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TUESDAY, MAY 21, 2019

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

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

Members present: Representatives Eshoo, Engel, Butterfield, Matsui, Sarbanes, Lujan, Schrader, Kennedy, Cardenas, Welch, Ruiz, Dingell, Kuster, Kelly, Barragan, Blunt Rochester, Burgess, 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. [Presiding] Good morning, everyone. The Subcommittee on Health will now come to order.

The chair now recognizes herself for 5 minutes for an opening statement.

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.

And the chair now recognizes the ranking member of the Subcommittee on Health, Dr. Burgess, for 5 minutes for his opening statement.

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 health care, 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.

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?

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 health care 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 balanced 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.

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

Ms. Schakowsky. I thank the gentleman for yielding. And I thank the chairwoman of this subcommittee for allowing me to wave onto 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 lifesaving 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.

And I yield back.

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 5 minutes for his opening statement.

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. 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 townhalls 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.

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

And the chair 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 health care, 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 reach witness for 5 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 5 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, PRESIDENT, COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS, ALLIANCE OF SPECIALTY MEDICINE; FREDERICK ISASI, EXECUTIVE DIRECTOR, FAMILIES USA; MARK MILLER, EXECUTIVE VICE PRESIDENT OF HEALTH CARE, ARNOLD VENTURES; AND DOUGLAS HOLTZ-EAKIN, PRESIDENT, AMERICAN ACTION FORUM

STATEMENT OF LISA JOLDERSMA

Ms. Joldersma. Okay. 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 health care 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:]

********** INSERT 1**********

Ms. Eshoo. We thank you, Ms. Joldersma.

And now, I would like to recognize Ms. Kristin Bass for 5 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, 4 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:]

********** INSERT 2**********

Ms. Eshoo. Thank you, Ms. Bass.

I now would like to recognize Dr. Feldman. You have 5 minutes for your testimony, and thank you again for being here today with us. You can proceed.

STATEMENT OF MADELAINE FELDMAN

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 payer.

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:]

********** INSERT 3**********

Ms. Eshoo. Thank you, Dr. Feldman.

I now would like to recognize Mr. Frederick Isasi for 5 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 need 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 health care. 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 three-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 three-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:]

********** INSERT 4**********

Ms. Eshoo. Thank you, Mr. Isasi.

I now would like to recognize Dr. Mark Miller for 5 minutes of his testimony, and thank you for being here. You may proceed.

STATEMENT OF MARK MILLER

Mr. 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 negotiation 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 resistence 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 Mr. Miller follows:]

********** INSERT 5**********

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 5 minutes of testimony.

STATEMENT OF DOUGLAS HOLTZ-EAKIN

Mr. 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 vigorously 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 Mr. Holtz-Eakin follows:]

********** INSERT 6**********

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 5 minutes to ask questions of our witnesses. And I will start by recognizing myself for 5 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. -- 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 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? 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 include 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 5 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 5 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. Okay.

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, increase 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 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.

Mr. 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 5 minutes.

Mr. Walden. Thank you, Madam Chair.

And I have got a question to Ms. Joldersma and Mr. Holtz-Eakin and Ms. 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. Okay. Dr. Holtz-Eakin?

Mr. 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. Okay. That is a good point. And I think I don't have too many people rushing me at townhalls 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?

Mr. 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. Okay. 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?

Mr. 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 5 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 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 increase 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 the 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 that 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 Pharmaceutical and could be purchased for free through an FDA program, right? Those are the kind of abuses we are talking about.

Ms. Matsui. Okay. Dr. Miller, do you agree?

Mr. 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. Okay. 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?

Mr. 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.

Mr. Miller. -- 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.

Mr. Miller. No.

Ms. Matsui. Okay. 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. Okay.

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?

Mr. 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. Okay.

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. Okay.

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

Ms. Matsui. Right. Okay.

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, 5 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?

Mr. 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 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?

Mr. 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. Lujan, for 5 minutes of

questioning.

Mr. Lujan. 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?

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

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

Mr. Lujan. 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 is discounts. There is rebates. There is 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. -- is it Isasi?

Mr. Isasi. Isasi.

Mr. Lujan. Isasi.

Mr. Isasi. Yes.

Mr. Lujan. 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. Lujan. 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. Lujan. -- 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. Lujan. 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, 5 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 is 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. Okay.

Dr. Feldman. -- but, conceptually, yes.

Mr. Griffith. Conceptually? Okay.

[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 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 5 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 for vetting 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 pay 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 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 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. Okay. Okay. 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. 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. Okay. 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.

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

Mr. 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. Okay. Fair enough.

Mr. 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. Cardenas.

Mr. Cardenas. 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 it 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. Cardenas. 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 decisionmaking 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. Cardenas. Okay. 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. Cardenas. Okay. I would like to point out that, on H.R. 2376, the Prescription Pricing for the People Act, it 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. Cardenas. Again, Madam Chair, I really appreciate the opportunity for us to cover this very important issue. And health care 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.

Now I 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 5 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 veteran 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?

Mr. 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?

Mr. 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 administering 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?

Mr. 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, 5 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 nine 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/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.

Mr. 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 studies 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?

Mr. 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 the 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; two, stock buybacks;

three, advertising; four, 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?

Mr. 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 --

Mr. Holtz-Eakin. That is a key part of it, yes.

Mr. Welch. That is right.

Mr. 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 heel these outrageous drug prices.

Mr. 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 5 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 entrepreneurs 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. Okay. 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 three-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 timeframe 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 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 payers 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?

Mr. 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.

Mr. Miller. Okay. 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. Okay.

Mr. Miller. That is a very important --

Ms. Kuster. And that is important.

Mr. Miller. Absolutely important.

Ms. Kuster. I concur.

Mr. 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. Okay?

Ms. Kuster. Okay.

Mr. Miller. Sorry about that.

Ms. Kuster. Got it.

Mr. 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?

Mr. 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 --

Ms. Kuster. Okay. Longevity or quality of life.

Mr. Miller. You could engage in other studies like hospitalization watch weighting, 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?

Mr. 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 --

Ms. Kuster. Right.

Mr. Miller. -- the drugs that do have competition? 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?

Mr. 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 --

Mr. Miller. Yes, and that is exactly where I was going. Just straight economics, a bigger volume, a 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 5 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. Okay.

Dr. Feldman. It is kind of a no-brainer, back to the patients.

Mr. Hudson. Okay. 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 undergoing 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. Barragan, is recognized for 5 minutes for her questioning.

Ms. Barragan. 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 two-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 because 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 60-day advance notification could have on the market, given the opportunity it creates for bulk purchasing, stockpiling, and --

Ms. Barragan. Okay. 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. Barragan. 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. Barragan. Okay. I am just going to take that as a yes, because it is just a yes or no.

Ms. Joldersma. Yes.

Ms. Barragan. I have other questions I want to get to.

Ms. Joldersma. The answer to that is yes.

Ms. Barragan. Thank you very much.

Ms. Joldersma. Yes.

Ms. Barragan. 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. Barragan. Okay. 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 good amendments, 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 60

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, is the chairlady likes to say, or rebates going, they say, well, they are going to 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?

Mr. Miller. Yes.

Mr. Carter. Okay. 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?

Mr. 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.

Mr. Miller. To the question that you are asking --

Mr. Carter. Thank you very much.

Mr. Miller. -- I think I would say that I would not do a prior notice.

Mr. Carter. You would not do a prior notice?

Mr. Miller. For the reasons that you are raising.

Mr. Carter. Thank you.

Mr. 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 5 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 more 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. -- Ms. Joldersma --

Ms. Joldersma. Call me Lisa.

Mr. Sarbanes. -- 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 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 an unfair 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, make 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?

Mr. 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?

Mr. Holtz-Eakin. I would suspect that at the outset, yes.

Mr. Gianforte. Okay. 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?

Mr. 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 it how it transpired.

Mr. Gianforte. Okay. 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?

Mr. Holtz-Eakin. I think they would be more costly to

provide and they would be more expensive.

Mr. Gianforte. Okay. Which is not the objective that we are shooting for.

Mr. Holtz-Eakin. Yes.

Mr. Gianforte. A question, if I could, for the whole panel. I support transparency across health care. 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 payer 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 health care. Are there other aspects of health care 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?

Mr. 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. Okay. 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 health care 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 5 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. Okay.

Mr. Holtz-Eakin. I think that is the chief concern.

And professional analysis of the data should be welcomed.

Mr. Guthrie. Okay. 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. Okay. 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?

Mr. Holtz-Eakin. You simply don't want to disclose the outcome of other people's negotiations, so that competitors can take advantage of it. So, that kind of transparency is actually counterproductive.

Mr. Guthrie. What would be an example of that?

Mr. 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, 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 5 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 10 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 10 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, okay.

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.

[The information follows:]

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

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.

[The Bills H.R. 2064, H.R. 2069, H.R. 2087, H.R. 2115, H.R. 2296, H.R. 2376, and H.R. 2757 follow:]

********** INSERT 7**********

[Whereupon, at 1:36 p.m., the subcommittee was adjourned.]