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EXAMINING THE DRUG SUPPLY CHAIN

WEDNESDAY, DECEMBER 13, 2017

House of Representatives

Subcommittee on Health

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 10:00 a.m., in Room 2123 Rayburn House Office Building, Hon. Michael Burgess [chairman of the subcommittee] presiding.

Members present: Representatives Burgess, Guthrie, Barton, Shimkus, Blackburn, Latta, Lance, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Collins, Carter, Walden(ex officio), Green, Schakowsky, Matsui, Castor, Sarbanes, Lujan, Schrader, Cardenas, Eshoo, DeGette, and Pallone (ex officio).

Staff present: Ray Baum, Staff Director; Mike Bloomquist, Deputy Staff Director; Adam Buckalew, Professional Staff Member, Health; Kelly Collins, Staff Assistant; Jordan Davis, Director

of Policy and External Affairs; Paul Eddatel, Chief Counsel, Health; Adam Fromm, Director of Outreach and Coalitions; Ali Fulling, Legislative Clerk, Oversight & Investigations, Digital Commerce and Consumer Protection; Jay Gulshen, Legislative Clerk, Health; James Paluskiewicz, Professional Staff, Health; Jennifer Sherman, Press Secretary; Danielle Steele, Counsel, Health; Hamlin Wade, Special Advisor, External Affairs; Jeff Carroll, Minority Staff Director; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Una Lee, Minority Senior Health Counsel; Rachel Pryor, Minority Senior Health Policy Advisor; Samantha Satchell, Minority Policy Analyst; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; Kimberlee Trzeciak, Minority Senior Health Policy Advisor; and C.J. Young, Minority Press Secretary.

Mr. Burgess. Subcommittee will come to order. I will recognize myself five minutes for an opening statement.

I want to thank everyone for being here today. We are going to talk about the U.S. drug supply and the complex way it is interwoven with multiple stakeholders involved in each step of the process.

Improving access to lifesaving treatments for consumers and patients should be a nonpartisan priority for every person in the room.

Two weeks ago, the Health Subcommittee held a hearing on the implementation of the 21st Century Cures Act. We heard testimonies from officials at the helm of the National Institute of Health and the Food and Drug Administration about the law's transformative impact on maintaining our nation's global leadership in biomedical innovation.

Built into that very concept is the expectation that innovative and breakthrough treatments will get developed, approved, and introduced into the therapeutic market to cure diseases or effectively manage chronic conditions so people lead healthier fuller lives.

Today's hearing will serve as an important educational opportunity to better understand the intricacies of our nation's drug supply chain.

To help us work toward that goal, we will hear from a diverse group of representatives -- 10, to be exact -- that represent many

facets of the supply chain process, and I do want to welcome each of you to the subcommittee this morning.

It is my hope that our discussion today is substantive and will be focused on the patients who are prescribed these medications because, at the end of the day, it is the patients who matter most in our conversation.

Practicing medicine, I cared most about prescribing for my patients a drug that was efficacious and safe, and really not wanting to think too much whether or not they would be able to fill their prescription at the pharmacy.

But now, the conversation has shifted to a complicated back and forth between doctors, patients, insurance companies, pharmacies about drug co-pays, prior authorizations, drug formularies, step therapies, amongst other things.

Over the last few years, we have also learned about acquisitions and mergers within the various drug supply chain as companies seek out increased integration of their operations with an eye towards more efficiencies.

Prescription drugs continue to play a vital role in the United States health care system. From significantly improving patients' lives to producing health care savings through fewer hospitalizations and medical procedures.

A patient's access to prescription drugs is a key health care issue for Americans and within that context now the debate is over affordability.

I will be frank with you. I expect disagreement this morning. But while there are legitimate differences of opinion, I recognize that every participant here this morning does aspire to the common goal of saving lives and alleviating human suffering.

And so out of these areas of disagreement, I hope to begin to identify areas of consensus so that we can begin delivering solutions to the problems that we do identify this morning.

These stakeholders here include pharmaceutical manufacturers that primarily research, develop, and produce brand name and generic drugs, biologic, and biosimilars. These medicines treat a spectrum of diseases and conditions from allergies, infections, hypertension to cancer, diabetes, and rheumatoid arthritis.

Next, the pharmaceutical wholesalers purchase these drugs and store them in regional distribution centers for delivery points that include our pharmacies, our supermarket retailers, hospitals, physician groups, and other health care providers.

Wholesalers also provide other ancillary services such as repackaging, consulting, inventory management, and patient discount programs.

Overall, pharmacy benefit managers manage prescription drug benefits on behalf of employer-sponsored health plans, health maintenance organizations, state and federal health programs including Medicare Part D, and Medicaid-managed care plans.

These managers impact the lives of 226 million insured Americans with most of them enrolled in private health plans. So they have a special role in the drug supply chain that includes determining payments and pricing for drugs, processing pharmacy drug claims, negotiating rebates and discounts from drug manufacturers, designing drug plan formularies, and operating mail order businesses.

Retail pharmacies have a large neighborhood presence representing large drug store chains, pharmacy departments in local supermarkets and big box retailers, and independent community pharmacies that occupy a unique and essential role within the drug supply chain.

Many drug stores contract with payers and pharmacy benefit managers to join health plan pharmacy networks. Some larger pharmacy chains have also entered into joint ventures with PBMs and insurers.

Finally, private health insurance plans are likely recognized by most Americans to have a direct impact on their ability to access prescription drugs largely due to the dictates of federal laws such as the Affordable Care Act on benefit requirements and out-of-pocket spending limits.

They employ utilization controls to manage cost such as multi-tier drug formularies, step therapies, prior authorizations for certain high-cost brand name medicines.

Again, I want to welcome all of our witnesses here today.

As you see, we have the entire panoply of the supply chain here before us.

I look forward to your testimony and we will recognize Mr. Green of Texas, the ranking member of the subcommittee, five minutes for an opening statement.

Mr. Green. Thank you, Mr. Chairman, and thank you to our witnesses for being here this morning.

Too many Americans face real barriers in accessing the medications they need. Annual drug spending in the U.S. is expected to reach more than $500 billion by 2018.

In 2015, the rise in prescription drug spending outpaced all other health care services, surpassing hospital care as well as physician and clinical services.

While new life changing and lifesaving therapies continue to enter the market each year, patients must be able to afford these treatments in order to benefit from these breakthroughs.

The issue of high drug costs is not a simple challenge with a simple solution. Instances of bad actors buying off -- buying up off-patent generic drugs with only one manufacturer astronomically jacking up the price has posed one type of challenge while breakthrough treatments capable of curing previously incurable disease but will have staggering price tags poses a different one.

These challenges are magnified by the proliferation of the high deductible plans which expose more and more consumers to the

full list of their medications.

We have a responsibility to explore the full spectrum of the supply chain to protect patients which are distinct for generic and brand name drugs and frustratingly complex.

The United States leads the world in biomedical development, but having 21st Century Cures means more -- much less if people cannot access because of the high prices.

It's important to also recognize that pharmaceutical companies sponsor the research that leads to these advances. We must find a workable solution that incentivizes competition in the pharmaceutical marketplace, reward value, and encourage the development of these affordable and high quality drugs.

We must also monitor steep prescription drug price increases when they rise, particularly when no additional research or development has occurred.

There are a number of policy proposals that are represented to address the issue of high prescription drug costs. Transparency and value-based approaches are some of the keys to market-based reforms that will lead to better prices, continued investment in research and development, and ensure that taxpayers receive a real return on their investment.

I want to note that in pursuit of the lower drug prices, Congress must be careful to avoid the policies that will diminish patient safety.

Filling out an application to the FDA is one step in what

can be a decades-long process to get from the lab table to the bedside.

Proposals that would lower FDA safety and effective standards effectively outsource FDA oversight to other countries, push the stage of three trials into the post-approval space are unlikely to translate into meaningful savings for customers and are likely to put patients at risk.

Making the FDA approval process as sophisticated and efficient as it can be is one thing, but rolling back patient protections in the name of lower drug prices is not an acceptable path.

We should be looking on how we pay for drugs and reward real value in the order of safety and meaningful, address the rising costs of prescription drugs.

Following our bipartisan work on the 21st Century Cures Act, our recent work to reauthorize the FDA user fee programs, it is my hope that we can advance bipartisan policies to address rising drug costs.

This problem demands a bipartisan and thoughtful process that includes a full spectrum of stakeholders. The American people expect us to work together to find answers and I believe we can do so.

I want to thank you for being here today and look forward to the day's construction -- discussion. And Mr. Chairman, I have one more minute. I'd like -- anybody would like to have a minute?

No? Okay.

I'd like to ask unanimous consent to place into the record, Mr. Chairman, a letter from AARP.

Mr. Burgess. Without objection, so ordered.

[The information follows:]

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

Mr. Burgess. I believe the chair actually already used your minute.

Does the gentleman yield back?

Mr. Green. I yield back.

Mr. Burgess. The chair thanks the gentleman.

Mr. Green. You owe me a minute sometime.

Mr. Burgess. Oh, next week.

The chair now recognizes the gentleman from Oregon, the chairman of the full committee, Mr. Walden, five minutes, please.

The Chairman. Dr. Burgess, thank you for holding this important discussion. I appreciate your comments and those of Mr. Green's about the full set of issues before us and the overwhelming desire by our constituents that we dive deep into the whole drug chain and figure out how we can put consumers first not only in developing new medicines and new innovation and the better pricing as well.

As Mr. Green mentioned, this community unanimously reauthorized and the president signed into law the FDA Modernization Act. This committee last Congress championed the 21st Century Cures Act with Congresswoman DeGette and Congressman Upton at the -- at the helm of that, celebrating its one-year anniversary.

But, clearly, there is more to be done, and as chairman of the committee, I felt it was really important that we hear from the entire sector from the development of new drugs to the final

end place where we buy them, we consume them, we use them.

For more than four years, members of this committee have listened to patients. We have listened to providers. We have listened to payers. You know, the federal government is one of the biggest payers in this effort and we are all about accelerating the discovery, development, and delivery of innovative drugs and medical devices. That was a lot of what was behind passage and implementation of 21st Century Cures.

We have heard from Dr. Gottlieb and we have heard from the head of NIH about the progress they are making already with the legislation we have enacted.

Today, though, we want to get a more full appreciation for the drug supply chain and I think you all would have to acknowledge its complexity, and we want to ask questions instead of jumping to conclusions.

I encourage members on both sides of the aisle to dismiss, to a certain extent, any of your preconceived notions and let's focus on how each stage of the drug supply chain impacts access, delivery, and delivery of drugs and, of course, costs.

We need to listen to the complex journey from molecular discoveries to patient deliveries that one does of medicine takes along the way and we all need to learn about the impact each participant in the supply chain has in the ultimate cost to patients.

And we have no shortage of witnesses today to help us gain

a better understanding and we appreciate you all being here. We have representatives from the manufacturers, the distributors, the payers, the pharmacists, the providers, and the patients.

And I promise today's hearing will be an informative discussion and, I dare say, not the last as we move forward to better educate ourselves and then look at the public policy changes that need to be made to move America forward in these areas.

So I thank you all for your participation. I think you'll find the committee is very interested in every step of this process and with that, Mr. Chairman, I would yield the balance of my time to the chairwoman of the Telecommunications Subcommittee, the gentlelady from Tennessee, Mrs. Blackburn.

Mrs. Blackburn. Thank you, Mr. Chairman, and I thank Chairman Burgess for the hearing and to each of you. We know it is the busy time of year. We are appreciative that you are here before us and, as Chairman Burgess said, we have the entire panoply of the system.

And most of my constituents will tell you they understand how their doctor, their insurance plan, and the pharmacy play into the prescriptions they receive.

They do not have the understanding, as Chairman Walden said, of the complex system that goes from research to the time they pick up that prescription and we are so interested in looking at this access, delivery, and cost issue within this entire spectrum.

It does affect health care delivery, and being from middle Tennessee, you know, we have a lot of health care in my congressional district and this is an issue -- this entire supply chain is an issue that we discuss often.

And we are excited about some of the new innovations that are coming your way with technology. So that will enter into our discussion today. Thank you for your presence and, Mr. Chairman, I will yield back to you the balance of the time and if there is another member who would like to claim that time.

Yield back.

Mr. Burgess. Seeing none, the gentlelady yields back. The chair thanks the gentlelady.

The chair recognizes the gentleman from New Jersey, the ranking member of the full committee, Mr. Pallone, five minutes for an opening statement, please.

Mr. Pallone. Thank you, Mr. Chairman.

This committee has spent considerable time examining the drug supply chain both through the Drug Quality Security Act and, more recently, through the 21st Century Cures, and today is actually the one-year anniversary of when President Obama signed 21st Century Cures.

Both of these legislative efforts were the result of considerable oversight and discussion as to how the drug supply chain worked, how it could be better secure and how we could encourage efficiencies to improve drug development.

And these bipartisan efforts have helped to address the post-market security of products and the regulatory review process. But neither effort focused on how prescription drugs move through the supply chain through the financial lens.

Prescription drug prices are higher than ever, and while the dramatic rise in prescription spending has come -- has come down a little, we know addressing drug costs continues to be a top priority for many American families.

The costs of prescriptions have forced so many American families to make tough choices. For some, it is a choice of filling their prescriptions or filling their tank of gas to get to work.

For others, they are leaving prescriptions unfulfilled, skipping doses, or cutting pill in half so they don't have to purchase their prescriptions that often, and none of these choices is acceptable.

Today, prescription drug spending represents about 14 percent of overall health care spending. It is no wonder that six in 10 Americans have said that lowering prescription drug costs should be a top priority for Congress and this administration and I am pleased that there has been such bipartisan interest in this topic both during consideration of the FDA Reauthorization Act and at recent member briefings, and I do believe that making prescription drugs more affordable for the average consumer is an issue that we all care about and can

support.

And that is why today's hearing is so important. This morning, we have the opportunity to better understand the drug supply chain and the often-complicated ways that drugs move through the supply chain to the patient.

As my colleagues have pointed out, we will hear from each of our witnesses about the role they play regarding drug delivery, the impact they have on the cost of drugs, and the value they bring to patients and consumers, and I hope and expect that today's hearing will serve as a foundation for future hearings on policy solutions that may help reduce prescription drug costs in our health care system.

While understanding how the supply chain works is critically important to this committee, I also would urge Chairman Walden to schedule a legislative hearing in the early part of next year to examine specific proposals to address the high prices of prescription drugs.

Our constituents want and expect us to take concrete action to address this growing problem. And the problems we are seeing in the supply chain cannot be addressed through one policy solution and all of our witnesses have a role to play in these solutions.

It is long past time for Congress to take a serious look at all solutions that will help American families to afford the medications they depend on and I look forward to further

bipartisan discussion on what that broad range of policy solutions may look like.

And I want to thank each of our witnesses for being here and look forward to learning more about your role in the drug supply chain and how we can improve access to drugs for patients in the future, and I would like to yield the remainder of my time to Congressman Lujan from New Mexico.

Mr. Lujan. Thank you, Mr. Pallone, and Mr. Chairman, thank you for this important hearing.

There is so much going on in the health care arena right now -- CHIP, community health centers, National Health Services Corps, special diabetes program, Medicare extenders, Puerto Rico's Medicaid program -- items that all need attention and need it now.

With all these priorities competing for attention, it would be easy to lose sight of which should be our guiding star -- finding ways to balance innovation and affordability.

We depend on different approaches to give us more time with the ones we love, whether it is a brother who lives with diabetes or a mother with a new cancer diagnosis. Our lives have been improved by many tools including pharmaceutical therapies.

To realize the promise of these innovations, we must ensure patients can access the cures that manufacturers spend so much energy and effort developing. It doesn't help to hold out hope for a cure if there is no hope that regular people can afford it.

It is unrealistic to think the answer to making prescription drugs affordable for everyone is ending the 340B program or allowing for off-label communication.

We must all look holistically at what affordable accessible health care means. I am also real interested, Mr. Chairman -- on a bit of a sidebar here -- because we have everyone in the room to work with you and make sure that we are pushing pain management treatments that are nonaddictive.

This is critically important. We have a huge problem facing our country and we need to work together to get that done. We also need serious treatments from everyone here to make sure that we are addressing the cravings that come from opioids and alcohol.

Simply having medications that make someone sick if they use is not going to stop the craving and not going to stop use.

I am hopeful this is the first of many hearings examining how we ensure affordable accessible prescription drugs and I look forward to working with everyone here on real solutions.

Thank you, Mr. Chairman.

Mr. Burgess. Chair thanks the gentleman. Gentleman yields back.

This will conclude member opening statements and the chair would remind members that pursuant to committee rules, all members' opening statements will be made part of the record.

And once again, we do want to thank our witnesses for being here today, taking time to testify before the subcommittee. Each

witness is going to have an opportunity to give a three-minute opening statement and that will be followed by questions from members.

So today, in order, we are going to hear from Lori Reilly, the executive vice president for policy, research, and membership at the Pharmaceutical Research and Manufacturers Association of America; Tom DiLenge, president, advocacy, law, and public policy, Biotechnology Innovation Organization; Chip Davis, president and CEO for the Association for Accessible Medicines; Elizabeth Gallenagh, senior vice president, government affairs and general counsel, Health Care Distribution Alliance; Mark Merritt, president and CEO for the Pharmaceutical Care Management Association; Matt Eyles, the senior executive vice president and chief operating officer for policy and regulatory affairs at America's Health Insurance Plans; Tom Nickels, the executive vice president for government relations and public policy from the American Hospital Association; Gerald Harmon, M.D., chairman of the Board of Trustees of the American Medical Association; Douglas Hoey, the CEO of the National Community Pharmacists Association; and David Mitchell, the founder and president of Patients for Affordable Drugs.

We do appreciate you all being here this morning. Ms. Reilly, you are now recognized for three minutes to give a summary of your opening statement.

STATEMENTS OF LORI REILLY, EXECUTIVE VICE PRESIDENT FOR POLICY, RESEARCH, AND MEMBERSHIP, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; TOM DILENGE, PRESIDENT, ADVOCACY, LAW, AND PUBLIC POLICY, BIOTECHNOLOGY INNOVATION ORGANIZATION; CHIP DAVIS, PRESIDENT AND CEO, ASSOCIATION FOR ACCESSIBLE MEDICINES; ELIZABETH GALLENAGH, SENIOR VICE PRESIDENT, GOVERNMENTAL AFFAIRS AND GENERAL COUNSEL, HEALTHCARE DISTRIBUTION ALLIANCE; MARK MERRITT, PRESIDENT AND CEO, PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION; MATT EYLES, SENIOR EXECUTIVE VICE PRESIDENT AND CHIEF OPERATING OFFICER FOR POLICY AND REGULATORY AFFAIRS, AMERICA'S HEALTH INSURANCE PLANS; TOM NICKLES, EXECUTIVE VICE PRESIDENT FOR GOVERNMENT RELATIONS AND PUBLIC POLICY, AMERICAN HOSPITAL ASSOCIATION; GERALD HARMON, M.D., CHAIR, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION; B. DOUGLAS HOEY, CEO, NATIONAL COMMUNITY PHARMACISTS ASSOCIATION; DAVID MITCHELL, FOUNDER AND PRESIDENT, PATIENTS FOR AFFORDABLE DRUGS

STATEMENT OF MS. REILLY

Ms. Reilly. Thank you, Chairman Burgess, Chairman Walden, and Ranking Members Green and Pallone.

My name is Lori Reilly and I am the executive vice president for policy and research at PhRMA and it is my pleasure to be here today.

Over the past 20 years, more than 500 new medicines have been approved to come to market to treat some our nation's most

challenging and costly conditions. In the midst of this progress, prescription drug medicine growth is growing slowly.

Just last week, CMS released new data to show that prescription drug spending in 2016 grew at 1.3 percent. That was lower than any other category of spending.

To put that into context, hospital spending growth grew at three and a half times that amount. In the last seven out of 10 years, prescription drug spending growth has been below national spending growth.

Today, medicines consume about 14 percent of the health care dollar and many assume, when they see that number, that all or substantially all of that flows back to the brand name manufacturers.

However, less than half of that, or 47 percent, is attributable to brand name drug spending. The remainder, 23 percent, goes to generic firms and 31 percent goes to the supply chain.

Going forward over the next decade, medicines are projected to remain 14 percent of the health care dollar and many question how is that possible knowing all of the new innovations that are coming to market in the coming years.

And there is a few reasons for that, the first being that over $100 billion worth of medicines will be going off patent over the next five years and that will put cost pressure as new generics and biosimilars enter the marketplace.

The second is the fact that there is significant cost constraint in the prescription drug market as three large pharmacy benefit managers buy on behalf of over 70 percent of all prescriptions in this country.

These PBMs exert significant cost pressure to keep prices and spending in check. One of the ways they do that is by extracting significant discounts and rebates from pharmaceutical manufacturers.

In fact, discounters and rebates increased 40 percent over the last four years and now total over $100 billion a year.

Unfortunately, oftentimes those discounts and rebates are captured by intermediaries and don't make their way back to patients. This problem has become more acute over time as we've seen a dramatic increase in the number of patients that today have a deductible for their medicine.

So take, for example, a patient who takes an insulin product with a list price of $400 and that medicine carries a discount of about 65 percent.

A patient with a deductible today goes to the pharmacy counter and will be asked to pay $400 for that medicine despite the fact that the insurance company is paying nothing while earning $239 on every sale.

Given the rapid rise in deductibles, this must change. Insurance companies and PBMs must be pushing these discounts and rebates back to patients to lower their out-of-pocket spending.

With that, my time is up and I look forward to questions today. Thank you.

[The prepared statement of Ms. Reilly follows:]

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

Mr. Burgess. Chair thanks the gentlelady.

The chair recognizes Mr. DiLenge for five -- three minutes for your opening statement, please.

STATEMENT OF MR. DILENGE

Mr. DiLenge. Thank you, Mr. Chairman, Ranking Member Green, Mr. Walden, Ranking Member Pallone.

Thank you for the opportunity to testify today about how to sustain the biomedical innovation that is bringing home and cures to the patients who need them the most.

I am Tom DiLenge. I am vice president for Advocacy, Law, and Public Policy. While BIO represents the entire biomedical ecosystem -- universities, startups, investors, large drug companies -- the vast majority of our members -- about 80 percent -- are small companies with no marketed products and no profits.

They rely heavily on outside investors and partners to fund the cutting-edge research that they do and it is these small companies that are leading 70 percent of the nearly 6,000 clinical trials that are underway today.

Another key fact -- almost 60 percent of all new medicines are innovated right here in America, more than the rest of the world combined.

We lead because America has a public policy environment that incentivizes the investment and innovation and this committee, on a bipartisan basis, has led the way on that for decades.

This is critical because while NIH funds really important research, it is the private sector that spends $150 billion every year in applied R&D to bring products from research to the

marketplace.

This investment provides more than 1.7 million American jobs and we are growing jobs at twice the rate of the national average.

More importantly, we are having an awe-inspiring record of public health accomplishment, transforming HIV/AIDS from a death sentence to a manageable condition, increasing cancer survival in children to 83 percent today, and hundreds of other new medicines for once-debilitating diseases.

We are saving millions of lives. We are saving trillions of dollars in the process. We are making discoveries that were once unimaginable -- immuno oncology, in which we activate the body's own immune system to attack cancer -- gene therapy, which we can repair defective genes or use the patient's own cells to make a medicine tailored for that patient.

Precision and personalized medicine is here. Thus, to understand the pricing dynamics of our market, it is important to consider a couple of facts.

Ninety percent of clinical programs fail. Ninety-two percent of our companies are unprofitable. Ten to 15 years and $2.6 billion, the average time and cost to bring a medicine through approval, that number has doubled since 2003, and nearly 90 percent of prescriptions today in America are for cheap generic copies of once-branded drugs.

Thus, it is the revenues from the 10 percent of successful clinical programs that have to be sufficient to incentivize this

entire wonderful innovation ecosystem.

We have repeatedly seen biotech investment jeopardized by the spectre of government price setting. The small companies are the proverbial canaries in the coal mine when it comes to that.

We also recognize that patients, even those with insurance cannot afford many of these lifesaving miracles. We share this commitment to solving the problem. BIO has joined the coalition with a lot of people at the table and others -- insurers, PBMs, patient groups -- to come up with market-based ways to lower drug costs. We'd love to work with this committee on doing that.

Reward volume, reward value, not volume, inject more competition, empower patients. So with Congress' continued support, we are going to put more Americans to work, we are going to lower health care costs, and we are going to heal the world in the process.

Thank you, and I am happy to answer any questions you have.

[The prepared statement of Mr. DiLenge follows:]

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

Mr. Burgess. The chair thanks the gentleman.

Mr. Davis, you're recognized for three minutes for an opening statement, please. And your microphone.

STATEMENT OF MR. DAVIS

Mr. Davis. Sorry about that.

Good morning, Chairman Burgess, Ranking Member Green, Chairman Walden, and Ranking Member Pallone, members of the subcommittee. Thank you for the invitation and opportunity to testify today.

As stated, my name is Chip Davis. I am the president and CEO of the Association for Accessible Medicines. We are the leading trade association for manufacturers of FDA-approved generic and biosimilar medicines.

Our members manufacture more than 61 billion doses of medication at over 150 facilities here in the United States on an annual basis.

As you know, Americans across the political spectrum are calling for action to lower the cost of prescription drugs, making it a foremost health priority, which is why we are all here today.

Despite a lot of well-intentioned rhetoric, over the last year the problem of high drug prices by and large continues unabated.

Last month, the nominee for secretary of health and human services, Alex Azar, said that drug prices are too high and must be lowered. FDA Commissioner Scott Gottlieb recently characterized drug costs as a public health concern.

Congress now has the opportunity to take meaningful action

to lower the cost of prescription drugs. Over 30 years ago, through Hatch-Waxman, Congress sought to strike a careful balance between encouraging innovation in drug development, which we all support, and accelerating access to lower cost generic alternatives for patients.

Unfortunately, the patient access side of Hatch-Waxman is absolutely unequivocally in jeopardy as we speak. This is due to a combination of factors including a failure of policy to keep pace with a changing pharmaceutical market, a growing market and balance between generic buyers and sellers, and an increase in anti-competitive business practices deployed by certain brand companies who have been increasing these activities so much in recent years that recently Commissioner Gottlieb counselled the industry last month, and I am quoting, "to end the shenanigans," during his formal remarks at an FTC hearing.

The generic industry operates in a rapidly changing often-commoditized marketplace with significant and unique pressures that distinguish it from the monopolized brands sector.

As a result, generics continue to experience accelerated price deflation. In fact, it is ironic in many ways that at a time when the overall costs of prescription drugs is such a high profile issue that generic medicines are currently experiencing an unprecedented degree of price deflation, which impacts the national health estimate figures that were mentioned previously.

In fact, according to IQVIA, which is formerly Quintiles IMS,

for 16 consecutive months generic drugs prices have declined.

Our members operate in a consolidated market where three large buying consortiums of wholesalers and retail pharmacies now control 90 percent of the retail generic market.

Portfolio decisions related to what medicines they will continue to manufacture, announcing pending closures of manufacturing facilities, and significant anticipated job layoffs in the generic sector are all things that we are currently experiencing.

Should the market not evolve itself and should Congress fail to take action, these trends will continue, threatening uninterrupted patient access to the needed generic medicines. When generics and biosimilars are available, competition increases and patients benefit from access to safe and affordable treatment options.

We have provided this committee with recommendations that Congress could take today to increase competition and increase patient access.

I thank you again for the opportunity to testify and look forward to your questions today.

Thank you.

[The prepared statement of Mr. Davis follows:]

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

Mr. Burgess. The chair thanks the gentleman.

Ms. Gallenagh, you're recognized for three minutes, please, to summarize your opening statement.

STATEMENT OF MS. GALLENAGH

Ms. Gallenagh. Good morning, Chairman Burgess, Ranking Member Green, Chairman Walden, and Ranking Member Pallone and members of the subcommittee.

Thank you for the chance to participate in today's hearing. Health Care Distribution Alliance represents 35 primary pharmaceutical distributors, the vital link between the nation's pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, and other providers nationwide.

Their expertise streamlines the supply chain to ensure safety and efficiency while achieving cost savings for our nation's health care system.

Without HDA members, pharmacies and providers would have to carry weeks of inventory and undertake the time consuming process of placing daily individual orders with every manufacturer.

By working with full line distributors, pharmacies can maintain just in time inventories, saving them the expense and staff necessary to carry extensive inventories or manage large storage facilities.

While our members are logistics experts, pharmaceutical distribution has evolved over the last decade. This is no longer an industry focussed solely on moving products from point A to point B.

In exchange for a variety of distribution and logistics

services that primary distributors provide to manufacturers, they charge bona fide service fees.

These fees, which are not passed on to the customer, represent a fair market value for services -- itemized services actually performed on behalf of the manufacturer that the manufacturer would have to perform otherwise for themselves.

Our industry is a very high-volume yet low profit margin industry with the industry margin just over 1 percent on average in 2016.

Moreover, in a recent 2017 study, the Berkeley Research Group concluded the pharmaceutical wholesale distributor profit on overall branded drug costs was just under 1 percent.

Traditional pharmaceutical wholesale distributors purchase pharmaceuticals from manufacturers based on the wholesale acquisition cost, or WAC -- a publicly available figure reported for each product by the manufacturer.

WAC represents the manufacturer's list price and does not include rebates, prompt payment or other adjustments in price resulting from downstream or proprietary negotiation.

Manufacturers set the WAC prices for their products and distributors are not privy to how that pricing decisions are made.

Primary distributors typically sell branded drugs to downstream customers based on those WACs established solely by those manufacturers.

Distributors might also sell generic drugs to downstream

customers based on WACs or they may be based in part on response to the market, which includes competing generic drugs.

In other words, wholesale distributors do not control the price of pharmaceuticals but rather the price of pharmaceuticals is dictated by list prices determined by their manufacturers and other market force including the WACs of generic drugs that compete with given generic drug products.

HDA distributor members add value within the supply chain and have minimal impact on the overall cost of drugs. Ultimately, the services provided by our members result in benefits to patients and consumers and have made the U.S. pharmaceutical supply chain one of the safest and most efficient in the world.

Thank you. I would be happy to answer any question.

[The prepared statement of Ms. Gallenagh follows:]

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

744 Mr. Burgess. The chair thanks the gentlelady.

745 The chair recognizes Mr. Merritt for three minutes.

746 Summarize your opening statement, please.

STATEMENT OF MR. MERRITT

Mr. Merritt. Thank you, Mr. Chairman, and members of the committee.

Pharmacy benefit managers are the industry that employers and others hire to negotiate discounts and reduce prescription drug costs.

We see too many reasons by drug pricing has become a focal point in recent years. First, as drug makers shift from making blockbuster drugs like Lipitor, which cost maybe $3 a day, to making much more expensive products like Sovaldi -- a great product but it costs $1,000 a day.

Second, in the face of rising medical costs, more health plans are raising deductibles in order to keep premiums as low as possible.

This means for the first time some patients who had grown accustomed to paying $2,500 for a $500 drug are now seeing how expensive some of these drugs really are.

It's important to note that while the subject of today's hearing -- the drug supply chain -- is important and worthy to be discussed, it has nothing to do with why drug companies raise prices.

As always, pricing power and pricing decisions in any industry are driven by supply and demand and competition, not supply chains.

Prices are set exclusively by drug companies with zero input from anybody else in the supply chain including PBMs. Further, supply chains are a routine part of how consumers access products in the marketplace today. Every industry uses them. They are not unique to health care or prescription drugs.

In the simplest terms, the prescription drug marketplace is like any other -- a market of sellers and buyers. Drug makers are the sellers and, like all sellers, set prices according to whatever they think the market will bear.

Likewise, buyers who we represent, want to pay as little as possible. These are the employers, unions, health plans, and government programs that hire PBMs to negotiate rebates, discounts, and other price concessions from drug makers and drug stores.

These savings are used to reduce premiums, cost sharing, and other expenses. And some drug makers have tried to blame their own pricing decisions on the supply chain but this makes little sense.

For example, Mylan used this excuse when they raised EpiPen prices 400 percent at a time when supply chain costs were relatively flat. Sovaldi had a launch price of $84,000 even though it involved no rebates at all.

Some of the highest prices are in Medicare Part B, as in boy, where payments are set by the federal government without negotiations from PBMs or rebates.

In any case, almost half of the RFPs large employers use when hiring PBMs now require PBMs to pass through 100 percent of the rebates and about 90 percent of rebates are passed through overall in the marketplace.

While PBMs are proud that, according to CMS, drug trend only grew 1 percent last year despite rising list prices, we welcome manufacturers to offer alternatives to rebates as a way to get discounts.

Payers -- our clients -- just want the lowest net cost wherever they can get them.

Thank you for having me here today and I look forward to answering any questions you may have.

[The prepared statement of Mr. Merritt follows:]

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

Mr. Burgess. The chair thanks the gentleman.

Mr. Eyles, you are recognized for three minutes to summarize your opening statement, please.

STATEMENT OF MR. EYLES

Mr. Eyles. Good morning, Mr. Chairman, members of the subcommittee. I am Matt Eyles, chief operating officer of America's Health Insurance Plans, the national association whose members provide coverage for health care.

I appreciate the opportunity to testify on behalf of our members this morning and my testimony focuses really on three topics.

First, the consequences of out of control drug prices, both excessive launch prices supersized price increases, and the impact they have on consumers and the factors pointing to a broken pharmaceutical market.

Second, any discussion of drug prices and the supply chain must begin with the list price, set solely by drugs companies, and which act as the starting point for plans and PBMs to negotiate lower prices for consumers.

Third, AHIP's policy solutions to promote more affordable drug prices.

Out of control prices are the result of drug companies taking advantage of a market skewed in their favour. Too often, this skewed market has granted economic power to drug companies through price-dictating monopolies.

For example, with no generic competitors, the list price of popular insulin increased almost 300 percent since 2007 while the

CPI rose only about 15 percent.

If you remember one message this morning, it is that the entire pricing process is driven off the list price of a branded drug, solely determined by the drug company, not anyone else, and the end result is everyone pays more.

AHIP's members negotiate with providers and drug manufacturers to cover high-quality treatments and services at the most affordable prices. Looking at the drug supply chain, we must keep two points in mind.

First, health insurers offer comprehensive coverage under the pharmacy benefit for prescriptions delivered through retail pharmacies. This represents about 70 percent of drug spending.

Second, plans provide coverage under the medical benefit for physician-administered drugs delivered in outpatient and inpatient settings. This covers about 30 percent of spending.

Our discussion today focusses largely on that first bucket covered under the pharmacy benefit but plans provide coverage for both types and therefore have a unique perspective into the broader drug market.

A 2017 AHIP analysis found that 22 cents of every dollar spent on insurance premiums goes towards prescription drugs. This is a conservative estimate by excluding hospital spending on drugs.

But here's the bottom line. The 22 percent outpaces spending on physicians, inpatient hospital, and outpatient hospital services. So when drug prices go up, insurance premiums

go up and that's an economic reality.

For the committee's consideration, we included recommendations in our written statement with three categories of policy solutions -- first, delivering real competition through generics and biosimilars; second, ensuring open and honest pricing with greater transparency into how drug prices are set and when prices increase excessively; and third, delivering value to patients by expanding efforts to link drug prices to clinical value and outcomes.

Thank you for the opportunity this morning. We look forward to working with the committee to find solutions to affordable medications.

[The prepared statement of Mr. Eyles follows:]

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

Mr. Burgess. Thank you, Mr. Eyles.

Mr. Nickles, you're recognized for three minutes, please, to summarize your opening statement.

STATEMENT OF MR. NICKLES

Mr. Nickles. Mr. Chairman, my name is Tom Nickles. I am executive vice president of the American Hospitals Association. I appreciate the opportunity to be here today on behalf of the --

The Chairman. Your mic's not on.

Mr. Nickles. Thank you very much -- our 5,000 hospital and health system members. I would like to briefly address three issues -- the drug supply chain, drug pricing, and the 340B program.

America's hospitals rely on innovative drug therapies to save lives every day. Modern pharmaceuticals play a critical role in getting patients healthy and helping them maintain that health.

The drug supply chain is, as Chairman Walden said, complex with the number of steps between the development and delivery of a drug. Hospitals primarily intersect with the drug supply chain in their role as purchasers and dispensers of pharmaceuticals.

At the beginning of the chain, our academic medical center members play a leading role in both the development and testing of new drug therapies.

Studies show that these efforts discover drugs that have a disproportionately important clinical effect in therapies that can be used for widespread public health concerns. Down the

supply chain all hospitals are major purchasers of drugs used in clinical settings.

Hospitals work with manufacturers and group purchasing organizations to negotiate the best prices for the drugs they use and reduce administrative expenses.

Most hospitals do retain some direct contracting with drug manufacturers primarily for branded therapies for which there is no competition.

Once a hospital acquires a drug and manages its supply in hospital-based pharmacies who work with prescribing clinicians to develop and manage the formulary following standards that take into account evidence-based clinical, ethical, legal, and other factors.

Pharmacists also manage the dispensing of medications to the appropriate clinical staff who then deliver the drug to the patient.

In terms of pricing, spending on pharmaceuticals, as has been noted, has increased dramatically over the last several years and the primary driver is higher prices.

We see both higher launch prices for new drugs and increases in prices for existing drugs. Limited competition and drug shortages have also facilitated this growth.

Whether GPO or a hospital is negotiating, the starting price, as has been pointed out, is the price set by the manufacturer. The ability of the GPO or hospital to obtain a discount off the

price largely has to do with volume and whether and how much competition exists. In instances where no competition exists such as for many of the new high-cost specialty drugs, large discounts are not available.

The burden of these high prices falls on all purchasers including patients and the providers who treat them. For example, hospitals frequently see patients show up in the emergency department or return for follow-up care sicker than when they left because they were unable to afford their drugs.

Hospitals as drug purchasers also face significant resource constraints as spending on drugs increase. Hospitals must make tradeoffs between investments in staff, technology, and facilities upgrade and paying more for drugs.

Lastly, I want to mention the 340B program which permits safety net hospitals to care for communities with a high number of low-income and uninsured to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

The 340B program enables these hospitals to serve their communities by reinvesting savings from reduced drug prices into programs that benefit vulnerable patients at no additional cost.

Thank you very much for the opportunity to testify.

[The prepared statement of Mr. Nickles follows:]

**********INSERT 8**********

Mr. Burgess. Thank you, Mr. Nickles.

Dr. Harmon, you're recognized for three minutes to summarize your opening statement, please.

STATEMENT OF DR. HARMON

Dr. Harmon. Thank you, Chairman Burgess, Ranking Member Green, distinguished members of the subcommittee.

I am Gerry Harmon. I am a practising family physician from Parleys Island, South Carolina, and chairman of the AMA Board of Trustees.

I think we can all agree that our goal is to ensure patients have access to the right medication at the right time. I want to speak to the physician's role of prescribing the most appropriate treatment and the challenges my patients and I face.

Affordability in price can indeed be a major barrier but so are the various administrative hoops that we have to jump through when prescribing medications. Such hoops includes things such as prior authorizations, frequently changing drug formularies, step therapy, nonstandardized forms, all put in place by insurance companies in an attempt to manage costs.

These barriers usually delay treatment for my patients and, clearly, take time away from patient care. As an example, in the few days I've been away from my practice on a trip such as today I received an email from a long-time patient who has recently changed his insurance coverage.

His blood pressure medicine that he's been stable on for years now is not on the new formulary under his new plan and he's down to his last 30 days of therapy. I am going to have to call

his pharmacy benefit managers -- PBM -- request a form and a fax number. Fill out the form with some data points and fax it back.

Eventually, I hope to get some ideas from the insurance company and/or the PBM about what types of different medications I might consider or steps I might follow in order to prescribe patients -- my patient's medicine.

I cannot do this in a standard form or electronically via email. My patient, meanwhile, is at risk for running out of medications or changing to a less effective therapy. Clearly, that's going to endanger his health.

He could end up going to the emergency room or having a serious illness such as a heart attack or a stroke, which adds enormous cost to the entire health care system.

Such efforts to maintain cost and value in such an otherwise stable patient are, clearly, misdirected.

In another venue, doctors who administer biologic medications to treat certain cancer, rheumatoid arthritis patients face even more costs and challenges than a primary care doctor like myself.

Small community practices in particular are at a disadvantage relative to hospitals and large practices when it comes to requiring biological medications for special patients. Patients usually have to pay a high co-pay for medicine.

We've alluded to that in other testimony. It could cost tens of thousands of dollars and the co-pay can be as high as 20 or

30 percent, and that's a bunch of money to my patient population.

When the patients cannot afford the co-pay, the physicians, who must pay for the medicines up front, cannot manage the debt and the patients are referred to treated in the hospitals or outpatient settings that are much more expensive. And these are just some of the challenges doctors face when helping patients navigate medicines.

What could help physicians like myself? We've offered some opportunities for improvement in our written testimony. There are so many opportunities. We can discuss them almost ad infinitum.

In closing, I would like to thank you. AMA looks forward to working with you on this issue.

Thank you.

[The prepared statement of Dr. Harmon follows:]

**********INSERT 9**********

Mr. Burgess. Thank you, Dr. Harmon.

Mr. Hoey, you're recognized for five minutes -- three minutes, please, to summarize your opening statement.

STATEMENT OF MR. HOEY

Mr. Hoey. Thank you, Chairman Burgess, and Ranking Member Green and members of the subcommittee for conducting this hearing and for the invitation to testify.

I am Douglas Hoey, CEO of the National Community Pharmacists Association. NCPA represents America's community pharmacists including the owners of 22,000 independent community pharmacies.

More than any industry segment, independent pharmacists are in under served rural and urban areas. Local pharmacists are the medication experts on the health care team and, importantly, to consumers nationwide. These health care professionals are easily accessible.

Pharmacists increase health care quality and decrease its costs by optimizing safe and effective medication use. Over the past few years, CMS has been testing new payment and care models across hundreds of community pharmacists and to date nearly 300,000 patients have been enrolled.

Early findings suggest high patient satisfaction, improved outcomes, and reduced overall health care spending with reductions of greater than a thousand dollars a year for those patients who received high clinical intervention.

To achieve that future promise, however, systemic barriers must be overcome. We believe intermediary parties, pharmacy benefit manager middlemen, are increasing pricing complexity and

contributing to higher prescription drug costs.

Since their inception, PBMs have morphed from claims adjudicators into little known and largely unregulated corporations, and despite their immense market influence, PBMs are not subject to industry wide regulation nor do they have an obligation to always put their clients' interests above their own.

Opaque PBM practices that require increased transparency including PBM-retained rebates and spread pricing, generic drug reimbursement schemes and pharmacy direct and indirect remuneration, or DIR, fees.

And I will expand on our members' current number-one concern, which are DIR fees. Now, these fees are assessed on pharmacies months after a prescription is filled. CMS has identified concerns from the rapid growth in DIR fees including higher beneficiary costs, accelerating patients into the donut hole, and the shifting of liability for Part B costs from plan sponsors to CMS.

In the recently released Medicare proposed rule, CMS explicitly states they are considering requiring all price concessions from pharmacies to be reflected at the point of sale.

NCPA strongly supports this approach. CMS estimates this would result in significant patient savings at the pharmacy counter as well as overall savings over a 10-year period.

In conclusion, it makes financial sense for Congress to demand increased true transparency into the prescription drug

marketplace for all taxpayer-funded prescription drugs and to fully utilize the expertise of the community pharmacist to identify potential savings.

Thank you.

[The prepared statement of Mr. Hoey follows:]

**********INSERT 10**********

Mr. Guthrie [Presiding.]: Thank you. The gentleman's time has expired and I recognize Mr. Mitchell for three minutes for your opening statement.

STATEMENT OF MR. MITCHELL

Mr. Mitchell. Thank you.

Chairman Burgess, Ranking Member Green, Chairman Walden, members of the committee, I am honored to be here today.

I am David Mitchell and I am founder of Patients for Affordable Drugs. We are bipartisan. We focus on policies to lower prescription drug prices.

We don't accept funding from any organizations that profit from the development or distribution of prescription drugs.

More importantly for today, I have an incurable blood cancer called multiple myeloma and prescription drugs are keeping me alive, literally. Right now, my treatment is five hours of infusions, carry a price tag of $450,000 this year. I am very grateful to the science and research communities for these drugs, and because my disease is incurable, it finds its way around drugs.

It mutates. I need innovation of new drugs if I am going to stay alive. This is not theoretical for me. It's, literally, life and death.

But my experience has taught me one irrefutable fact and that is that drugs don't work if people can't afford them. Since our launch in February, we've built a community of almost 20,000 Americans from every state.

Patients tell us terrible stories of skipping doses, cutting pills in half, even declaring bankruptcy because of the price of

their drugs. They're scared, they're angry, and they need help.

I am going to highlight a few policy solutions for the drug supply chain. First, however, it is critical to note that prices set by drug corporations with government-granted monopolies are at the headwaters of the pricing problem.

When retail prices set by drug corporations go up, all the players in the system make more money -- drug manufacturer, PBMs, doctors, hospitals. The people hurt are patients, consumers, taxpayers, and employers who foot the bill.

But the drug supply chain downstream is also a big part of the problem. Here's a patient perspective on some elements.

One, we should allow Medicare to directly negotiate lower prices for patients. Every other developed country in the world does this. We should, too.

We need increased transparency throughout the supply chain. Three pharmacy benefit managers control almost 80 percent of the market and negotiate in secret, leaving consumers, taxpayers, and policymakers in the dark.

Co-pay coupons and patient assistant programs are phony charities. They are designed to do one thing. That is keep prices high. They are not charity. They are marketing. According to City Research, for every $1 million spent on charitable donations, drug corporations reap as much as $21 million in return. We should lower drug prices and make co-pay coupons unnecessary.

Finally, we have to ensure that patients pay based on rebated, not list prices, and that patients with insurance don't pay more than they would if they paid cash.

Gag clauses are wrong -- should be outlawed. I am extremely encouraged that members on both sides of the aisle are here today focussing on drug pricing because, in my experience, the most enduring legislative solutions have come with bipartisan action.

Thank you.

[The prepared statement of Mr. Mitchell follows:]

**********INSERT 11**********

Mr. Burgess. Thank you, Mr. Mitchell, and I want to thank the entire panel for their testimony and we will move into the question/answer portion of the hearing.

We'd like to recognize the gentleman from Oregon, Mr. Walden, chairman of the full committee, five minutes for questions, please.

The Chairman. I want to thank the chairman very much and, again, I want to thank all the witnesses today. You have helped us get -- scratch the surface, get a better understanding of -- from the start to the finish -- from the molecular development to the patient who's on a lifesaving drug.

And, obviously, you have also outlined for us differences of opinion about how we achieve more affordable health care and not just -- we are looking at this, by the way, not just at the drug chain but across the entire industry of health care.

And it is a big one, it is an expensive one, and I know when I go home to Oregon it is on top of everybody's minds. They may complain about their insurance premium or this, that, or the other thing.

But at the end of the day, they all want to know why -- you name it in health care -- why it costs what it does or they want to know what it costs, because of lack of transparency.

I mean, you don't even know. I mean, there are all these schemes and things and I think we are all trying to get to the bottom of it and my goal is to have an informed process beginning

today that lets you all make your case.

And I would just be curious, as you all have heard each other talk, and we finished with Mr. Mitchell, who I've met with before in my office, and sorry for what you're going through, obviously, but you make a very compelling case.

You make some pretty strong statements about what needs to be changed and I would like to go to the other end because some of those are targeted at the pharmaceutical companies and see if we can get a response from Ms. Reilly on what Mr. Mitchell said and how we should be guided in this, and if others want to weigh in along the way that would be good as well.

Ms. Reilly. Well, thank you for the question and I think a lot of what I heard out of David's mouth are things that we do agree with.

For example, today, as I talked about and others talked about, our companies do provide robust discounts and rebates to pharmacy benefit managers and insurers, and unlike almost any other part of the health care system, those rebates and discounts aren't passed back to the patients.

If a patient with a deductible today ends up in the hospital before they reach their deductible, the price they pay is a negotiated price that that insurance company has negotiated on their behalf.

It seems strange that if a patient instead needs a pharmaceutical before they reach their deductible that they're

asked to pay a full unnegotiated price for the medicine and don't get the benefit of that discount and actually earn money on every transaction. That doesn't seem right to me and I think that does need to change.

CMS just, earlier this year, posted their new Part D rule. In it, they put a request for information out about the potential for passing through discounts and rebates in the Medicare Part D program.

We actually think that's a good first step. Today, the evidence suggests by CMS that PBMs prefer medicines with high list prices and high rebates because for those products they can use those rebate dollars to keep their premiums low and they also put people into catastrophic quicker and passing through --

The Chairman. Right. So I want to -- I want to give them a chance to respond to that because I assume they will want to.

So let's go to the insurance plans. You have heard what Ms. Reilly said about consumers paying the full freight here and not being covered by insurance and no negotiation. Is that accurate? Is there something we should do about that?

Mr. Eyles. So thank you, Chairman Walden, for the opportunity. What I would say is health plans negotiate on behalf of their members and consumers every single day across all parts of the supply chain, whether it be providers or drug manufacturers.

To put this into context, I think you probably heard some

of the statistics thrown around that 90 percent of the prescriptions are generic that are filled in this country. So that means about 10 percent are filled through retail -- that are brands.

Not all of those brands offer rebates. There's a large number of brands that don't offer rebates. So really we are trying to focus on a much smaller problem when the bigger problem really comes back to the price.

Using Ms. Reilly's example earlier of insulin of $400 a vial, a decade ago that vial was only about $90. Right now, if prices of insulin increased only by the consumer price index rather than much, much higher rates, we'd only be paying about $100 per vial, all right, if you're just following inflation. We wouldn't be having this discussion about rebates --

The Chairman. So --

Mr. Eyles. -- if it didn't start with the price.

The Chairman. So who can tell me why that insulin is the price it is today?

Ms. Reilly. I would say, Chairman Walden, the net price of insulins have not changed all that significantly. What has changed is the levels of discounts and rebates that are being demanded in part because it is an extremely competitive market.

As I mentioned before, insurance companies, PBMs, in the Part D program, for example, they like high list prices that come with high rebates because they can then use those rebates to keep their

premiums low, attract patients to their health care plan.

Unfortunately, what the problem is is they're not sharing those rebates and discounts back with patients as they do if a patient ends up in the hospital or uses a physician and that's what needs to change.

The Chairman. All right. My time has expired. We didn't get to the PBM's view of this. I hope we do, coming forward, because this is the debate.

Because at home the constituents say why is insulin $400 when it used to be a hundred dollars or whatever the number is, And that's repeated time again, whether it is EpiPen or whatever. We can't answer that either because I am not sure there is a good answer.

So with that, Mr. Chairman, I've exhausted my time and I, again, appreciate your willingness to have this hearing and yield back.

Mr. Burgess. Chair thanks the gentleman. Gentleman does yield back.

The chair recognizes the gentleman from Texas, Mr. Green, five minutes for questions, please.

Mr. Green. Thank you, Mr. Chairman.

A Harvard study found that there are more than three-quarters of the public believe that name brand prescription drugs are too high and an issue primarily driven by price increases in the absence of additional competition.

Biologics represent the majority of these high-priced drugs representing seven out of the 10 highest grossing pharmaceutical products in 2015.

A landmark 2014 Rand study also estimated that biosimilars could save as much as $40 billion through 2024 in the United States alone, and we have another study from IMS Health opening markets to biosimilar competition health care systems could realize savings of more than 10 billion euros in the E.U. alone between 2016 and 2020.

The cumulative savings over the next five years in the E.U. and the United States would be 49 billion in euros.

Mr. Davis, Mr. Merritt, do you agree that we should support policies to encourage a workable pathway for biosimilars that we can -- as we in Congress do encourage bringing these product online and encouraging uptake by physicians and plans for their patients? Mr. Davis first.

Mr. Davis. Congressman, thank you for your question.

The short answer is yes, we represent biosimilar manufacturers today in addition to generic manufacturers, and as you stated, biosimilars hold the potential for so much promise in terms of increasing access and realizing savings because they will provide competition to the increasingly costly degree of specialized medicine and personalized medicine, moving forward.

There's a couple challenges with respect to making sure that we realize the full potential of biosimilars here in the U.S.

market. One is getting them to market, which is why we need to create some Fast Generics Act pass so that our members can actually gain access to the samples to do the pharmaco vigilance to the apply to the FDA to get biosimilars to the market.

And then the second thing we have to look at, and we have to be candid about this, is right now there are eight biosimilars that have been approved by the FDA. There is only three on the market. The other five are tied up in litigation -- endless litigation.

So if we ultimately want to -- we have a lot of catching up to do in terms of you mentioned the E.U. They are light years ahead of us in terms of utilization, access, and savings on biosimilars.

We have the opportunity from a policy perspective to catch up. The federal government started scoring savings for biosimilars in 2014 fiscal year. The first one wasn't on the market until September of 2015. So we have more work to do there.

Mr. Green. Mr. Merritt.

Mr. Merritt. And I -- and I would agree with what Chip said. I mean, biologics are the future. Specialty products are the future and they're very expensive. They're very great products, as David Mitchell mentioned.

But right now, they're often unaffordable and the key is competition. Biologics already have 12 years of exclusivity. We'd like that to be down to seven so we can get competition started

faster.

We'd like these drugs to be -- have the same name the way generics do with brand drugs on the regular market and a host of other things because without competition you're not going to have savings and if you have more and more brand protection for every little minute change you make and if litigation ties these up for years and years, you know, for a month, a couple of months, a year of being tied up in litigation can cost consumers billions of dollars. And so we are very aligned with the generics on this.

Mr. Green. Mr. Chairman, I believe that our government's approach to approving and integrating biosimilars in our health system would impact overall potential for competition and access to more affordable life changing drugs for patients.

Let's hope we can continue to support this developing market so that patients can realize the value and benefit of such treatments.

Mr. Eyles, the complexity of the drug supply chain is hard to overstate as evidenced by all 10 of our witnesses this morning. They've been in the growing chorus calling for greater transparency in the drug supply chain.

Some states have already taken action. California recently enacted legislation that would require reporting of certain price hikes and legislation that would be introduced in both the House and the Senate -- that has been introduced would create a similar federal requirement.

What we've already seen is some good actors taking meaningful steps to increase transparency. For example, Sanofi and Janssen have agreed to disclose their drug price increases each year. Sanofi also announced it would put limits on how much it will increase drug prices.

But as you note -- you note in your testimony that more could be done to encourage open and straightforward price setting and highlight the need for disclosure of intended launch price.

Could you discuss further why the disclosure of intended launch price would be helpful to insurers and how you believe such a disclosure be operationalized?

Mr. Eyles. Thank you, Ranking Member Green.

Yes, we've been very supportive of greater transparency into really both when it comes to launch prices and price increases.

While we are not supportive of controlling prices, we think it is important to have more information out there in the public domain about exactly how prices are set. Right now, pharmaceutical prices are set in the black box.

When a new product gets launched with a price of $475,000 no one really understands how that got set.

Mr. Green. Well --

Mr. Eyles. We think ahead of time, having additional visibility into how prices get determined by the manufacturer and then price increases over time, particularly those on higher cost drugs and those that exceed certain thresholds, it'll be important

to understand other parts of the health care system have oversight and controls on them.

For example, insurers have to report all of the inputs into their rates before they get approved. We are not looking to have specific approval of drug prices but we do think it is important to have greater transparency and greater dialogue around how are prices being set up front.

Mr. Green. Well, Mr. Chairman, thank you. I know I am over time.

But transparency always works and, like you said, it works in other parts of the health care delivery system. So thank you for the time.

Mr. Burgess. Gentleman yields back. Chair thanks the gentleman.

The chair recognizes the gentleman from Kentucky, Mr. Guthrie, vice chairman of the Health Subcommittee. Five minutes for your questions, please.

Mr. Guthrie. Thank you very much. Thanks for everybody being here today and it is really a great day to start this process. I was invited not long ago to the White House with the majority leader and we met with the president. I want to tell you, we walked away with the president wanting action on this issue.

He's very focused on it. I think this is the beginning of a process that will lead and -- my hope will lead to an action as we move forward.

I have some prepared questions but I will get back to what the chairman said. I don't think we ever got a really good answer.

If insulin is a competitive product and it was $90 10 years ago and it should be $100 if you just went through the standard inflation, why is it $400? It's got to be somewhere between here and here it has increased in price and maybe, Mr. Merritt, you'd like to address that.

Mr. Merritt. Yes. I mean, what happens -- and this happens with a lot of drugs but you see it a lot in insulin is there are insulin products but they have new methods of administration -- actually some better methods of administration and that creates a whole new patent protection for these products.

And so that is how the prices go up and, again, on a very basic point, drug makers can charge whatever they want for a product. That's not saying a price is right or wrong but it has nothing to do with anybody at this table except for the drug manufacturers.

All that we can do is get the biggest rebates possible, the biggest discounts possible, pass it on to the plans and employers and have them use it to reduce premiums, cost sharing, or whatever each plan wants to.

But just the fact that we don't control the price, that they have patent protection with minor changes in the products, again, making the products better, that's what gives them that pricing power.

Mr. Guthrie. So the insulin -- so Ms. Reilly, that would -- so innovation has come from PhRMA. Therefore, you have invested the research dollars so you're recapturing those resources dollars, therefore it is four times what it was?

Ms. Reilly. Well, Mark is correct that there have been significant advancements in insulin. We now have long-acting insulins. We have an insulin that's injectable with pens and other things.

But, again, I would say the list price of the medicine is not what the manufacturer retains and in the case of the insulin marketplace, there are multiple competing products.

What manufacturers have retained over the last five years has been stable or declining and part of the reason for that is we do have PBMs that are buying these medicines that, again, CMS, MedPAC, and others have demonstrated that what they prefer is a high cost price and a high rebate.

That lowers the net price considerably. The rebates on average in the insulin market space are 65 percent.

Mr. Guthrie. Well, who sets the list price then? For what the PBMs have to charge, who sets the list price?

Ms. Reilly. Well, and I want to respond to something that both Mark and Matt said with regard to the list price. The list price is not set in a vacuum.

Our companies have to engage with PBMs and insurance companies every day in determining the list price and their

preferences, quite honestly, matter significantly and they matter to the extent that if they want a high list price with a high rebate and they're telling a company when they control a hundred million lives, an individual one, that is their preference if that product is to get on formulary.

Commonly, PBMs choose -- pick and choose amongst insulins and they say to a company, if you don't give me the price I want, you're off my formulary, and if you are buying on behalf of a hundred million Americans, more than countries like France and Germany, the leverage they exert is significant.

Mr. Guthrie. So would you argue your market price is the list price less rebate? You know that going in --

Ms. Reilly. Yes. Yes.

Mr. Guthrie. -- therefore, you have to set a higher list price to get the market price that you think you need to cover your -- same way with biologics?

Ms. Reilly. Just to stay -- to stay flat. Yes.

Mr. Guthrie. To stay flat.

Mr. Merritt. If I could -- if I could just jump in for a second, it would be an anti-trust violation for those discussions to ever happen.

Those discussions don't happen. Manufacturers set the price according to however they want to move their products, whatever they think they need to do. PBMs have zero input into that. Health plans have zero input into that.

Of course, we get the biggest rebates that we can, but remember, this is a chicken and egg thing. If the price goes up, we are going to get a bigger rebate because our clients, Matt's companies and others are going to demand us to get bigger and bigger discounts. But the --

Ms. Reilly. I would argue --

Mr. Merritt. No, I am not done yet. But the list prices are the list prices, and that is a drug maker thing. It has nothing to do with --

Mr. Guthrie. Well, let me --

Mr. Bucshon. Mr. Chairman, I -- Mr. Chairman --

Mr. Guthrie. Not -- let me --

Mr. Bucshon. He interrupted her testimony.

Mr. Guthrie. I am going to -- let me -- because I want to -- I want to -- I am going to give you -- I am going to let you finish your thought. Then --

Mr. Merritt. Yes. That's what I am saying. It's just a basic thing. I think sometimes you can try to over -- not you -- just can try to over complicate the whole issue of supply chain.

Supply chain is just how you distribute products. Every industry uses them. They're not exotic. They all use rebates.

Mr. Guthrie. I got about 40 seconds. Yes, let me go back to -- I want to --

Ms. Reilly. I would say you have to ask the question that if our revenue is flat or declining in the space of insulin and

the list price is increasing? It's benefiting everyone that's paid off of the list price including the PBMs and the health plans.

Mr. Guthrie. So the argument the rebate doesn't go to the consumer?

Ms. Reilly. No, it does not get passed --

Mr. Guthrie. Do you have an answer for that, Mr. Merritt?

Mr. Merritt. It does. It goes to the client who may use it for -- to reduce the cost of that particular drug, the cost sharing, or more commonly it is used to reduce overall.

Mr. Guthrie. I guess I will have Administrator Eyles and AHIP. So the rebate does go to the consumer?

Mr. Eyles. They go to people who purchase health insurance coverage. Yeah, they go to everyone. That's right. So when you look at filings that insurance companies have to file with every state department of insurance, there are specific lines dedicated to pharmaceutical rebates and when rates get approved those rebates are taken into account. There are different --

Ms. Reilly. I would argue that's a perversity of insurance.

Mr. Guthrie. Time is expired. I wish I had more time with that but, I mean --

Ms. Reilly. Right. The purpose of insurance is for healthy to subsidize the sick. We are evolving to a system where the sick are subsidizing the healthy through rebates.

Mr. Burgess. Gentleman yields back his time. Chair thanks the gentleman.

The chair recognizes the gentleman from New Jersey five minutes for questions, please.

Mr. Pallone. Thank you, Mr. Chairman.

I have long believed that one critical component of the successful drug supply chain is a robust generic manufacturing presence and market.

Generics can continue to play a role in fostering increased competition and affordable access to medications, which is why I've continuously worked to provide generics with a level playing field and supported increased assistance and incentives including most recently through the FDA Reauthorization Act as a way to encourage a strong generic presence in our pharmaceutical market.

So I wanted to ask Mr. Davis a couple questions. In your testimony you noted that generics operate under a very different business model than brand drug manufacturers.

Can you further discuss how the business model for generic drugs is different than brand drugs and the different considerations generic drug manufacturers take into account when making product development decisions?

Mr. Davis. Thank you, Ranking Member Pallone, and thank you for your leadership on ensuring a level playing field. I am happy to address that.

The debate that you just heard between the branded industry and the PBMs and the insurers on rebates as a percentage of list price and discounts are for 11 percent of all prescriptions in

the United States.

It is not the generic business model. So if there is one thing I leave this committee with today it is to think of generics differently than the way you think about policy that impacts the branded industry.

We are a commoditized, not monopolized industry. As a result of that, the way the supply chain actually leverages driving prices down to where we are in 16 consecutive months of price deflation is by combining their resources and leveraging their purchasing ability where there are now three wholesaler retail pharmacy consortiums that are controlling 90 percent of the generic supply chain.

So you have three suppliers who are driving the prices down lower than they have ever been before in the generic marketplace and as a result of that they are moving what are -- increasingly towards what are called single forcing contracts meaning they want to partner or contract with one generic company to fill a majority of their portfolio of purchasing needs.

As a result of that, what we have seen is, quite frankly, an unsustainable supply chain for generics, moving forward, if in fact we can ensure that there is robust competition on the buyer side in addition to the seller side.

In 2000, there were approximately 200 wholesalers on the market. Today, there are three that control 90 percent of the supply chain. The buyer side is three.

We are still 20 to 30 competitive generic manufacturers all competing for that business, and economics will dictate over time that you will see more consolidation on our side in an effort to level out that negotiating table.

Mr. Pallone. All right. I mean, I want to ask two more questions.

You talked about how generic manufacturers operated in this commodity style market as a result of the multiple manufacturers marketing the same product.

But do you want to explain a little better how that -- the role that plays in bringing the generic drug to market?

Mr. Davis. Happy to do so. You have --

Mr. Pallone. And then I've got one more question.

Mr. Davis. Sure. You have a situation, Congressman, where the ability for a generic manufacturer, when you actually get to what's called commoditized pricing in the generic marketplace, a decade ago it took eight, nine, or ten generic competitors to get to 80 to 85 percent off the reference for the originator price.

You get there now as soon as three, four, or five generic entrants, which is why the FDA commissioner has prioritized not just the first generic application at FDA but the first, second, and third.

Our companies have to make decisions in a commoditized market that has varying price fluctuation upward and downward about what the sustainability is of the competitive market in any therapeutic

area.

So that's a significant factor in determining if they go to market once they get approved and if they stay on the market once they are approved.

Mr. Pallone. All right. Then lastly, let me just ask briefly about the rebates. We've heard quite a bit of debate about the appropriateness or value of rebates in the drug supply chain.

So what role, if any, do rebates play in the negotiations a generic drug manufacturer undertakes with payers and how does reimbursement traditionally work for generic drugs?

Mr. Davis. Thank you for that. It's an important distinction. As I said, for 89 percent of the prescriptions in the U.S. that are generic, the traditional rebate model by and large does not apply.

Generic companies are reimbursed in many ways based upon two things -- their ability to meet that wholesaler demand with the three who control 90 percent of the market.

By saying can you meet our volume requests and are you willing to meet the price that we are actually going to tell you we are going to pay for that product -- let's take generic Crestor, for example, rosuvastatin -- and if you don't -- and if you're not willing to offer it at 10 cents a capsule, one of your 19, 20, or 21 other competitors that are also marketing that will and we will cut you out.

So it is really about volume and ability to keep your price as low as possible. So it is an example of the market actually working.

Mr. Pallone. All right. Thanks a lot, Mr. Davis.

Mr. Burgess. Gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentlelady from Tennessee, Mrs. Blackburn, five minutes for questions, please.

Mrs. Blackburn. Thank you, Mr. Chairman.

I appreciate that, and I appreciate the discussion that we are having here this morning on this issue. I will say I am a little surprised. There's a lot of finger pointing that is going around.

But I will tell you all I think there is more than enough blame to go around for what we see transpiring in the marketplace and with the high cost.

And listening to you all, I will tell you there is absolutely -- it confirms to me why so many of my patients -- my constituents will say as a patient who takes something regularly, they have tried to find other options in the marketplace -- programs like Good RX or I know there are several others -- because they are very frustrated.

And Mr. Mitchell, I appreciate the concerns that you bring to bear as a patient and someone who is using something. This is an issue that we need to address and we need your best efforts

in solving this.

So I am going to focus on not things in the past but as we move forward and let's put our attention there, and for each of you on the panel -- and we are going to start with Ms. Reilly and work all the way down -- what change would you like to see in the marketplace or what change in law should we make to make certain that, as Chairman Walden said, we are focused on access, delivery, and the cost of these pharmaceuticals to patients.

Now, you are only going to have about 30 seconds. So Mr. Merritt, listen -- make that good and concise for me. Okay. Ms. Reilly, you are on. Let's go right down the panel.

Ms. Reilly. Great. I would say two things. The first, as I mentioned before, passing through those robust discounts and rebates that totalled over $100 billion last year back to patients. That would lower patient drug costs immediately.

The second, which is more of a mid to longer-term option, is moving our system towards one where-which moves towards a value-based system away from volume. Let's reward companies that deliver medicines that are delivering the outcomes that patients and payers want.

Mrs. Blackburn. Thank you.

Mr. DiLenge. Thank you.

I mentioned at the outset that we are part of a coalition with insurers, PBMs, and others, and one of the ideas is in fact exactly what you were talking about in terms of patient

information.

We need to empower patients. Right now, they do not have good information about their choices. They don't know about their formularies. Their formularies are constantly changing throughout the year.

Their prices are changing, their co-pays, their co-shares. They can't -- if they had more access to good information they'd be able to find cheaper medicine.

Mrs. Blackburn. Okay. Time's up.

Mr. Davis. Congresswoman, thank you.

There are three things that we would recommend. The first is to repeal the misguided Medicaid penalty on generic drugs. It was passed in the fall of 2015 as part of the balanced budget agreement.

It actually punishes generic manufacturers in the circumstances where they don't take a price increase and serves as a disincentive.

Pass the CREATES Act, as I mentioned earlier, and include biosimilars in the coverage gap for Part D to ensure a robust biosimilars market, moving forward.

Ms. Gallenagh. Thank you.

As wholesalers, we don't actually take positions on transparency or on pricing issues. But I would say that our members would support anything that examines greater competition in the market place and better access for patients.

Mrs. Blackburn. Okay.

Mr. Merritt. I agree with a couple things that were said before. Value-based contracting would be great. The patent reforms that Chip and the generics industry have talked about, and also something that we haven't talked about and may not come up today but electronic prescribing.

We'd like doctors to be able to look at the formularies before they prescribe the drugs so patients aren't surprised at the pharmacy as they can choose the least expensive option available.

Mr. Eyles. Solutions that bring more competition through generics and biosimilars. That's the first thing. That's very important.

The second is greater price transparency, both about how prices get set and how prices are increased, and we'd agree that it's important to also move towards value-based pricing and outcomes-based pricing.

Mr. Nickles. I would agree with a number of the things that have been said already -- greater competition, greater transparency. I would agree on the CREATES Act as a piece of legislation that should move forward and, of course, as I mentioned in my statement, protecting the 340B program.

Dr. Harmon. I would tell you that not only is Mr. Mitchell the patient -- formal patient representative. All of us in the room are either patients or caregivers for patients. So we all wear that same appellation.

As a provider, as a physician, what I would like to see is transparency. It's been alluded to. That's not just a buzzword. It needs to be a reality and I need to administer -- to eliminate these administrative hassles that interfere with delivering care for my patients. Thanks.

Mr. Hoey. I have three suggestions. One would be the transparency with spread pricing. That's what the pharmacy has paid and what the employer is charged, which are two different things. The employers charged more.

The second would be pharmacy DIRs at the point of sale or prohibiting pharmacy DIRs altogether, and then the third would be eliminating the conflicts of interest that exist between a price giver and a price taker.

So they're giving prices but they're also taking a price, and there is an immense conflict of interest. Thank you.

Mr. Mitchell. I would focus on promoting competition and making Hatch-Waxman work as intended. That means no more pay for delay. There's a bipartisan bill to do that now.

The CREATES Act is an incredibly important bipartisan bill. It would save more than $3 billion. That is important. But all elements of patent abuse that extend patents beyond what you intend with our laws should be addressed to promote competition because competition lowers prices.

Mrs. Blackburn. You all did a great job staying under the time limit. I thank you all.

And as I yield back, I will just say listen to what you said. Transparency, competition -- basically, focussing on the patient and those are worthy goals.

I thank you for the hearing and I yield back.

Mr. Burgess. Gentlelady yields back. Chair thanks the gentlelady. Chair yields to the gentlelady, Ms. Matsui from California, five minutes for questions, please.

Ms. Matsui. Thank you, Mr. Chairman.

High drug prices are really at the top of the mind of our constituents and we've seen recent examples of extreme bad actors raising prices purely for profit motives.

Congress does need to review and better understand drug pricing to ensure that we are incentivizing research and innovation and development of new drug treatments and cures without creating loopholes that can be taken advantage of.

Drug pricing is particularly complicated because it is not transparent to the public and because drug companies often end up with monopolies, which we all know can drive up costs.

We need an approach that focuses on the patient and the cost to the health care system, which will be tethered by ensuring that there is sufficient competition in the market place.

Where there is more than one option for a drug or treatment, costs tend to be driven down. As we move toward precision medicine, we move away from multiple treatment options per person.

So this is something we will only have to grapple with more

and more. I know we talked about this. Let me follow up here.

Ms. Reilly, when drug companies set the initial list price for the drug from which all of the components of the price follow, do manufacturers also publish or make available how they determine the list price?

Ms. Reilly. Well, companies -- and to be honest, as PhRMA we don't engage with our companies in terms of how they price their products. We can't for anti-trust reasons.

However, many companies have talked about their philosophies with regards to how they price their product and they look at a number of factors.

They look at the prevalence of the disease. They look at existing treatments that are already in the market.

Ms. Matsui. Because is it really -- how about the research and development costs that the company has done?

Ms. Reilly. Research and development is a cost of doing business that, obviously, has to be recouped. But companies really are focussing on the value that a given medicine is bringing to market and the list price that we come up with is very much negotiated with the purchasers of the product.

A PBM or insurance company does not have to cover our product. In fact, some proudly talk about the fact that they exclude certain products from formularies if they don't get the price that they want. So they're not done in a vacuum.

Ms. Matsui. All right. Let me switch here.

Dr. Harmon, when a doctor prescribes a drug, how often do they know how much it will cost a patient?

Dr. Harmon. Representative Matsui, they really only know if they do it a lot, because if I -- Denovo prescribe a drug I have no idea. You heard it from some of the other panellists.

Increase transparency on drug pricing and availability and formulary would greatly enhance my ability to adequately and accurately prescribe the right treatment for the right patient at the right time.

Ms. Matsui. So when doctors are familiar with certain drugs that they prescribe, they know to recommend to their patient if they have two generics that do the same job as a named drug.

Do you tend to use this price information in a systemic way or anecdotally from what they hear from the patients?

Dr. Harmon. Systemically. I try to be an evidence-based prescriber. So I deal with my medical literature and up-to-date treatments that are made available to me. I make that decision, Congresswoman Matsui.

But also 99 percent of the time I write on my prescription blank or I sent the electronic prescription substitution authorized.

Ms. Matsui. Okay.

Dr. Harmon. Generics are available. Rarely do I prescribe the brand name. The only exception is if I know that their insurance plan ahead of time will authorized the brand and

actually have a better affordability to the patient than a similarly priced generic.

Ms. Matsui. Okay. Thank you.

I want to switch here to on -- I want to ensure that we continue to encourage innovation and development of new cures and the ability to profit as part of that when you are in such a risky business.

But I think the profit has gotten way out of control in many cases. I want to make sure the potential for profit is truly incentivizing innovation, not just lining investors' pockets.

Mr. DiLenge -- is it DiLenge? What are examples of biologic companies that are innovating but also keeping prices low?

Mr. DiLenge. I think the vast majority are, and so we've seen over the -- particularly over the last couple years but we've seen incredible market competition in biologics, not necessarily by biosimilars.

I agree with Chip on some of his comments there. But among branded biologics there is intense competition. In fact, the time to entry for the second biologic in a class has dropped dramatically.

And so what you are seeing is a lot of great competition in there and the second and third products are coming in usually cheaper than the first.

Ms. Matsui. Okay.

Mr. DiLenge. So we are seeing a lot of good competitive

market dynamics in biologics.

Ms. Matsui. Well, I would say so, but I think when you increase more competition and eliminate the monopolies, because there are still some loopholes and ways for players along the chain to take advantage of this system with our without competition.

So do you see -- I guess Mr. Mitchell -- do you see policy solutions that encourage innovation but close loopholes?

Mr. Mitchell. Can you pose that question again, ma'am? I didn't hear it.

Ms. Matsui. Okay. Do you see policy solutions that encourage innovations but close loopholes?

Mr. Mitchell. I think, most importantly, that we want to incentivize companies to invent new drugs and not invest time to milk money out of old drugs -- time and money to milk money out of old drugs and that's why I place the emphasis in what I said to the lady from Tennessee on closing patent loopholes --

Ms. Matsui. Right.

Mr. Mitchell. -- that allow them to get more time beyond that which you intend under Hatch-Waxman instead of focussing their attention on developing new drugs, making more innovation.

Ms. Matsui. All right. Thank you very much.

Mr. DiLenge. Ms. Matsui, if I just may respond real quick, I think it's important to emphasize that the time to market for generics has stayed the same for two decades.

So the idea that there is all this patent evergreening and

that innovators are getting all these new patents and pushing out the time for generics the data just doesn't support that. Thank you.

Ms. Matsui. Okay. Thank you. I yield back.

Mr. Burgess. Gentlelady yields back. Chair thanks the gentlelady.

The chair recognizes the gentleman from Texas, Mr. Barton, five minutes for questions, please.

Mr. Barton. Thank you, Mr. Chairman and Ranking Member Green, for holding this hearing. We have established the number of witnesses we can have on one panel because there is no more room.

[Laughter.]

You know, so we know that the number now is 10. This committee has jurisdiction over quite a bit of the U.S. economy.

The three most complicated issues we deal with in terms of pricing are the price of gasoline -- when it's up everybody's mad at us -- the price of prescription drugs, which we are talking about today, and the price of cable TV. And I may be using a misnomer for cable TV. It may not be cable TV anymore.

But of those three, the one that is most complicated and the most byzantine pricing mechanism is drugs. I take six prescription drugs every day.

I had a heart attack six years ago and I have, you know, high blood pressure and so I take six drugs. I couldn't tell you what

those drugs cost. My insurance companies pays it. I pay a little bit of a deductible so I know what my deductible is when I get them filled every three months. I get a 90-day supply.

You know, and some of them are Plavix or Plavix, Lisinopril, Lipitor. Those are some of the name brands, and I think everything I am taking now is a generic. I don't believe I use any of the name brands.

So it's good to have this hearing. I hope we learn something from it. It would be nice if we could come up with a simplified system for drug pricing and perhaps this hearing will begin that.

My specific questions are going to deal with the pricing of biosimilars. Now, Congresswoman Eshoo and I worked together several years ago to get a biosimilar title in what's now called the Affordable Care Act and there is just -- it's been one rocky ride trying to get biosimilars to the marketplace.

And recently Congresswoman Eshoo and I led a letter that 48 other members signed asking them to have a separate code at CMS for biosimilars.

Mr. Davis, you represent both the generic drug companies and the biosimilar drug companies. You mentioned in your written testimony that biosimilars are more complicated, difficult to develop than traditional drugs. Could you expand on that briefly, please?

Mr. Davis. Sure, Congressman. Thank you for the question.

Biosimilars are a subset of biologics. So the reverse

engineering process associated with biosimilars is heavily science weighted and much more expensive over time.

So development programs for biosimilars can cost $150 million to $400 million in advance of filing the application. So what we need to recognize is that there are similarities in terms of the value that competition from biosimilars will present to traditional biologics in the market once they get there that is akin to the traditional small molecule versus generic competition that we've seen for years in the branded side.

At the same time, we do need to recognize that they are a different class of drug and as a result of that through the leadership of you, Congresswoman Eshoo, and others, be able to have a pathway established here in the U.S. as part of the Affordable Care Act through BPCIA.

That pathway, as was suggested earlier, has not gone as smoothly as possible and there are several policy reasons why we are where we are, not the least of which was the potential to have different J codes for the originator product and all of the competitors in a separate one at CMS.

Because of the leadership of this committee, CMS has announced a plan change to that as of January 1. So thank you for that as well.

Another solution that would increase the uptick in interest on the part of our members to make the investments they need to to bring biosimilars to market will be making sure that

biosimilars are treated like biologics in the Part D coverage gap.

So it's actually our members asking to be held to the 50 percent discount to make sure that the value that biosimilars from a pricing perspective doesn't get lost as people go through the Part D program.

Mr. Barton. Mr. DiLenge, as Mr. Davis just said, CMS has announced that they're going to reverse their earlier policy and assign a separate HCPCS code for each biosimilar rather than have a single payment rate.

Do you believe that his promotes a more vibrant and sustainable market for biosimilars and hopefully over time reduces prices?

Mr. DiLenge. Absolutely. We need to be able to incentivize for the reasons that Mr. Davis said. You need to really incentivize the biosimilar marketplace differently than you would a traditional generic marketplace.

And so while you have all the generics in the same code and that works for that marketplace, it does not work for biosimilars. It won't spur the investment.

I talked earlier today about the investment that's required for all types of innovation but biological innovation in particular is very, very expensive and you need to have the right incentives, and the federal government, the way they code -- it sounds really arcane, coding, but it actually does impact what investors think about going into markets.

Mr. Barton. Okay. Thank you, Mr. Chairman.

Mr. Burgess. Gentleman yields back. Chair thanks the gentleman.

Chair recognizes the gentleman from Oregon, Dr. Schrader, five minutes for your questions, please.

Mr. Schrader. Thank you, Mr. Chairman. Very good hearing. Probably should have a follow-up, given the breadth of the group in front of us here.

At the outset, I am not someone that blames the pharmaceutical industry or the supply chain for the problems we are seeing. This is just an outgrowth of industry developments and the innovation that's out there, as pointed out, a lot of the starts on these innovative drugs fail -- you know, 90 percent failure rate.

That's not generally a good business model. But these guys do it because they care about the marketplace and there, hopefully, is a profit to be made at some point in time. I would remind everybody that pharmaceuticals are not the highest cost in our health care system.

But at the same time, they are one of the fastest rising costs and my guess is they will continue to increase in cost because of the tremendous excitement and innovation in precision medicine. It's wonderful.

I mean, things -- as a little old country veterinarian that I had to do and I now look at as almost a barbaric kind of way

are going to be so refined that people will not have some of the great side effects that we see today in the marketplace.

But having said that, we are also stewards of the taxpayer dollar and as things get expensive and we have this wonderful opportunity in this country and hearing everybody talk about innovation that's now occurring in particular in this country that's great.

But we have to be able to afford things and therefore we have to ask some tough questions and hopefully work on how do we all together make this medication at least slightly more affordable to the taxpayer and, frankly, to folks in the individual marketplace also.

So having said that, Mr. Davis, can you talk to me a little bit about the REMS issue and restrictive access abuse -- that sort of thing. Why, in particular, do we need an effective enforcement mechanism to address that?

Mr. Davis. Congressman, thank you for the question and I would be remiss if I didn't start by thanking you for your leadership on this issue as well as Congressman Welch.

Mr. Schrader. Mic.

Mr. Davis. I am sorry. My wife would say it's not a problem so --

[Laughter.]

It's important because -- let me start with REMS was created in 2007 as part of the reauthorization for the prescription drug

user fee program then, and REMS, in terms of insuring patient safety is a very important program.

The original statute -- the authorizing statute -- also said that REM should not be used for the unintended consequences of delaying competition from generics.

The challenge we have is that's exactly what, in many instances, it is being used for and the reason that there is no remedy for it is because there is no sufficient enforcement mechanism in the authorizing legislation from 10 years ago, and there have been constant efforts on the part of generic manufacturers in 2012 as part of the first generic user fee agreement that coincided with the reauthorization of the PDUFA.

They came very close. There was a provision in the Senate version that actually would have remedied this issue. It's five years later and it still exists. And if you want a robust biosimilars market and you want to make sure that competition gets to market sooner rather than later, claiming patient safety issues that have never been documented after the FDA certifies generic manufacturers will appropriately handle the samples they need to do the pharmaco vigilance is just an excuse to prolong monopolies beyond their intended effect.

Mr. Schrader. All right.

Mr. Merritt, talking about PBMs, I remember a day 20 years ago when they were, you know, the godsend, if you will, to reducing drug prices and having someone knowledgeable deal with the panoply

of drugs that are out there and getting it.

I would like to think that still exists, obviously, or people wouldn't be using you. There is a supply and demand. The reason they use PBMs is because they think they're getting value.

Some insurers had moved away from that a little bit here very recently and everyone talks nowadays about this black box, and given the fact that you guys have to talk about some of the rebates when you are reporting to Part D and CMS.

Is there a way to inject some transparency in what you do without giving away proprietary information in the private insurance market?

Mr. Merritt. Yes. That's a great question.

Yes, Medicare Part D is a great example because consumers have transparency. They choose their plans. They can see what the premiums are, what the cost sharing is, what the drug selection is of every plan, which is why you have 90 percent satisfaction with Medicare Part D.

I agree with something Dr. Harmon said. It would be nice if there was that transparency in the doctor's office so people weren't surprised -- the physician, the pharmacist, and the patient -- as to what a drug actually costs a patient because Lori is correct, the cost sharing is different for different plans because different plans have different goals and different populations.

So if there was electronic prescribing and doctors and

patients seeing what the actual out-of-pocket costs were in the doctor's office I think that would really help.

Mr. Schrader. Very good. Well, I've got a ton of questions probably like everybody else here and I appreciate all the participants on the panel.

I guess, Mr. Chairman, it'd be nice maybe to have a work group at some point in time, work with all our participants, the patient groups also, about what are some of the best solutions because I don't think there is a silver bullet here that's going to require everyone to get in the -- in the boat together and figure out how do we make sure we still have the most vibrant innovative pharmaceutical market in the world that is increasingly doing amazing things, from my perspective.

Thank you, Mr. Chairman. Yield back.

Mr. Burgess. Chair thanks the gentleman. Gentleman yields back.

Chair recognizes the gentleman from Illinois, Mr. Shimkus, five minutes for questions, please.

Mr. Shimkus. Thank you, Mr. Chairman.

This is a great panel. Appreciate you all being here. I would recommend that we break it down. There's too many -- because I think all of us want to talk to each one of you.

I know you can all come and visit with us but to have that interaction. Some of you are going to get lost in the shuffle and we apologize for that.

I've spent a lot of time in this health care arena on orphan drugs, on antibiotic resistance. So and I, like, some of my colleagues, understand the 90 percent failure rate, understand the R&D.

We want to make sure there is a return. We are the innovators in the world but we just have to -- we have to be careful.

And then we've got these how do you provide lifesaving drugs to a small population that you can't get a return just from selling that drug to that individual. So that's all part of this debate.

The antibiotic thing, which Gene Green and I have worked on, you know, we are floating tradeable vouchers somehow, having the company get some way to get a return on that so that they can have a ready-made supply of something which you, hopefully, don't have to use. Can you imagine asking a company to have something on the shelf that you hope you don't use?

So that's why you all are there for the right reason, trying to make the system work. I am -- I really -- I really do appreciate it.

This transparency debate is also key. It gets us frustrated and you just talk about drug prices in a hospital setting, but the hospital has a federal mandate called EMTALA -- emergency room. Anybody can go.

High cost -- how do they balance that versus an outpatient clinic that doesn't have that mandate of that service? I think you always win with being transparent and then you help educate

the consumer, and then the consumers say, well, that's why I have to pay a little bit more because, shoot, the hospital's paying for this emergency room access, which they have to do.

So health care is a most challenging and frustrating payment process that we have and many years I tried to stay off this committee because I didn't want to deal with it. They kept throwing me back on so I am stuck with it.

[Laughter.]

But I want to -- I really want to talk to one provision too that I hear. I want to go to the local pharmacist. I think one provision that just really gripes me is this clawback issue.

So here's what happens. Doctor gives a prescription to a patient. A patient goes to a pharmacist. They pay the transaction or the insurance, and then months later tell me what happens. It's hard to believe.

Mr. Hoey. You're leading right up to it, Congressman, exactly to the punch line. So months later, the money that the pharmacy collected from the consumer is taken back by the insurance plan, or the PBM.

So for --

Mr. Shimkus. And the drug probably have already been consumed.

Mr. Hoey. Hopefully it's worked and that patient is doing fantastic on it. But the payment is still in play.

So the pharmacy basically is forced to act like a mule to

take the money from the patient and then that money is then clawed back from the pharmacy to the health plan or the PBM.

Mr. Shimkus. Can someone tell me why? Can someone defend that practice? Do you really want to try?

Mr. Merritt. No. No, I am actually -- we don't defend the practice. It's an outlier behavior. It's something that is outlier behavior in the industry and we understand frustrations on that. And to the degree it exists, it exists rarely and hopefully more rarely in the future.

Mr. Shimkus. Well, when our local pharmacists come to see us, especially the community-owned small ones, they show us. They show us the bill.

They show us the receipt, and it's -- so I hope that people are listening to the hearing and saying -- and saying, we got to fix this because it's just not right to offer a service, pay the -- pay the cost and then for someone else later on to say, oh, you got to give us money back because whatever parameter. It's not truth in advertising.

It's not truth in billing, and I am tired of it. I really am and I hope it gets fixed.

With that, Mr. Chairman, I am going to yield back before I get more angry.

[Laughter.]

Mr. Burgess. The chair thanks the gentleman. The chair would remind the gentleman that he was the ranking member of this

subcommittee when we were in the minority and I was down on the first row. So he's got a lot of time in service here.

[Laughter.]

Chair recognizes the gentlelady from Colorado, Ms. DeGette, five minutes for questions, please.

Ms. DeGette. Thank you, Mr. Chairman.

Over the last six months, as many of the these panellists know, I've been working with Congressman Tom Reed, who is my co-chair of the Diabetes Caucus on what's going on with insulin prices around drug pricing.

And what we've learned across the drug chain -- the whole drug chain is that there is a lack of transparency, which we've been talking about a lot in the hearing today, and we've also learned that there is a lot of finger pointing, which we've also seen in this panel today.

It's kind of good. It's frustrating to have 11 witnesses but you hear all of that. And so I want to kind of focus on this issue of the complex web of financial and contractual relationships between the players here with the idea that maybe we can get to some more transparency and the ultimate goal being to help the patients.

Ms. Reilly, I heard you talking about your view of how the market is working in your opening statement and I agreed with almost everything you were saying but you left one things out and the thing you left out is why the price of insulin is $400 to begin

with.

Now, I know there is a lot of different delivery systems. There's a lot of different kinds of insulin. We've moved away from the animal insulin. We don't have a generic yet, although that's coming soon, et cetera, et cetera.

But some would say it's not just -- it's not just the other players. PhRMA has a role in this, too.

So I want to ask you and two other witnesses a very simple question as we go forward, and that is this. Will PhRMA, AHIP, and PCMA each agree to work with your member companies to share information with us about your contract with other supply chain players including sharing specific examples of contract terms?

Obviously, I don't want to undermine confidentiality. But until we know what the contract terms are it's really hard for us to get that transparency.

Yes or no, Ms. Reilly.

Ms. Reilly. Well, we as --

Ms. DeGette. Yes or no would work.

Ms. Reilly. I don't have access to those contracts, Congresswoman.

Ms. DeGette. Can you work with your -- can you work with your members to try to get us that information?

Ms. Reilly. You -- you could probably work independently with them. As a trade association, we are not -- cannot be privy to confidential information.

Ms. DeGette. You're not going to help.

Okay. Mr. Merritt, can you help us with that?

Ms. Reilly. It's a violation of anti-trust.

Mr. Merritt. Yes. Yes.

Ms. DeGette. Okay. And Mr. Eyles, can you help us with that?

Mr. Eyles. Yes.

Ms. DeGette. Okay.

Now, I want to -- I was listening with great interest to Mr. Guthrie's questions about the -- about the PBMs and I want to ask you a couple of questions, Mr. Merritt, about this because I heard you say that the rebates always go back to the consumers.

But I know from my investigation they don't always go back to the consumers in the -- in the form of lower drug prices. Isn't that correct? Yes or no.

Mr. Merritt. Well, yes in the sense that --

Ms. DeGette. Thank you.

Mr. Merritt. No, but we give the rebates to the plans and then they sometimes --

Ms. DeGette. Right. But they don't always go back in the form of lower drug prices.

And -- and so I want to ask you sometimes the PBMs actually make money off of the rebates paid by the pharmaceutical companies. Is that correct?

Mr. Merritt. That totally depends on the client. The

client --

Ms. DeGette. But it could be -- it could happen, right?

Mr. Merritt. If the client wants that to be that way.

Ms. DeGette. Yes. That answer is yes.

Now, my understanding is that some of your member clients pass some but not always all of the rebates onto their insurance or employer clients. Is that correct?

Mr. Merritt. It's determined by the insurer but --

Ms. DeGette. Right. That's correct. Some do, some don't.

Mr. Merritt. A hundred percent of the -- 100 percent of the big employers requires 100 percent pass through of those rebates.

Ms. DeGette. But not everybody, right? Not everybody?

Mr. Merritt. Probably because they don't want to.

Ms. DeGette. Right. That answers -- yes. Okay.

Is it true that PBMs sometimes make money off administration fees paid by pharmaceutical companies that are separate from rebates?

Mr. Merritt. There are different fee agreements and there are different ways that we have to work --

Ms. DeGette. And so the answer to that is yes, too, isn't it? I am sorry?

Mr. Merritt. Yes.

Ms. DeGette. Thank you.

Now, do your member companies sometimes include price protection clauses intended to insulate PBMs from drug price

increases in your contracts with pharmaceutical companies?

Mr. Merritt. They're intended to insulate our clients from price increases.

Ms. DeGette. And so that answer is yes, right?

Mr. Merritt. Well, our clients. So I guess it would be that was there to insulate our clients from price increases. They want those there.

Ms. DeGette. Okay. Member companies sometimes include price protection clauses intended to insulate PBMs from price increases in contracts in pharmaceutical companies -- yes or no?

Mr. Merritt. I guess it would be no.

Ms. DeGette. Okay. Do these price protection clauses sometimes allow your member companies to make additional money through clawbacks when a drug's price increases?

Mr. Merritt. I am not aware of that in the clawbacks.

Ms. DeGette. Yes. So if a drug price increases they can get clawbacks. Ms. Reilly, you were nodding.

Mr. Merritt. Oh, I see.

Ms. Reilly. Well, I was -- yes, I actually have a document right here and it states Express Scripts has more than 90 percent of brand manufacturer contracts include price protections.

Ms. DeGette. Can I get a copy of that?

Ms. Reilly. Absolutely.

Ms. DeGette. And Mr. Chairman, I would like to put that into the record.

Mr. Burgess. Without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 12**********

Ms. DeGette. Okay. Now, I have -- Mr. Chairman, as you can imagine I have many more questions and I apologize for making you answer yes or no. We have five minutes.

I am going to submit these to the witnesses and I thought the idea that Mr. Schrader had to have a task force is an excellent idea.

Thank you. I yield back.

Mr. Burgess. Chair thanks the gentlelady. The gentlelady yields back.

The chair recognizes the gentleman from Ohio, Mr. Latta, five minutes for questions, please.

Mr. Latta. Well, thank you very much, Mr. Chairman, and to our panel, thanks very much for being here today. It's been a very, very interesting discussion we've been having this morning.

Several years ago, I sponsored the legislation on track and trace, you know, to make sure -- you know, from making sure that we don't have adulterated counterfeit drugs entering the market. So this has -- this has been a really fascinating hearing that we've been having today.

And I am also working on legislation right now to modernize and reform the FDA's OTC monograph system. I would like to talk a little bit more about that to see how we examine ways to modernize the regulatory infrastructure of the prescription drugs.

As members, I believe we should always be looking for avenues to reduce burdensome regulation, foster innovation, spur

competition, and provide certainty for consumers and businesses.

And as we go forward, how can Congress help modernize the regulatory infrastructure at the FDA in order to bring these new medicines to market in a quicker manner? Because we had the hearing earlier this fall that was really fascinating to see how long it's been taking, you know, going back to 1972 when you are looking at 45 years.

So Ms. Reilly, if I could ask you, you know, what can we do as members as we look at legislation to help modernize this infrastructure at the FDA?

Ms. Reilly. That's a great question, and I would congratulate this committee on recent passage of the Prescription Drug User Fee Act, PDUFA and GDUFA as well, because that's a significant step forward in terms of modernizing the agency.

I also think Commissioner Gottlieb has done a number of things on his initiative to move this in the right direction.

There are a handful of areas that I think still need further work. Combination products -- EpiPen has come up on a number of comments here before and I think more needs to be done to ensure that when we have combination products, be it auto injector products like EpiPen that you have got two different parts of the agency that need to work more closely together so that we can spur competition, get those products to market sooner.

I think innovative clinical trial design is another area. As was mentioned before, the medicines that are coming to market

are very different than the medicines that came 20 years ago. And so we need to modernize clinical trial design and the regulatory tools that are used to review those products as well.

And then I would say we need to continue to advance prescription-focused drug development. Having the patient at the center through the process of the Food and Drug Administration is vitally important but ensuring that patients I also heard as reimbursement decisions and coverage decisions are made -- are equally as important.

Mr. Latta. Thank you.

Mr. DiLenge or -- and Mr. Davis, would either of you like to comment on ways in which the FDA modernization or increased generics on the market would also help benefit our consumers and the patients out there?

Mr. Davis. Congressman, thank you for the question.

Yes, and then first I would second the recommendations that Ms. Reilly made. I think relative to the generic market, again, the leadership of this committee to pass the user fee agreement for the generics, we are only in -- really, are at the beginning of our sixth year of the user fee program with the FDA. The brands had a 20-year head start in many ways.

So that system is much more refined. I think there is a shared both commitment and responsibility between our sector and the agency to make sure that we are driving as much effectiveness and efficiency through the generic and biosimilar approval

processes.

A simple example is first cycle approvals for generic applications historically have been very, very low -- abysmally low. Under the leadership of Dr. Gottlieb, that has already begun to change.

Mr. Latta. Let me ask you this. Why has this been so, you know, dismal in the past? What has caused that?

Mr. Davis. Quite frankly, I think if you look back I would certainly say on behalf of our members through the first GDUFA implementation the first five years engagement between the FDA and the industry in the first couple of years as the Office of Generic Drugs probably could have been more robust and mutually productive.

By the time the FDA started having goals -- associated time line goals associated with approving ANDAs, they were well on their way to have already built OGD.

The aggressive time lines in GDUFA too -- eight months for a priority review, 10 months for a standard ANDA -- will go a long way towards enhancing competition, getting ANDAs approved and then getting that competition out to the market.

Mr. Latta. Mr. DiLenge, would you like to comment?

Mr. DiLenge. I would just completely agree with that. You know, we've learned a lot on the innovator side about how you improve first cycle approvals by the -- by the FDA. That is critical to getting even more brand to brand competition in the

marketplace.

We are doing that now on the -- on the innovators side. The generic industry, I think, can learn a lot from what we went through over the last 20-plus years of GDUFA and really learn with the new GDUFA how they can interact with the agency in a better way to get more generic drugs through the process quicker on the first tray.

Mr. Latta. Thank you very much, Mr. -- Mr. Chairman. My time is about to expire and I yield back.

The Chairman. Would the gentleman yield?

Mr. Davis. If I could just add one follow-on comment?

Mr. Latta. Go ahead.

Mr. Davis. It's critically important for us to get more ANDAs approved earlier. Then we also need to make sure that there is a market where the license -- those holding those licenses will go to the market and not be tied up in endless delay through patent filings, extensions, evergreenings, and product topping as well.

That is -- where Tom and I would disagree is that is increasingly a significant issue that's keeping generics and biosimilars from the market.

Mr. DiLenge. And we do respectfully disagree with that. There is really no data to show that.

Mr. Latta. Thank you. And now, Mr. Chairman, my time has expired and I do yield back.

Mr. Burgess. Your time expired a long time ago. But I do

-- I need to recognize -- I need to recognize the chairman for an informational message.

The chairman is recognized.

The Chairman. Yes, I -- thank you, and with the indulgence the committee, I know a couple of members have asked about we need to have a work group. We need to have some sort of rump group to address this issue.

Consider yourself on it if you are on the Health Care Subcommittee. That is the job of this committee. That is the job of other committees -- subcommittees that are looking at other things. The ONI Committee is looking at 340B issues, about to issue a report.

But this is where we are going to do regular order right here on the Health Subcommittee to look at the issues that you all are helping us get a better handle on and I think there may be an opportunity to come back after the 1st of the year and continue this discussion.

It, I am sure, isn't the most fun thing for all of you to be at the same table together but it sure helps us, have you each go back and forth and tell us your points of view.

And so I appreciate the committee's indulgence. But the notion we are going to have a splinter group go off and do something, put a nail in that one because this is the splinter group.

This is the Health Subcommittee. This is the Energy and

Commerce Committee and we are going to go through regular order to get the answers that will work for consumers.

With that, I yield back, Mr. Chairman.

Mr. Burgess. I thank the chairman for the observation. This is indeed the smoke-filled room.

The chair recognizes the gentlelady from California, Ms. Eshoo, five minutes for questions, please.

Ms. Eshoo. Thank you, Mr. Chairman, and I want to thank Chairman Walden for the comments that he just made because it's important that the work not only begin here but that the members are responsible for shaping a policy around what we are discussing, which is so important.

I want to thank all the witnesses, all 10 of you. Because I've listened to most -- just about every -- well, everything since we began, it's a good exercise to just sit still and to listen to the questions that are asked and the answers that are given.

Here are my observations. Number one, and I am proud of this -- the United States of America and its genius has produced lifesaving drugs not only for people in the United States but for people around the world.

So the research, the development that comes out of both the biotechnology industry, the pharmaceutical industry are really very, very important and I am proud of the work that I've done over the years to help advance that.

I am a firm believer in it. The other observation I have

is if we were starting from scratch and you all designed the system that you are here to talk about today, it is -- it really sounds like a Rube Goldberg plan, I have to tell you.

You know, and I don't blame any one of you. You're all -- you have told your story. You're sticking to your story. But the fact of the matter is is that it's not working well at all and it's not healthy to have the antipathy in the country against you.

It's a very unhealthy thing. It really is, because on the one hand, people need the drugs. We had members speak to their own conditions and what they need to take.

So this is crying out for reform. This is crying out for reform. And I think what I would just put you all on notice on -- about is that we are going to reform. We need to reform. We have to answer to our constituents.

We have to answer for what the costs are in the system that we oversee. The federal government is the major player and payer in the United States of America when it comes to health care.

So there is going to have to be some give and take on these issues. Mr. Davis, I just want to say something about REMS. Yes, it put into place in 2007 and it was put into place to protect patients. You know that.

Now, the FDA is the one that identifies the issues that need to be identified relative to safety and it's why we have REMS. I mean, one of the drugs that comes to mind is sodium oxybate,

commonly called the rape drug.

So you said some things about REMS that I don't think are really accurate because the safety relative to these drugs that are very, very dangerous if they get into the wrong hands -- that we all need to gather around that. That's a must.

That's not a Republican issue, a Democratic issue. It's there for a very good reason because those drugs, as I said, if they fall into the wrong hands it's dangerous.

I want to thank pharmacists. I have to tell you, in my community in California and Silicon Valley it's very difficult to find a small druggist anymore. They're gone. They're gone. They're gone. It's all the big guys now.

And I am not saying that they may not be doing a good job for people to get their prescription drugs. But I can't name one small druggist anymore including a cousin of mine that was in the business his entire adult life.

So that says something about money because money is part of the business, and I think that that's a real loss in my communities and I guess communities in different parts of the country.

And to our friend at the end of the table, I think that you are a walking advertisement for the good things we did in the ACA because you would not be covered for anything in terms of what you are going through were it not for the reforms of the insurance industry that we took on in order for you to be covered and at least have peace of mind that you have coverage and that their

-- the lifetime limit caps were lifted as well because of the horrendous costs that pile up very quickly when you are dealing with what you are dealing with and I really -- I wish you well.

I really wish you well, and thank you for bringing together people on a bipartisan basis. We need you to work with us and congratulations on not being dependent on the money of anyone that's involved in the industry because it then actually, I think, diminishes or brings questions, you know, to the effort.

So thank you to all of you and those are my observations. But I think that they more than hint at the work that we need to do because this is -- if there were a chart that was brought into the hearing room today, starting with the top -- research, development, and then where it goes and who's involved at every level -- it would outdo Johnny Carson's roadmap that he used to point to.

So thank you, Mr. Chairman, and I look forward to being a part of the solution at this -- at this committee relative to the cost of drugs in our country.

Mr. Burgess. Gentlelady yields back. Chair thanks the gentlelady.

The chair recognizes the gentleman from New Jersey, Mr. Lance, five minutes for your questions, please.

Mr. Lance. Thank you very much, Mr. Chairman, and my thanks to the panel.

Ms. Reilly, CMS recently announced in a proposed Part D rule

that it wants to require Part D sponsors to pass through a portion of manufacturer rebates and pharmacy price concessions at the point of sale.

What is the ideal way in which you think this should function?

Ms. Reilly. Well, thank you for the question and I think it is important and this is an important step I think that CMS is asking for information on this very issue.

I think when Part D was originally designed the notion was just that, that the discounts and rebates that are negotiated -- and they are significant in Part D -- they're larger than in the commercial marketplace -- find their way back to patients at the point of sale.

Today, those dollars are used by health plans and, you know, not disagreeing with keeping premiums low is an important goal. We believe, however, in work that we've done that not only could discounts and rebates get passed back to patients, that we could do it in a way that actually saves the government money -- you know, upwards of $20 billion over 10 years if we are able to pass those discounts back to patients because it will delay the time in which a patient enters the catastrophic phase of the benefit where the government picks up a large share of the cost and it will also lower the amount that the government is paying for low-income subsidies.

I think the proposal that was put forth in the CMS request I think needs some fine tuning. They talk about pass through of

discounts through a class of medicines.

We think it actually would work better if it was done on an individual product basis because, quite honestly, companies are not all that interested in providing greater rebates if they're going to be enhancing their competitors.

Confidentiality is important, I think, to make this work. But I would argue this is a good step forward and could be transformational into changing some of the misaligned incentives that exist in the system today that, again, as CMS has previously noted, encourages insurers to pick drugs with high list prices and high rebates.

We want them competing on delivering drugs that provide the best value at the lowest net price and this is a good step in that direction.

Mr. Lance. Would anyone else on the panel like to comment? Yes, sir.

Mr. Merritt. You do see some point of sale rebates happening in the commercial market where you have the whole health plan want to say, hey, look, we will raise premiums slightly in order to do that.

We are seeing that happen there. In Medicare it's difficult because CMS has noted this would raise cost to taxpayers by about $80 billion and would increase premiums for patients. And the reason that happens is because Part D reimburses plans based on the premiums and if the premiums go up so does the cost to the

government.

And so I think when you think about point of sale costs you shouldn't think about it in terms of reducing costs overall. It doesn't reduce costs overall.

It just shifts costs to taxpayers if it's done wrong in Medicare and from healthy people to sicker people who need the medications and that's a policy decision as to how CMS wants to approve it -- look at it.

One thing CMS said is if they do approach this they want to do it in a cost-neutral way. I think that's the thing that we are working on right now is trying to figure out how that would even happen.

Mr. Lance. Thank you.

Yes, sir.

Mr. Hoey. Congressman, we would say that the rebates allow for shell games to be played and because of the rebates those are often an unreliable -- I mean, we do support pass through to the point of sale.

However, we believe that it enables shell games if it's not properly monitored and already we are starting to see rebates being relabeled.

So what was a rebate yesterday is no longer a rebate. It's an administrative fee. It's some different category so it doesn't fall into that rebate bucket.

So it's -- there is a lot of shape shifting going on in the

-- that further complicates the pricing of the product.

Mr. Lance. And whose responsibility should it be to make sure that that does not continue to occur? Does that require a statutory change or purely a change from the executive branch, in your judgment.

Mr. Hoey. I think it would require a statutory change for that to happen. I do not think that the -- that CMS -- I can't speak for them, of course, but I don't know that they would say they have the regulatory authority to really police that.

Mr. Lance. Mr. Mitchell, you wanted to comment?

Mr. Mitchell. Yes, Congressman, if I may, please.

I just want to bring it back to the patient impact of those out-of-pockets paid on retail rather than rebate. The 12 highest out-of-pocket costs for drugs on Medicare Part D annually range from $4,4000 a year to almost $12,000 a year.

This really hurts people whose median income is around $26,000 a year. We need to fix something in the system and the proposal from the Trump administration to allow the point of sale price paid by patients to be based on rebate if not retail is a good step in the right direction.

It will move some money around unless you change benefit design. But we think the tradeoff is great to help people who are bearing the greatest burden and spread it a little more, even though it may have a slight premium impact.

Mr. Lance. Well, thank you. I got through one of five

questions and I am already over time.

I yield back. Thank you.

Mr. Burgess. Chair thanks the gentleman.

The chair recognizes the gentlelady from Illinois, Ms. Schakowsky, for five minutes for questions, please.

Ms. Schakowsky. Thank you for holding this hearing today, Mr. Chairman.

I think it's long overdue that this subcommittee and committee work on skyrocketing drug prices.

AARP reported that in 2015 the average drug price was $13,000 per drug for a year's supply and that's almost of a quarter of the median U.S. household and four-fifths of the average Social Security benefit.

Now, of course, not all of that money is out-of-pocket costs. But somebody ends up paying.

Mr. Eyles, I want to ask you a question. Does the insurance industry have meaningful input into the list price?

Mr. Eyles. No. We don't have any input into the list price.

Ms. Schakowsky. And does the insurance industry have any information about what the various factors that go into it including how much spending goes to research and development?

Mr. Eyles. No, that's not reported.

Ms. Schakowsky. So let's take Sovaldi for a minute. Gilead bought Sovaldi for about $11 billion, investing zero dollars in R&D, and made about $11 billion in year one by jacking up the list

price to $84,000 per treatment-per cure, really.

We learned this from Dr. Gerry Anderson, professor of public health at Johns Hopkins University. Dr. Burgess hosted him at a round table.

And according to a Senate investigation, we found out that Sovaldi's business model was to reach about 20 percent of the people with Hep C. There's one out of five people who might be able to afford it, and that includes people on Medicare.

If their co-payment would be $5,000 they probably couldn't afford it. And the rest of the people, well, too bad.

Insulin -- we talked a bit about insulin. Mr. Eyles mentioned the decade increase. What I had was about 300 percent including the percent -- including the period, by the way, that Alex Azar, who is now nominated to head HHS, was at Eli Lilly. And we know the names of people who died because they could not afford to get the insulin they needed.

You know, so this business model, this idea that we can just jack up prices past what people can afford, I wondered if our consumer could speak to that for just a minute.

Mr. Mitchell. Well, it's not just insulin. Insulin prices have gone up 300 percent over the past 10 years and it's because we have an oligopoly that controls the price of insulin. They move their prices in lockstep and they increase prices because they can.

But you should also look at other drugs like multiple

sclerosis drugs.

They have increased 500 percent in price from 2004 to 2017, and when PhRMA says actually, you know, our treatments are lowering cost of care, in 2004 the drugs accounted for 50 percent of treatment costs for multiple sclerosis but in 2017 they account for 75 percent of treatment costs.

The drug I was on for five years called Revlimid, made by a company called Celgene, increased its price this year by 20 percent. This is a drug that was invented in the 1950s and which is being kept off of generic is preventing a generic.

Ms. Schakowsky. So -- excuse me, so is your point that there was no additional research and development. The price just went up?

Mr. Mitchell. The price just went up. That's all.

Thank you, Congresswoman.

Ms. Schakowsky. Thank you. I appreciate that.

I want to get to the issue of rebates. Pharmaceutical companies talk on TV and if you can't afford -- during these ads that are ubiquitous -- if you can't afford your drug come to us and maybe we can help you and my office, we take advantage of that.

But I wanted to ask, really, yes or no, Ms. Reilly, do drug companies get a tax break for those rebates?

Ms. Reilly. For the donations, yes.

Ms. Schakowsky. For the donations. So if you set a list price that is up here and then you have a rebate to make it cheaper

for some, is it the difference between the list price and the rebate that is considered a donation?

Ms. Reilly. I would have to -- I would have to get back to you on that. I am not sure how that --

Ms. Schakowsky. But it could be as much as $100 billion because that's what you were saying was about the donation. You said $100 billion.

Ms. Reilly. No, no, no. No, no, no.

Those aren't donations. A hundred billion dollars are the rebates that our companies provide in terms of discounts for insured patients, right. That's totally separate from patient assistance programs that help patients that lack insurance. That's a totally different issue.

Ms. Schakowsky. How much is -- how much? How much is that money and -- well, I am over time. I would like to know how much goes into those programs and --

Ms. Reilly. I would be happy to --

Ms. Schakowsky. -- how much of a tax break companies get for lowering the price.

I yield back.

Mr. Burgess. Gentlelady yields back. Chair thanks the gentlelady.

Chair recognizes the gentleman from Virginia, Mr. Griffith, five minutes for your questions, please.

Mr. Griffith. Thank you all for being here. I have to tell

you, though, you all have raised my blood pressure today. Everybody is saying that this is the problem and that's the problem and -- and the bottom line is we have our working group, as the chairman said, which is going to be this subcommittee.

I believe you all need a working group because if you all don't solve this we are going to come in and come up with an answer and it may not be an answer that you end up liking.

Now, one of the things I've heard today that I do like is transparency, and I understand Mr. Mitchell needs the manufacturers of the drugs -- biologicals, whatever -- Mr. Mitchell needs a consumer patient advocate, needs the insurance companies out there -- we all need that.

We need our doctors. We appreciate that. Love my pharmacists. As you all know, I really think they're front line folks for health care and most people, at least in districts like mine that are mostly rural, they've known their pharmacist for years. They trust their pharmacist. They want their pharmacist's input, and we appreciate that.

But here's the question. Without transparency, Mr. Merritt, I can't figure out for the life of me why the insurance companies can't deal directly with the manufacturers and the pharmacists and what value is it that you are adding?

Because what we've got is we got a big black box, and we dump the drugs in and we got all this -- we got people pointing fingers. And I am not going to ask you because that's a question we are

going to have to answer another day. I only have three and a half minutes left. That'll take hours.

But what I am seeing and what the public sees is we've got this big black box called the PBM. They're saying the have to raise their prices so they can then give you a bigger discount and sometimes Mr. Eyles and the insurance companies like that and sometimes you like it and sometimes you get rebates back and sometimes you take money from the pharmacists back after they've already filled the prescription, or the insurance company does.

But it all comes back. For the life of me, if we don't get some transparency in there -- and there must be something you are adding to the system and I look forward to you telling me after the meeting in a written form what that is.

But I think we have to have some transparency so the average citizen in the United States understands why it is that you all are up here pointing fingers at one another and it comes back in big part to what's going on inside that big black box called the PBMs.

Now, that being said, on the call back, as I call it, or DIR fees, as you know, Mr. Hoey, I have a bill in along with my friend, Mr. Congressman Welch, and we've introduced a bipartisan bill that would put an end to this retroactive collection fees from pharmacies.

And it's interesting because we heard Mr. Merritt earlier say that's an outlier. But when I hear from pharmacists in

Pennington Gap and in Pulaski and in Salem and in all the small towns in my rural district with 29 jurisdictions that they're having a problem with this, I think it must be the big boys and all of my small pharmacies are the outliers who are getting hit by this. Is that -- has that been your experience?

Mr. Hoey. DIR fees are prevalent across every pharmacy that we know of that does business with Medicare Part D, which is every pharmacy. So DIR --

Mr. Griffith. So it's not an outlier, from your perspective?

Mr. Hoey. No. The consumer co-pay clawbacks, I would not call them an outlier. Those are really one PBM that's doing the most damage there.

But DIRs is across the board. It's suffocating independent pharmacies and it leads to some of the consequences that the Congresswoman from California alluded to.

Mr. Griffith. And, you know, it's interesting because they apparently do this analysis on Part D. I've been reading through the CMS rule analysis and at one point they say, our analysis of Part D plan payment and cost data indicates that in recent years DIR amounts Part D sponsors -- that would be the insurance companies -- and their PBMs actually received have consistently exceeded bid projected amounts and in another part of that analysis it says that that means it goes to their profit line.

Mr. Mitchell and the consumers out there aren't seeing all

that in those savings. That's going to profit. Does that happen a lot, Mr. Hoey?

Mr. Hoey. Oh, absolutely. So the DIR fees -- I think the CMS analysis from January show that DIR -- over $80 billion have been paid in DIR fees over the last six years. And so where those DIR fees are going, some of them may be going to lower premiums. Maybe --

Mr. Griffith. And I suspect some of them are going to lower premiums.

Mr. Hoey. But some of it may not be going to that.

Mr. Griffith. But here's the problem that the American public sees and if I've heard about it I know others have and those may ask questions about it as well and that is I've heard stories -- and they're, you know, anecdotal and people don't want me to use their names and so forth -- where they've gone to their pharmacist.

The pharmacist has told them this is how much it's going to cost and as I think it was Mr. Mitchell testified people are cutting their drugs in half or not taking all their doses they're supposed to, and the pharmacist will say, well, you know, if you pay cash and don't use your insurance you can actually get it cheaper.

Because of all the finger pointing going on down on this end of the table as to who's made the prices go up, you are actually better off to deal outside the system and just buy it for cash.

Have you found that to be true?

Mr. Hoey. That is -- that is correct in some cases, and the pharmacies that do that are taking their business life in their own hands.

Mr. Griffith. I understand that. That's why I can't talk about it.

Mr. Hoey. Yes, sir.

Mr. Griffith. Can't talk about it much. So here's the bottom line, folks. If that doesn't say that there is something stinking in Denmark, nothing else does.

We are going to have to work on it and that's why you see Democrats and Republicans upset today.

I yield back.

Mr. Guthrie: [Presiding.] Gentleman yields back.

The chair recognizes Mr. Sarbanes from Maryland for five minutes for questions.

Mr. Sarbanes. Thank you, Mr. Chairman. Thank the panel.

I want to thank in particular Mr. Hoey for your testimony and for the work of the association. I agree with just about everything that my colleague just finished saying and I hope, as many members have emphasized today, that the message is getting through that on a bipartisan basis we are kind of reaching the end of our tether.

And a lot of it just has to do with trying to catch smoke when it comes to how this pricing works. I mean, we have the whole

chain represented here, I gather, and I listened to all your testimony as I was navigating the traffic coming in from Baltimore this morning.

So I did -- I did listen carefully, and I guess, Mr. Hoey, I would be interested -- anybody else who wants to volunteer -- but transparency is a word we hear over and over and over again.

Are there two or three things -- what are the two or three things -- not to set you up in direct opposition with Mr. Merritt but what are the two or three things in terms of more transparency on the part of the PBMs that you would predict the PBMs would scream the most about if those provisions were put in place?

Mr. Hoey. We've talked about some of them as far as the rebates. That would certainly --

Mr. Sarbanes. Yes.

Mr. Hoey. -- cause, I think, a great deal of consternation. I think also there -- on the generic side -- and Chip mentioned earlier that 90 percent of the prescriptions are generic and there are very few rebates for those 90 percent. However, they're sort of a de facto rebate that the PBM industry has created.

One of those is through the consumer co-pay clawbacks that we talked about. As we indicated, it's not every PBM that does that but it's about a third of the market.

The second is on the MAC prices. So a MAC price is on the generic side and what the PBM does is they set a ceiling for that generic price.

That ceiling varies from -- can vary from pharmacy to pharmacy, from day to day, from hour to hour. So the pharmacy actually has no idea what it's going to be paid for a generic product at any time.

In fact, when the consumer walks in for a prescription, the consumer often doesn't know what they're going to pay for that generic price, for that generic prescription, the pharmacist has no idea, and really, the only entity with the perfect information is in the middle and that's the PBM.

And until the PBM tells the pharmacy what to charge the consumer, the pharmacy has no idea what they're going to be paid and then what to charge the consumer.

And furthermore, with DIR prices now, not only does the pharmacy not know until it processes that prescription, but it still doesn't know until months later when more money is clawed back from it.

So those practices make it almost impossible to run a small business and to predict cash flow, to invest in capital, and to hire employees.

Mr. Sarbanes. I appreciate it. I can't help but see an analogy when we talk about how the prices can change from hour to hour and, frankly, as the PBMs would say that their role is critical and satisfying on demand need for drugs and, you know, the more I listen to it the more it sounds much like the discussion we have of the purchase and pricing of electricity.

We've been doing a lot of hearings in this committee on electricity -- modernizing the grid, how purchasing of electricity has these middle operators that have to assemble the resource and then sell it up the line and so forth.

So that, to me, is a powerful analogy and, frankly, where it gets my head, just to send a shudder through the panel here today, is to the idea of regulation approaching a kind of utility regulation when you come -- when it comes to drugs, which are needed by just about every American at some point in their life. This is something that traffics in the public space when you look at it that way.

So this is where I come from, and somebody on the Republican side said that if these -- if the drug supply chain can't be improved then we may start out in a place that you all don't -- you don't like.

But that's where my head is, and with that I yield -- I yield back.

Mr. Burgess. [Presiding.] Gentleman yields back. The chair thanks the gentleman.

Chair recognizes the gentleman from Florida, Mr. Bilirakis, five minutes for questions.

Mr. Bilirakis. Thank you, Mr. Chairman. I appreciate it. Thanks for holding this hearing and I thank the panel as well.

I want to start off with -- quite a few of my constituents bring this up to me when I am home on the weekends -- what about

the importation of drugs from Canada, are they safe, and is it something -- is an idea that has merit.

Why don't we start with Ms. Reilly, please.

Ms. Reilly. I think there is, unfortunately, a misnomer that importing drugs from places like Canada -- our belief is that oftentimes, particularly when people go on the internet and they think they're buying a drug from Canada it often is not coming from Canada.

In fact, in the past when the FDA did its investigation and ordered drugs from so-called Canadian internet pharmacies found that over 80 percent of them were coming from countries all over the world and many of those were not the medicines that they purported to be.

You know, is it fair to say that if I walked into a Canadian drug store today to purchase a medicine would it be safe? Yes, it would.

But the Canadian market is 10 percent of the U.S. market and has repeatedly said that they don't intend nor will be responsible for supplying the U.S. drug market.

The idea of importation raises significant concerns from a safety perspective. We've heard from every FDA commissioner, both administrations going back for over 20 years.

Trying to guarantee the safety of medicines that are coming in from all over the world is near impossible and would jeopardize a supply system today that has been remarkably safe for Americans.

Mr. Bilirakis. How about Mr. DiLenge? Do you want to comment on that?

Mr. DiLenge. Yes. First of all, I agree, obviously, with everything that Lori said but let me add another dimension to this, which is by importing what are you importing? You're importing basically price controls on American intellectual property that other governments have imposed through their negotiations of drug prices.

They don't negotiate the foreign governments. They impose prices because they're single purchasers, and what they are doing is, because I talked about it earlier, that vast majority of innovation is occurring in the United States.

They are basically imposing price controls on American intellectual property. It should be investigated as a trading practice -- an unfair trading practice -- and we encourage that the Trump administration is trying to look at this finally as a trading practice problem.

Mr. Bilirakis. Anyone want to weigh in? Maybe there is a opposing view.

Mr. Davis. Congressman, I would just add from the generic perspective, and I respect and agree with the safety concerns that both Republican and Democratic administrations have found through the FDA commissioners, there is a practical effect with respect to generics.

Because we have a more robust market-based competitive

environment for generics here in the U.S., generics cost less in the U.S. than they do in Canada. So it begs the question why would you be importing something that's more expensive there?

Mr. Bilirakis. Okay. Thank you. I will move on to the next question.

Mr. Merritt and Mr. Hoey, CMS recently published their 700-page proposal rule for Medicare Part D for calendar year 2019. One component was their -- was their proposed implementation to the drug management program for at-risk beneficiaries from the Comprehensive Addiction Recovery Act of 2016 and that was my initiative -- my provision.

This drug management program, or lock-in, as we call it, is used in Medicare -- of course, Medicaid programs and private insurance currently.

Have you had a chance to review the regulations and what are your thoughts on CMS' proposed implementation? We'll start off with Mr. Hoey.

Mr. Hoey. Yes, Congressman, we have had a chance to take a look at that and overall we support -- we support the way the Part D lock-in program is structured.

We would contrast that on the Medicaid program the prescriber and the pharmacy that the patient is locked into is chosen by the beneficiary and that's not the situation with Medicare.

The Medicare -- in the Medicare plan it would be assigned by the plan. So we are concerned about that freedom of choice

from the consumer.

Also, with the Medicaid plan it's administered by the state and the Medicare program it would be administered, again, by the plan. So we are concerned about that.

And lastly, we would be concerned by -- since the Medicare plan is administering it, any situation where the patient would be locked into a plan that also owns pharmacies or they're locked into their own mail order pharmacies.

Mr. Bilirakis. Okay. Fair enough.

Mr. Merritt.

Mr. Merritt. Sure. I mean, the key with protecting at-risk patients is to make sure that they're going to one doctor and one pharmacy and that -- those two medical professionals are communicating.

The challenge in the past has been doctor shopping and other addiction-related behaviors in which people are dying. It's a real epidemic.

The challenge we see at our first look at this is there are too many processes where you can't simply work with an assigned -- a particular pharmacy in a local area to a beneficiary and that they have, you know, six months essentially to work the system and not be at any particular pharmacy and we think for the at-risk patients -- not for all patients, not for all drugs -- but for at-risk patients on things like opioids, that's a recipe for disaster.

In six months people can literally lose their lives, and the whole goal of this program, I think, is patient safety and I think that's what the president has been talking about, too. We do congratulate -- appreciate your leadership on this, though.

Mr. Bilirakis. Sure. Absolutely. Thank you. I look forward to working with you in the future and get it right because safety is -- if we are not safe nothing else matters as far as that is concerned.

Well, I don't have any more time, unfortunately.

Mr. Burgess. Gentleman's time has expired.

Mr. Bilirakis. Does anyone want to add something --

Mr. Burgess. No. The gentleman's time has expired.

Mr. Bilirakis. All right. All right. All right.

[Laughter.]

Mr. Burgess. The chair recognizes the gentleman from Missouri, Mr. Long, five minutes for questions, please.

Mr. Long. Ahead of Peter? Okay. I didn't realize that.

Thank you all for being --

Mr. Burgess. I thank -- I thank the gentleman for pointing that out. But Mr. Welch is not on the subcommittee. Do I have that correct? And as a consequence, we will hear from subcommittee members first.

Mr. Long. Okay. I --

Mr. Burgess. So you are recognized for five minutes.

Mr. Long. I appreciate it. Thank you. Now that I have one

minute left --

[Laughter.]

-- you know, in 1966 there was a movie, "Ten Little Indians" and when I look at our 10 witnesses here today, you know, they were -- all these witnesses were in -- I mean, Indians were invited -- 10 little Indians -- all these folks were invited to a luxury mountaintop resort where they started getting knocked off one by one from an unseen source. Nobody knew if it was one of them or who did it.

So I am thinking that if we had you all go off for the weekend and come back, whichever one of you comes back next week you'd have the perfect response to all of this and we could get this deal settled.

But it's like Morgan said, everybody's blood pressure gets raised on this. But if you think that the government is going to solve -- but if you think that we are the ones to come up with a solution, I hope that we can figure out something between then and now.

Let's see. Mr. Merritt, I am given to understand that Express Scripts -- one of your members or your members is the only or one of the only PBMs that have implemented a comprehensive opioid solution.

I myself have three friends that I grew up with that have all lost children within the last few years to this opioid crisis and to combat the devastating impact of opioid abuse, which

includes, according to this, a seven-day fill, enhanced fraud, waste, and abuse prevention with providers and pharmacies as well as disposal bags for medication waste.

Can you tell us a little bit more about this program and when your other member companies will be initiating similar programs?

Mr. Merritt. Well, let me talk about it as an industry as a whole, and I do really appreciate those moves by Express Scripts.

I think what we see is that we are able to identify or the PBMs are able to identify people who are at risk. You can look at people who try to get the same scripts filled at multiple pharmacies, have gone to the same doctor to try to get multiple prescriptions.

You can track drug stores that have unusual dispensing patterns or -- which aren't many but they do exist -- and then providers or physicians who have unusual practices of prescribing and with that information you can identify at-risk people.

It really is important to do the most important thing with any addiction is to limit the supply and have monitoring, as we were just talking about with Congressman Bilirakis, of medical professionals.

And, again, this is not for regular people who don't have a problem. This is for at-risk people on particular drugs. Express Scripts has done a lot on that regard. We do see that happening in the industry more.

We are supporting electronic prescribing legislation right

now, which would require these drugs to be electronically prescribed by physicians to a certain pharmacy so that safety could be improved. But, you know, we do see our industry taking a lot of good strides in this.

Mr. Long. In my state of Missouri we don't have a drug registry. We are, I think, the only state that doesn't have it. Our governor has tried to implement that but it hasn't really gotten off the ground.

We are down in the southwest -- at least my district, southwest corner of the state joining Arkansas, Oklahoma, and Kansas, and the doctors that work the late shift on Friday night and Saturday night in these ERs, folks will come up from Arkansas, Kansas, over from Oklahoma -- we are very close to all those states -- and their Dr. White is always retired. Dr. White retired in Arkansas and I really need my opioids.

So they'll come in and they'll want to get their prescription filled. Well, guess what? That doctor has got two choices. He can fill that prescription or, according to Obamacare where you have to rate your physicians, the doctor can say, I am not going to -- I am not going to, you know, fill this prescription for this guy.

I know that, you know, he's addicted to it and he needs help but he doesn't need me to prescribe this. So he doesn't fill it then the guy rates him down on his rating and then he's no longer able to -- so it's a -- it's a huge problem.

So anything that you can share that you can help us with in that regard. Like I said, being the only state that doesn't have the registry it's -- and being right down in the corner where you get three other states that all do and all the folks come in on the weekends, Friday, Saturday night, fill up the ER begging these doctors for their opioids.

Ms. Reilly, real quickly, some call for government -- some call for government negotiation in Part D, framing the issue as if there is no competition in the marketplace or negotiation happening now when nothing could be further from the truth.

Can you tell us about the current role in negotiating the Part D program and how that's been responsible for bringing down prescription drug costs?

Ms. Reilly. Absolutely. I think Part D has been the model of success with regards to competition. Today, as I mentioned before, those three large pharmacy benefit managers, they buy on behalf of 70 percent of all prescriptions in this country and they move their market leverage whether they're buying on behalf of Medicare beneficiaries are those in the commercial market to put additional cost pressure.

They've done it in such a way where we've had high beneficiary satisfaction. Costs of the program are half of what they were expected to be when Medicare Part D passed and premiums have been low.

In fact, there was an amendment offered in this very

committee to try and set premiums at a price of around $50. That's never even gone into effect.

We've never had an average premium that high. I think that speaks to the testament of the private market where there is a significant amount of competition.

I mean, we talked earlier today -- I think the evolution of the Part D program is to ensure that that robust competition and those rebates that are collected get passed back to the beneficiary to lower patient out-of-pocket costs.

Mr. Long. Okay. Thank you.

And Mr. Chairman, I don't have any time but if I did I would yield it back.

Mr. Burgess. Chair thanks the gentleman. Gentleman yields back.

We have been in this hearing a long time and my goal is to proceed without taking a break because then we will have votes on the floor in a little while and they'll want to have to then delay things.

But if anyone does need to take a quick break if you will just do so quietly and then join us back and I think the committee would understand.

So with that, I will recognize Mr. Bucshon of Indiana five minutes for questions, please.

Mr. Bucshon. Thank you, Mr. Chairman.

Mr. Nickles, you seem kind of lonely there. No one has asked

you any questions so I figure I might as well do that.

[Laughter.]

Mr. Nickles. Thank you.

Mr. Bucshon. Yes. I mean, you mentioned 340B. It's a program that I support. I have a lot of rural hospitals that really depend on it.

But I am concerned about the dramatic expansion of the program since the Affordable Care Act and I want to make sure that the program is being used for its original intent.

And in that vein, I want to first remind everyone what the definition of a grantee is so that we know what the question is. Grantee eligible for 340B include black lung clinics, comprehensive hemophilia diagnostic treatment centers, federally qualified health centers, Native Hawaiian health centers, Ryan White HIV/AIDS program grantees, et cetera. You get -- you understand what grantees means.

So what I would -- what I would say is in the interest of making sure that the program is being used for its original intent, would you be supportive of reporting requirements for hospitals similar to what 340B grantees are required to support such as providing the number and percentage of individuals who are dispensed or administered 340B drugs disaggregated by insurance status, and the aggregate amount of reimbursement received for drugs purchased under 340B and/or provide contracts that would verify that a hospital meets the legal criteria for 340B

eligibility?

Mr. Nickles. Thank you very much for the question, and to your point, 340B is a very important program to your hospitals, to rural hospitals throughout the country.

It's worth noting that the expansion of the 340B program, which occurred in 2010, did expand largely to rural hospitals, to children's hospitals, and to cancer hospitals. So the dramatic increase has been because of the additional --

Mr. Bucshon. Fair enough. I mean, approximately half the hospitals in America are participating at this point, right?

Mr. Nickles. Right. Right. Right. Many of which --

Mr. Bucshon. Which means half the hospitals in America must be in rural areas. I mean --

Mr. Nickles. Well, actually almost half are in rural areas. That's correct.

Mr. Bucshon. Yes. Okay.

Mr. Nickles. But also remember that cancer hospitals, children's hospitals, and then DSH hospitals also qualify for the program. So it's more than just rural.

Mr. Bucshon. So the question is, you know, I mean, it seems to me if grantees, the ones I described, have -- and it's complicated, I understand that -- have requirements to justify their participation in 340B that it would only seem fair that pretty much every participant in the program should be able to show that they're benefiting low-income citizens, hospitals that

can't require -- can't buy expensive cancer medicine.

And so the question stands. I mean, do you -- you all support that type of a change? Because right now, as you probably know in the law it doesn't really prescribe that you have to justify where the money that you save is going and the reality is is, you know, in order to make sure, from our standpoint, that the program is being utilized properly we need that information.

Mr. Nickles. Right. So you are correct. The eligibility for the program is in statute and not based on anything else. So there is -- there is subsets of my membership those are the ones who qualify.

Having said that, we think they should all continue to qualify but I do agree that further transparency in terms of where the dollars go is something we are certainly willing to discuss with the committee. We've been discussing it with HRSA for many years.

Mr. Bucshon. Right. That's the point -- you are discussing it for many years but we are not getting to an end point. So the question is it's an up or down -- it's yes or no. You support -- you support transparency and this type of thing or you don't.

I mean, it's -- you know, we can -- I mean, I understand the strategy if you don't support it is to draw this out for -- until we give up and decide not to try to change the law. I mean, it's an up or down question to me.

I am all about transparency. I was a heart surgeon before.

You know, I asked my hospital that I worked at once, hey, what does it cost -- what's the actual cost to do -- a patient comes in, goes to the cath lab, gets a cath, goes to the OR, I do a three-vessel bypass surgery, what's the cost, and they said, well, we can't tell you that. And, honestly, they probably couldn't, you know, necessarily.

So I am all about transparency. You know, if the -- if the consumer knows, if the public knows, what's wrong with that?

Mr. Nickles. Right. No, I would say we are certainly in favor of increased transparency but not in favor of changing the statutory qualifications for the program that would result in rural hospitals being thrown off the program.

Mr. Bucshon. Well, that's not what we are trying to accomplish. It's --

Mr. Nickles. But if you want to talk about transparency --

Mr. Bucshon. It's the -- it's the hospitals in rich suburban areas that are participating, that are buying up medical practices outside of their urban area and then adding all of those practices of the 340B program that I am concerned about.

Mr. Nickles. Right. And, again, those hospitals though still do have to qualify for the program based on the definition.

Mr. Bucshon. Okay. Fair enough.

Mr. Nickles. But I -- but I do want to answer your question, which is yes, we are willing to discuss transparency and try to work on that with you.

Mr. Bucshon. All right. Fair enough.

I yield back.

Mr. Nickles. Thank you.

Mr. Burgess. Chair thanks the gentleman. Gentleman yields back.

Chair recognizes the gentleman from North Carolina, Mr. Hudson, five minutes for questions, please.

Mr. Hudson. Thank you, Chairman Burgess and Ranking Member Green, for holding this important hearing today. Thank you for all the witnesses. I know we've been here a long time. I've gone to the bathroom four times. I haven't seen you all get up. So congratulations on your fortitude.

[Laughter.]

But I do really appreciate this discussion. I had hoped that today we could start peeling back the onion a little bit on this complex issue of the drug supply chain and really start the process of finding solutions and I think we've really taken a really good step in the right direction. I think there is been some great discussion back and forth. I know it is a challenge to have 10 folks at one table.

But I think the ability to have this exchange has been really helpful, certainly for me, and I am excited to continue to work on this, Mr. Chairman.

I would sort of pose this first question maybe to the whole panel and whoever is interested in jumping in. But as more and

more patients gravitate towards this issue we discuss -- that's been discussed several times today about, you know, people moving towards low-premium high-deductible plans, due to the high cost of insurance plans available today. Patients need to be educated on how to best utilize these plans.

Numerous studies have come out recently that show patients are not engaged in normal shopping behaviors such as discussing cost of service, comparing cost and quality services, or negotiation -- negotiating the price of services. Because patients are responsible for the full cost of their health care before they meet their deductible, expensive treatments during the deductible period can result in patients not adhering to their treatments, resulting in worse outcomes.

My question to whoever would like to answer this is what are you doing to educate patients on the tools available to them to lower their out-of-pocket costs specifically as it relates to drug treatments before they meet their deductible.

So, I don't know -- Mr. Eyles, I am sure you want to --

Mr. Eyles. Sure, Congressman. Thanks for the question because it's a really important one, particularly how we engage patients and then consumers so that they have the information that they need.

And, you know, our members are committing to -- committed to developing the tools. Most of them have very robust web-based tools so that people can go on, understand whether their physician

is in network or not, what the differences are between formularies, co-payments, what qualifies for being covered before the deductible.

So at least for most individuals preventive services are covered, you know, before the deductible with no cost sharing so that people can go and get their annual physicals and understand, you know, what's available to them.

One of the challenges that we have, for example, with high deductible plans that are paired with a health savings account -- and, again, our members are very supportive of that -- are some limitations on the ability to cover services that would be defined as preventive ahead of time. So we think there are some important modifications that we could make to HSAs to improve them, make them better.

But our members are committed to having very robust tools so that people understand cost, quality, and the status of their providers.

Ms. Reilly. I would just also add, and I would agree with Matt's comment about the need for a clarification in the IRS guidance to ensure that to the extent employers and others what to be able to offer a high-deductible plan with a health savings account that they can offer preventative services, things like diabetes medicines before the deductible.

I think the other important piece is we know from all of the literature that patients pick a plan based on premium price, and

the lower the premium the higher the likelihood they gravitate towards those plans.

What they don't often realize is by signing up for a low-premium plan they're signing up for a plan with a deductible that may be as high as $5,000 and that they will be responsible for all of the costs until they hit that point.

One of the things that we pushed the previous administration on is to develop an out-of-pocket calculator similar to what exists in Medicare Part D where an individual can enter the information what drugs am I on, what physician do I use, so that they can get a real-life calculation in terms of what their costs are going to be depending on the plan that they pick.

You know, we don't really have that yet today for the exchange plans and I do fear that oftentimes people end up buying plans which are not in their best interest, that aren't going to cover the medicines they need, where their doctor is not in network, and that's a problem and needs to be improved, and transparency that allows patients to make better choices should absolutely be paramount.

Mr. Hudson. Mr. Hoey, did you want to jump in or anybody else?

Mr. Mitchell. I would just add those are both good ideas. I had a patient contact me over the weekend who's taking an expensive subcutaneous drug for her cancer. The price went up $1,400.

She said, I can't get anyone to explain to me why. I don't know who raised my price -- my doctor, my insurer, the drug company. Somehow, there needs to be a way -- all of what Ms. Reilly just said needs to be done but there needs to be a way for patients to get their questions answered.

It could be online. It could be on the phone. But the system is impenetrable for us and somehow something that approximates what happens in other industries where customer service is important needs to manifest itself on drug pricing.

Mr. Hudson. Anybody else want to jump in?

Mr. Hoey. I think -- you know, as far as at the counter that's one area where pharmacists -- we-we are sort of a rare breed in that we know the cost of the drug in some cases. We don't know when we are going to get paid but we know the cost of the drug and we know some -- you know, the therapeutic effectiveness of it.

So we can often help the patient, kind of guide them through, especially when they're hitting prior authorizations that Dr. Harmon mentioned or some of the other hurdles that they hit at the counter. We can sometimes help them with that, especially in those high-deductible plans.

Mr. Burgess. The gentleman's time has expired.

Mr. Hudson. Guess I should have paid better attention, Mr. Chairman. I apologize.

Thank you for the answers.

Mr. Burgess. Well, the only reason I interrupt is the gentleman from Georgia, who has been very, very patient, and the gentleman from Georgia is recognized for five minutes for questions.

Mr. Carter. Thank you, Mr. Chairman, and thank all of you for being here today.

Mr. Merritt, I will start with you. Quite often, pharmacists are complaining about the fact that they're being threatened for mailing or delivering drugs by the PBMs because the PBMs own their own mail order pharmacies.

As you well know, pharmacies get contracts from PBMs unless it's a closed network and they can either accept that contract and the terms of that contract or they can't.

If they accept it, then they can service the patient. If they don't, then they can't service the patient and that's what they're left with.

Just a yes a no answer, if you will, Mr. Merritt -- do you agree that pharmacists should be able to tell patients that if they pay cash for a medication they can get it cheaper? Yes or no.

Mr. Merritt. Yes.

Mr. Carter. You do agree with that? Then why is it that these contracts that I referred to earlier have gag clauses in it where it says that if the pharmacist indeed lets the patient know that if they pay cash it'll be cheaper that they could be

kicked out of this contract and that contract can be terminated?

Why is that? Can you explain that to me? If indeed, as you have said earlier, you are in -- you are in favor of transparency, why are the gag clauses in there? Can you explain that to me?

Mr. Merritt. I don't know, and we as an industry don't defend that practice at all. So, I mean, we want people to pay the lesser of and in fact almost all the plans work together. The PBMs work together with what's called lesser of logic so that automatically the person will pay the less.

Mr. Carter. Then why are the gag clauses in there? Why are they in there if you don't -- if you truly want to take care of the patient, if you truly want them to get their medication why -- why is the pharmacist running the risk of being kicked out of the plan if they -- if they offer this information to the patient?

Mr. Hoey, do you ever get any of your members complaining of this?

Mr. Hoey. All the time. Our members are intimidated and most of the time will refuse to go on the record because of basically a business death penalty if they're caught talking to media, talking too much.

Mr. Carter. Mr. Hoey -- excuse me, Mr. Merritt, during the years through -- 2010 through 2015 CMS has said that DIR growth and rebate growth has grown 22 percent per year whereas the Part D gross drug costs have only increased 12 percent.

Can you explain why that difference is there? Why the DIR

has grown 22 percent but the Part D drug costs have only grown 12 percent? Is there a reason for that?

Mr. Merritt. Well, DIR -- direct and indirect remuneration -- is an important discounting tool in Medicare Part D. The federal --

Mr. Carter. Can you explain why it has -- that difference exists? If the Part D costs have only increased 12 percent, why have the DIR fees increased 22 percent?

Mr. Merritt. Remember that -- sure, and I understand. The PBMs -- we get the discounts where we can. We pass them back to the plans and the plans use them as they see fit.

Sometimes usually they want to reduce premiums. They want to reduce overall cost sharing. It depends on their individual strategy.

Mr. Carter. And how far do these clawbacks of these DIR fees go? Are you aware? How far back do they go? Because I can tell you that my wife's pharmacy in March got a bill for $10,337 that went back not five months but five years.

Now, let me ask you about that. Those DIR fees, did you credit the government or the consumer with that? Did you -- did you go back those five years and credit the government? Because what happens is this.

We got a Part D program that has, as you well know and everyone on this panel well knows, has a doughnut hole in it. You pay so much -- Mr. Mitchell, I am sure you are in this. I am sure you

have Medicare. You pay so much until you get in that doughnut hole, then you have to start paying for it. That means that everyone out here who buys drugs has to start paying for it if you are on Medicare. And when you charge those higher prices -- the list prices we've been referring to it as -- that pushes people into the doughnut hole even more.

Now, listen. It gets even better, folks. What happens next is that when you get pushed out of the doughnut hole, guess who starts paying for it then? The taxpayer. All of us. We get to share in it.

My question to you, Mr. Merritt, are you sharing that? Are you sharing that with CMS to let them know, hey, you need to credit them back with this? Are you?

Mr. Merritt. Yes. CMS is aware of the DIR. They see all this information and they've been very clear --

Mr. Carter. So when my wife's pharmacy got hit for the $10,337, this PBM went back and credited CMS with that and went back to the patient and said, oh, you shouldn't have been in the doughnut hole that quickly -- we are going to go back and reimburse you that? So I just want to know because -- because she's going to ask me tonight about that $10,337.

You know, I mentioned it was $10,337 because that's how much it was, and Mr. Hoey, have you had other -- any other of your members who have experienced these type of things?

Mr. Hoey. Both on the retroactive. We had a call this week

from a member in the Midwest who went back five years, six figures on DIRs. Had another one just this year, also in the Midwest, one pharmacy taken back over $100,000 in DIRs from, really, three different plans.

Mr. Carter. Okay. The last thing I will say is this. All of you said we need more transparency and I will tell you -- Mr. Merritt, according -- I pulled out your mission statement earlier today and it says pharmacy benefit managers reduce prescription drug costs and improve convenience and safety for consumers. Reduce prescription drug costs.

Mr. Merritt. Right.

Mr. Carter. How is that working out for everybody? If it were working out we wouldn't be here now. If it were working out then we wouldn't have had a 1,553 percent increase in prescription drug costs since PBMs started -- 1,553 percent increase.

Mr. Merritt. CMS said the growth was 1 percent last year.

Mr. Carter. Mr. Merritt, transparency is the key. The most immediate, the most significant impact that we can have on drug prices is to have transparency.

Thank you, Mr. Chairman, and I yield back.

Mr. Burgess. Chair thanks the gentleman.

Chair recognizes the gentleman from Vermont. Not on this subcommittee but we welcome you today and you are recognized for five minutes for questions.

Mr. Welch. Thank you very much and thank you for having this

hearing. I thank the panel. It's very helpful.

First of all, this hearing is not about the value of the pharmaceutical industry. They create life-saving and pain-relieving drugs. It is not about trying to stifle innovation. Everyone on this panel wants to support that.

It is about the lack of restraint and the pricing power that the pharma industry has that is resulting in immense heartache for families, and you can create a life-extending pain-relieving drug. But if you kill folks with the price -- you kill taxpayers with the price then it's not accessible.

So I want to talk a bit about that. First of all, my colleagues have talked about transparency. That's essential. The opaqueness of the market works for the benefit of the folks pricing it.

Ms. Gallenagh, you said at the very beginning that the whole chain down the line starts with the list price, correct? And I think a number of people on the panel agreed with that. The pharma companies establish the list price, correct?

Ms. Gallenagh. Yes.

Mr. Welch. They have no restraints on what they can do?

Ms. Gallenagh. I would say that the constraint is only our negotiation which, again, our net price is not what we -- what we earn, right, the list price.

Mr. Welch. Let me ask you this. Just get some things established here.

When a company creates a product it gets a patent, correct?

Ms. Gallenagh. Correct.

Mr. Welch. And it gets a period of exclusivity.

Ms. Gallenagh. Correct.

Mr. Welch. It has a monopoly over that product for a period of time?

Ms. Gallenagh. It can sell that particular product. It doesn't prohibit competing products that have the same effect, for example.

Mr. Welch. That particular product --

Ms. Gallenagh. But we see significant competition well before patent --

Mr. Welch. Do you have a problem answering the question?

Ms. Gallenagh. No, I am just trying to clarify.

Mr. Welch. That product for which you got a patent is something over which you control the price, correct?

Ms. Gallenagh. We control the price in negotiation with the purchaser of the product. Correct.

Mr. Welch. And the price that you set is based upon meeting obligations to shareholders in a return on profit, correct?

Ms. Gallenagh. It is based on a number of factors -- the value the medicine provides and the like, yes.

Mr. Welch. Is it the case that at the end of that patent period that it is something given by public policy in return for -- as incentive for doing the research any of your member companies

have used legal maneuvers to extend that period of original exclusivity in the patent?

Ms. Gallenagh. It's impossible to extend the length of a particular patent. The current system works this way as a result of Hatch-Waxman.

Mr. Welch. Hold on a second. Have you ever heard the term evergreening?

Ms. Gallenagh. I have heard the term evergreening. Of course.

Mr. Welch. And evergreening is extending the life of -- the control. Is that correct?

Ms. Gallenagh. No. Evergreening -- the --

Mr. Welch. Has a company in your industry, in your organizational group, ever paid another company for -- in return for not bringing their competing product to the market?

Ms. Gallenagh. Companies have entered into what's known as a patent settlement wherein a generic company is trying to enter the market before the expiry of a patent.

Mr. Welch. According to you?

Ms. Gallenagh. Excuse me?

Mr. Welch. According to your company. If you pay somebody off not to bring their competing product to market, then you enjoy --

Ms. Gallenagh. The generic company --

Mr. Welch. -- the pricing power of that exclusivity perk.

Ms. Gallenagh. The generic company is trying to bring a product to market prior to the patent expiring. There is --

Mr. Welch. Isn't there an argument over whether -- the patent period is a set period in time.

Ms. Gallenagh. Absolutely.

Mr. Welch. Exactly. So --

Ms. Gallenagh. And it cannot be extended beyond that.

Mr. Welch. It doesn't take a genius to figure out when that period is up. It's called looking at a calendar, right?

Ms. Gallenagh. Correct. But drug --

Mr. Welch. Okay. So are you familiar -- are you familiar with a recent effort by Allergan where they took their products and paid the Mohawk Indian tribe to take, quote, ownership, as I understand it, as a way of having better defenses against competition?

Ms. Gallenagh. They -- yes, I am familiar with that and they used that through a process called inter partes review.

Mr. Welch. Can you give me any other example in the entire economy of the United States where the owner of a valuable intellectual property would pay someone else to take ownership of that product?

Ms. Gallenagh. That has been used in other -- universities have used that, yes. It has happened.

Mr. Welch. And give me a specific example.

Ms. Gallenagh. I can get back to you on it. But I know there

are universities that have --

Mr. Welch. You don't have any -- a specific example now?

Ms. Gallenagh. I will get back to you. I know it exists.

Mr. Welch. Is there anyone here who can justify a practice where a seller of a product, like a pharmacy, after selling it, five months, six months, or a year later has to rebate under a DIR? Can anyone justify that? Anyone -- business model would it work with that situation?

Ms. Gallenagh. If I understand your question, if you are asking whether discounts and rebates are common in industries then I would say absolutely. It is very common for industries to discount and rebate their products. That's not uncommon.

Mr. Welch. So -- all right. So the situation that you've been describing your company could work with if some other -- if that happened to the pharmacy or if that happened to pharma?

Ms. Gallenagh. Different issue than what's happening in the pharmacy. Absolutely.

Mr. Welch. So you justify what's happening to pharmacists?

Ms. Gallenagh. No, I don't justify what's happening in the pharmacy. Absolutely not.

Mr. Welch. All right. Sir, please.

Mr. Davis. Congressman, I just wanted to add for a clarifying point around the patents, you are right, there is -- and to the point that was made, a finite period of time as to when an individual patent is supposed to end.

There is no such limitation on the number of patents filed on a product to extend its monopoly beyond the main ingredient patent that was originally filed and the best example of that is Humira, which generates the most revenue of any product in the U.S. and in the world at $16 billion per year.

In the three years leading up to the main ingredient expiry on that drug, that manufacture filed 50 new patents on that product.

So even if they were ultimately struck down, that company continues to enjoy a monopoly while litigation ensues and that is why it is so important to maintain the IPR process in addition to the court process that we have in federal court.

Mr. Welch. Yield back. Thank you.

Mr. Burgess. Gentleman's time has expired. Chair thanks the gentleman.

And I think we've been through the entire subcommittee with the exception of your chairman so I am going to recognize myself five minutes for questions, and I may not take all five minutes because most of the information has been -- has been put out in front of the public today.

I want to underscore what Mr. Griffith's line of questioning started with and the recent publication from the National Academy of Sciences on "Making Medicines Affordable: A National Imperative," in the preface of that report, which is lengthy, but in the preface they make the statement that public concern has

reached a tipping point, and they go on to cite several examples that may have caused that tipping point to have been reached.

But going further, they say those examples have had a sufficient impact on the health of citizens to attract -- such as to attract sustained public attention and concern.

A September 2017 survey of adult American priorities for Congress through the end of the current year found lowering prescription drug prices to be the highest ranked above minimum wage, reducing the deficit, rebuilding the nation's infrastructure, reducing taxes, or any other of the six items considered.

So Mr. Griffith's point well taken and this has been a very informative panel. I want to thank all of you and I know there have been some differences of opinion. We expected that. In fact, we welcome that.

Mr. Griffith's admonitions that there may be solutions that you -- I mean, you are smarter about this stuff than we are by a lot and you may have solutions that you can arrive at, not necessarily individually but in collaboration.

And I would just submit to you that those solutions may well be better than anything we or a federal agency can impose. But I guess the other side of that is if we are not moving towards some solutions to this problem then there likely will be some type of action, perhaps not by this subcommittee this year, perhaps not by this subcommittee next year, but there will be action taken

whether it be by agency or legislatively.

Now, Mr. DiLenge, I am going to switch gears a little bit. I do want to ask you because some of your testimony -- written testimony is actually fascinating -- Mr. Nickles, in his testimony, gave us a list of several medications that were very high in price and one of them was Keytruda and a drug that was developed for malignant melanoma, and the United States president who was president when I was in medical school -- Jimmy Carter -- publicly disclosed in July of 2015 that he had metastatic melanoma to his liver and his brain. And, of course, I thought the next story in that sequence was a state funeral.

However, a year later, he's speaking at the Democratic Convention. A year ago or a little bit less than a year ago he was at President Trump's inauguration. I mean, it is a fantastic story -- that when Jimmy Carter was elected president I was in medical school. That story would not have happened.

Can you speak to that?

Mr. DiLenge. Yes. It's just one example of so many incredible miracles. There's no other word for what happened with Jimmy Carter.

Mr. Burgess. It's a gift. It's a gift.

Mr. DiLenge. It's a gift. It's a miracle, and that is what the hard men and women who worked in our companies, and again, let me remind you all these are mostly start-up companies.

They are trying to raise capital every day. I will give you

one quick story of one of our companies right on the cusp of success -- started in 2002, has raised $4 billion in public and private investment and partnerships with larger companies.

It spent about $2.5 billion so far in R&D. It is hoping to get its first approval of a dramatically important drug next year from the FDA, and that's after 15 years, okay, of every day working. They've had to -- they've had setbacks. They've had to reduce their staffs because it's been hard to raise capital throughout that whole time period.

This is the reality of what this body does. When it makes public policy it is directly impacting the investment decisions that are being made in companies like this one every day -- can we afford to get that capital, to advance that R&D, to get to the next Keytruda. That's exactly what is at stake here.

Mr. Burgess. And I don't want people to become discouraged from hearing this from the information that we've gotten in this hearing. I am optimistic.

There have been people in my office just very recently, one with a potential gene therapy for a specific type of blindness and one with a therapy for hemophilia. Hemophilia, for crying out loud.

I mean, this was -- this was never something that I thought when I was in training that we would -- that day we would ever see and it will have a profound impact on Mr. Eyles' business because of the ramifications. And these individuals also were

talking about how do we prepare the -- whether it's CMS or private insurance -- how do we prepare the payers for what is in development because, again, I consider it a gift to humanity that they are providing.

Yes, there is going to be cost associated with that, with one of these -- one of these therapies that we're talking about it was a one-time therapy so a lot of research and development costs will have to be recouped on that one injection or one treatment -- whatever it is.

Mr. DiLenge. And I can I just add that, you know, our industry has been criticized over the years for basically wanting people to be addicted to drugs, right, that we just want chronic conditions and we don't ever want to cure people -- we just want to keep them on drugs for the rest of their life.

These new biotech miracles are actually going to cure people and a lot of them is maybe one-time injections of gene therapy. And that is why you have -- when you look at the pricing of those it's going to be shocking. Let's be honest about that. But the value that they deliver is much -- far beyond those prices.

Mr. Burgess. And some of us have urged to allow the things that are in development -- to allow discussions with CMS and payers before the FDA approval just because of the --

Mr. DiLenge. Thank you for your work on that, sir.

Mr. Burgess. -- because it is so important.

And Mr. Merritt, I just want -- you mentioned something in

your response to a question. I found it intriguing. I've been a big advocate of physician drug monitoring programs or prescription drug monitoring programs, I guess I should say -- the PDMPs. I know it's another layer we put on your life, Dr. Harmon. Apologize about that.

But it is useful to know if someone is getting multiple prescriptions. But then you alluded to that with the data that you have available you can know who is at risk even before they might be identified as a risk to themselves or family or their -- or their physician.

So that's pretty powerful information, and I don't know if there is a way for you to share with the person who is providing the care.

But I hope we can find a way that your claims data or whatever we would call it can actually have a profound beneficial impact on what has become a national -- a national crisis.

So, you know, perhaps we will enter into more discussions about that. But that was an intriguing thought that you gave us today and I appreciate that.

So once again, thanks everyone, for being here.

Mr. Green, did you have any concluding thoughts?

Mr. Green. No, Mr. Chairman.

Mr. Burgess. Anything else to add for the record?

I want to thank all of you for your testimony and remind members that there are -- oh, wait.

I need to submit statements for the following for the record: the American Pharmacists Association, Senior Care Pharmacy Coalition, Coalition for Affordable Prescription Drugs, National Multiple Sclerosis Society, Express Scripts, Alliance for Transplants and Affordable Prescriptions.

[The information follows:]

**********COMMITTEE INSERT 13**********

Mr. Burgess. Pursuant to committee rules, I remind members they have 10 business days to submit additional questions for the record. I ask the witnesses to submit those responses within 10 business days of the receipt of those questions.

Without objection, the subcommittee is adjourned.

[Whereupon, at 1:15 p.m., the committee was adjourned.]