In 2017, the National Multiple Sclerosis Society received, \$8 million USD in support our work. This represented less than 4% of the organization's revenue in 2017. Additional detailed information on our financial relationships with the pharmaceutical sector can be found on the Society's website at - <https://www.nationalmssociety.org/About-the-Society/Financials/Sources-of-Support/Pharmaceutical-Support>.

Recently, the Society's activists brought a full slate of drug pricing legislation to the Hill as a part of our Public Policy Conference Hill Day. This slate of legislation would improve access to MS medications by removing barriers to generics, reining in price increases and capping out-of-

pocket costs in Medicare Part D. We urge Congress to closely examine these proposals as you engage in conversations around advancing a larger drug pricing package.

Reining in Price Increases

The CURE High Drug Prices Act (S.637), introduced by Sen. Richard Blumenthal, 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 Society has endorsed the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act, 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 Society also supports the Prescription Drug Sunshine, Transparency, Accountability and Reporting (STAR) Act, 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 these pieces of 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 in the MS market

The Society is concerned with anticompetitive practices that may be delaying the entry of lower

cost generics into the market and urges Congress to 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.

Cap Out-of-Pocket Costs in Medicare Part D

The Society supports the RxCAP Act (S.475) from Senator Ron Wyden, which would cap out-of-pocket costs in Medicare Part D by eliminating cost-sharing for beneficiaries once they reach catastrophic coverage. The price of MS DMTs has skyrocketed in the 16 years since passage of the Medicare Modernization Act of 2003, which created the Part D drug benefit. As a result, so has the out-of-pocket costs for beneficiaries living with MS because co-insurance is tied to the price of the prescription drug. Given the current market for MS DMTs and prescription drug prices overall, Congress should update Medicare policy to reflect the growing out-of-pocket costs for Medicare beneficiaries and pass the RxCAP Act.

As we noted above in the MS experience, one generic manufacturer cut its list price in half, but due to other incentives in the system, this move had little to no impact on the costs to the system or, importantly, on patients' out-of-pocket-costs. One beneficiary with MS shared that

while researching a Medicare Part D plan for 2019, he found that his annual out-of-pocket burden varied only by \$80 whether he chose the generic or brand- despite a more than \$50,000 difference in the drugs' respective list prices. Therefore, we urge Congress to discourage mixing generics on brand tiers to better incentivize the use of these therapies.

According to a recent report, the average coinsurance for the MS DMTs in Medicare Part D is 30 to 33%^{vii}. This could mean a monthly out-of-pocket cost burden of thousands of dollars for this treatment alone. Even the MS generic DMTs are often found on specialty tiers in Medicare, coming with co-insurance that offers no relief from overwhelming cost-share burdens. People with MS are frequently in the Part D catastrophic coverage phase in the first quarter of the year and their average annual out-of-pocket for their DMT alone is \$6,000^{viii} (See Appendix 3). Additional prescriptions to manage the symptoms of MS, rehabilitation and neurology services, periodic magnetic resonance imaging (MRI), laboratory tests, durable medical equipment needs, and other associated costs add to the ongoing financial burden of living with MS. The average one year direct medical costs per person with MS has been estimated as more than four times the amount compared to the general population.^{ix} We also urge you to explore policies that would allow out-of-pocket costs for those with significant health expenses to be spread more evenly throughout the year so that they are not a disincentive to receiving treatment. This includes deductibles, co-pays, and co-insurance amounts, which often are a barrier to people getting the treatment they need.

Recommendations for a legislative package targeting increasing drug prices.

Drawing from the Society's recommendations, we urge Congress to put together a legislative package that makes medications affordable for those who need them. Any legislative effort must ensure that medications, and the process for getting them, is simple, affordable, and transparent.

We urge Congressional leaders to advance proposals that:

- Increase transparency from manufacturers, insurers and pharmacy benefit managers and require justification from manufacturers on price increases.
- Advance proposals that allow the federal government to act if price increases are found to be excessive or unjust.
- Require health plans to provide processes for both approvals and exceptions to utilization management protocols.
- Ensure any reform of the rebate system makes certain that the rebate is passed directly on to the consumer, regardless of whether that rebate occurs in person at a pharmacy counter or via a specialty pharmacy.
- Examine issues surrounding patent and market exclusivity that may be helping to keep prescription drug costs high.
- Cap out-of-pocket costs in Medicare Part D by eliminating cost-sharing for beneficiaries once they reach catastrophic coverage.
- Address anticompetitive practices that may be delaying the entry of lower cost generics and biosimilars into the market.

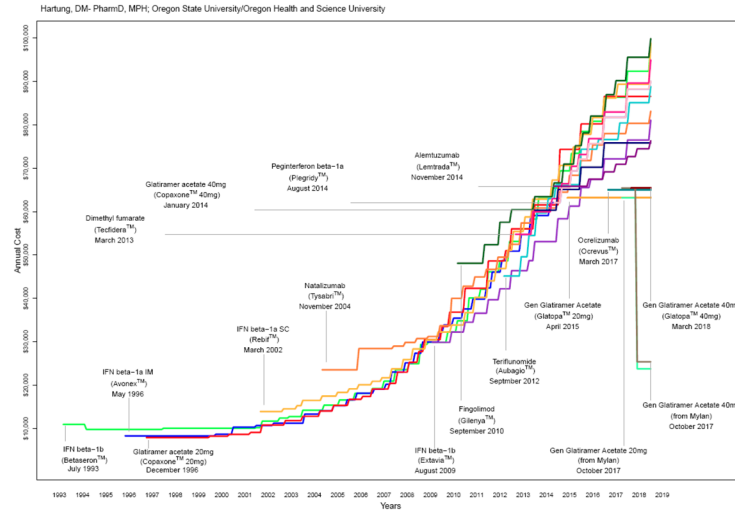
Thank you for the opportunity to provide the Society's perspective to inform your discussions around a larger drug pricing package. If you have any questions on our comments or need additional information, please contact Leslie Ritter at Leslie.Ritter@nmss.org or 202-408-1500.

Sincerely,

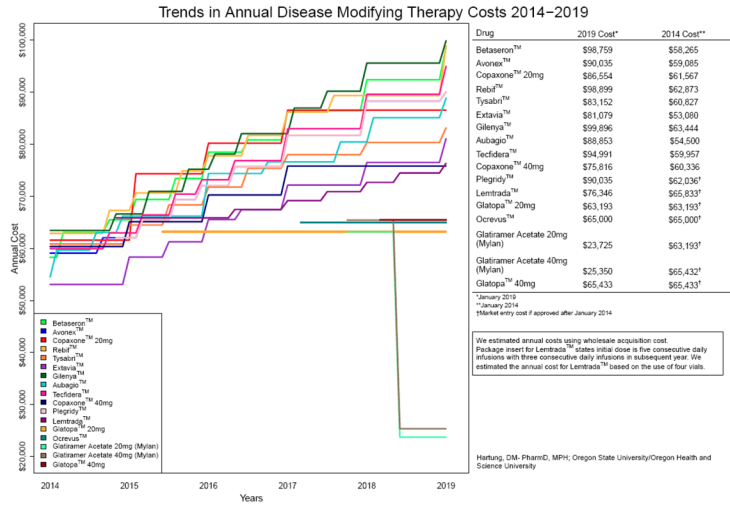
A handwritten signature in cursive script that reads "Bari Talente".

Bari Talente, Esq.
Executive Vice President of Advocacy
National MS Society

Appendix 1



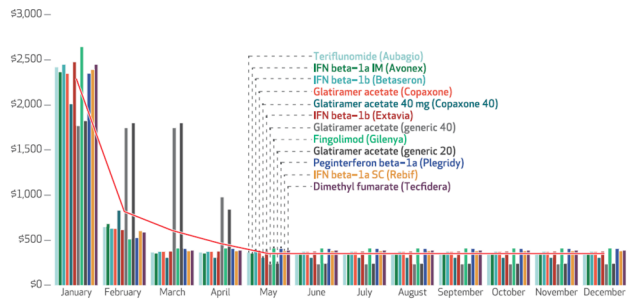
Appendix 2



Appendix 3

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.

Hartung DM. Trends In Coverage For Disease-Modifying Therapies For Multiple Sclerosis in Medicare Part D. Health Affairs. February 2019. doi:10.1377/hlthaff.2018.05357

¹ Mitchell T. Wallin, William J. Culpepper, Jonathan D. Campbell, Lorene M. Nelson, Annette Langer-Gould, Ruth Ann Marrie, Gary R. Cutter, Wendy E. Kaye, Laurie Wagner, Helen Tremlett, Stephen L. Buka, Piyameth Dilokthornsakul, Barbara Topol, Lie H. Chen, Nicholas G. LaRocca. *Neurology* Mar 2019, 92 (10) e1029-e1040; DOI: 10.1212/WNL.0000000000007035

² MS Coalition. The Use of Disease Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color. Accessed December 26, 2018.

³ Hartung DM. Economics and Cost-Effectiveness of Multiple Sclerosis Therapies in the USA. *Neurotherapeutics*. 2017 Oct;14(4):1018-1026. doi: 10.1007/s13311-017-0566-3.

<https://www.ncbi.nlm.nih.gov/pubmed/28812229>

⁴ Hernandez, Inmaculada et al. "The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Cost of Drugs." *Health Affairs*. Vol.38, No. 1.

<https://doi.org/10.1377/hlthaff.2018.05147>

⁵ National MS Society. Make MS Medications Accessible: Recommendations.

<https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Advocacy/Recommendations-Make-MS-Meds-Accessible.pdf>. Accessed February 27, 2019.

⁶ Lupkin, Sydney and HJancock, Jay. Trump Administration Salutes Parade of Generic Approvals, But Hundreds Aren't For Sale. <https://khn.org/news/trump-administration-salutes-parade-of-generic-drug-approvals-but-hundreds-arent-for-sale/>. February 7, 2019. (Accessed February 28).

⁷ Hartung DM. Trends In Coverage For Disease-Modifying Therapies For Multiple Sclerosis in Medicare Part D. *Health Affairs*. February 2019. doi:10.1377/hlthaff.2018.05357 .

⁸ Hartung DM. Trends In Coverage For Disease-Modifying Therapies For Multiple Sclerosis in Medicare Part D. *Health Affairs*. February 2019. doi:10.1377/hlthaff.2018.05357

⁹ Campbell JD et al, 'Burden of MS on direct, indirect costs and quality of life: National US Estimates', *Multiple Sclerosis and Related Disorders* (2013), [March 2014](#) Volume 3, Issue 2, Pages 227–236



Sound Policy. Quality Care.

May 1, 2019

RE: HR 2113, the "Prescription Drug Sunshine, Transparency, Accountability and Reporting (STAR) Act of 2019"

Dear Member of Congress:

The undersigned organizations of the Alliance of Specialty Medicine (the "Alliance") write to express our concern about provisions in H.R. 2113, the "Prescription Drug Sunshine, Transparency, Accountability and Reporting (STAR) Act of 2019" that could impact patient access to samples of drugs and devices. The Alliance represents more than 100,000 specialty physicians from thirteen specialty and subspecialty societies. The Alliance is deeply committed to improving access to specialty medical care through the advancement of sound health policy.

As you may know, the House Ways and Means Committee reported out the STAR Act on April 9, 2019. We are concerned that Section 3 of the legislation, entitled "Requirement for Manufacturers of Certain Drugs, Devices, Biologicals, and Medical Supplies to Report on Product Samples Provided to Certain Health Care Providers," will have a chilling effect on the provision of such samples to patients by manufacturers.

As specialists, we often treat patients in need of expensive medicines and devices. In recent years, out-of-pocket burdens have increased sharply for patients, all while utilization management restrictions have made it more difficult than ever for them to access needed treatments. Because of the delays imposed by insurers and pharmacy benefit managers, physicians often must rely on samples to begin treatment for conditions such as rheumatoid arthritis, for which time is of the essence. Insurers may take weeks or even months to approve treatment, but some conditions do not afford patients with that much time to wait.

The STAR Act would require manufacturers to report, as part of their other sunshine reporting requirements, the value of the samples they provided to physicians during the reporting period. Underlying this new requirement is the flawed premise that these samples are of value to the physician. Additionally, such a reporting requirement may lessen companies' willingness to provide samples. As noted above, with today's aggressive utilization restrictions, physicians must sometimes rely on these samples to begin treatment. If the Congress must move forward with

this new reporting requirement, we urge you to simultaneously reform insurers' ability to delay treatment through step therapy, prior authorization, and other utilization management tools.

On behalf of our patients in need of expensive treatments, we urge you not to advance the STAR Act until these concerns are addressed. Please do not hesitate to contact any of the undersigned organizations, should you have questions or require additional information.

Sincerely,

American College of Osteopathic Surgeons
American Gastroenterological Association
American Society for Dermatologic Surgery Association
American Society of Plastic Surgeons
American Society of Retina Specialists
American Society of Cataract and Refractive Surgery
American Urological Association
Coalition of State Rheumatology Organizations