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PROFITS OVER CONSUMERS: EXPOSING HOW PHARMACEUTICAL COMPANIES GAME THE SYSTEM

THURSDAY, SEPTEMBER 19, 2019

House of Representatives

Subcommittee on Consumer Protection and Commerce

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 10:30 a.m., in Room 2322 Rayburn House Office Building, Hon. Janice Schakowsky [chairwoman of the subcommittee] presiding.

Members present: Representatives Schakowsky, Castor, Veasey, Kelly, O'Halleran, Blunt Rochester, Soto, Rush, Matsui, McNerney, Dingell, Rodgers, Upton, Burgess, Latta, Guthrie, Bucshon, Hudson, Carter, Gianforte, and Walden (ex officio).

Staff present: Jeff Carroll, Staff Director; Evan Gilbert,

Press Assistant; Lisa Goldman, Counsel; Alex Hoehn-Saric, Chief Counsel, C&T; Megan Howard, FDA Detailee; Jerry Leverich, Counsel; Dan Miller, Policy Analyst; Joe Orlando, Staff Assistant; Alivia Roberts, Press Assistant; Tim Robinson, Chief Counsel; Chloe Rodriguez, Policy Analyst; Benjamin Tabor, Staff Assistant; Mike Bloomquist, Minority Staff Director; Bijan Koohmaraie, Minority Counsel, CPAC; Tim Kurth, Minority Deputy Chief Counsel, C&T; James Paluskiewicz, Minority Chief Counsel, Health; Brannon Rains, Minority Staff Assistant; and Kristen Seum, Minority Counsel, Health.

Ms. Schakowsky. The Subcommittee on Consumer Protection and Commerce will now come to order.

And the chair now recognizes herself for 5 minutes for an opening statement.

Throughout today's hearing, you will hear many different terms used to describe the problem that we are trying to address today -- product hopping, hard switching, soft switching, and evergreening. But whatever the word is, or the phrase, the bottom line is this: drug manufacturers are gaming the system to make more money at consumers' expense, and that has to stop.

Big Pharma says that high-priced and high prices and exclusivity are essential to innovation. But competition is actually more central to innovation, and the opposite of what Big Pharma wants. Experts suggest that about 78 percent of the drugs that get new patents are not new drugs. They are new patents for existing drugs.

Instead of truly innovating, drug manufacturers are taking advantage of the anti-competitive environment we have created by recycling old medicines into new formulas -- into new formations.

The problem goes beyond several bad actors, and you will hear about over -- that you will hear about over and over again today -- Humira, Revlimid, Suboxone, just to name a few.

The 100 best-selling drugs on the market, about 70 percent

have their protective -- had their protection extended at least once, and about 50 percent have had their protections extended more than once. Many companies are actually withdrawing new -- withholding new and beneficial discoveries about their drugs from consumers until they can use the innovation to block competition.

Mr. Carrier's testimony provides a series of alarming examples. One manufacturer's main reason for not seeking FDA approval for off-label uses of their drug was that it "wanted to reserve them for a promotional campaign for its reformulated product."

Another manufacturer obtained FDA approval for a once daily version of their Alzheimer's treatment, but waited 3 years until generic competition for their twice daily drug was imminent before they released it. Big Pharma actually blocked the innovation that they claimed to treasure -- innovation that could have helped patients until the time was most profitable.

I am proud to preside over this hearing in the Consumer Protection Subcommittee because Congress must take direct action to protect American consumers from the deceptive commercial actions that the drug manufacturers take to gouge consumers.

FDA is responsible for protecting public health by ensuring the safety, efficacy, and security of drugs. FDA does not adjudicate patient claims, and I agree with the agency's conclusion that they should not be tasked with doing so. And

though the FTC has brought some cases for anticompetitive practices, it does not have explicit authority to challenge anti-competitive hard and soft switches.

Americans should not have to hope that the FTC can stop Pharma's gaming of the prescription drug market. They should be able to count on it. And Americans should not have to wait years for costly lawsuits to play out and find that the generic has decided to settle with the brand name company for a hefty sum to keep their drug off the market, also known as pay-for-delay.

So I look forward to learning from our witnesses today as I craft a bill to protect consumers from Big Pharma's gaming tactics. This legislation will encourage the courts to view these gaming practices as anti-competitive and discourage manufacturers from engaging in these type of practices to begin with.

So we owe it to the American people, and I will be doing everything I can in my power to do so. So I yield back my time.

The chair now recognizes Mrs. Rodgers, our ranking member for the Subcommittee on Consumer Protection and Commerce, for 5 minutes for her opening statement.

Mrs. Rodgers. Thank you, Madam Chair. Good morning and welcome to everyone to the Consumer Protection and Commerce Subcommittee. I am proud that America has led the world in research, cutting edge therapies, cures, saving lives, and

improving the quality of lives for countless, here in America and around the world.

I am also proud of the work of this committee in passing 21st Century Cures, bipartisan legislation that will continue to keep us on the forefront. This really is an exciting time, but there are so many possibilities for every disease, every condition, and patients should always be put ahead of corporate profits.

So we need to make sure certain companies are not gaming the system to increase profits at the cost of patients. Patients should also be put ahead of government actions that limit access to lifesaving treatment.

Product hooping occurs when a drug company attempts to switch patients from an older version of a drug to a newer version. Sometimes they withdraw the old drug and replace it with a new modified drug. Or they keep the old drug on the market and shift the market towards a new drug with a new marketing strategy.

The concern here is when bad actors use this tactic to game the system and limit consumer choices with unaffordable cost. We should be focusing on addressing those instances without harming innovation. So bad actors who are intentionally acting to monopolize the market and limit patient choice are held accountable.

But not all product withdrawals or modifications are

anti-competitive. Bringing improved drugs to the market to compete with older products is often what we need. It gives patients access to more medications and treatments, and oftentimes in a safer, more effective way to heal.

For instance, there is a drug treatment for degenerative muscular disease that has required a delivery of the needle through the eye. The company later developed a method for doing it in the arm. Now I don't know about any of you, but I think I would prefer to have it in my arm. Yet under some current proposals, bringing the safer and preferred delivery could be labeled "anti-competitive." If a shot in the arm sounds better to you, too bad. Government regulations say no. That is not how it should be.

Increasing access to affordable treatments and prescription drugs usually is a bipartisan issue. The Energy and Commerce Committee unanimously passed several bills this year tackling drug prices. Unfortunately, they were packaged with another group of bills related to the Affordable Care Act that made it partisan when it came to the floor.

But I am proud that this administration has done more to lead in reducing the cost of prescription drugs than, well, any -- probably at any time. In fact, prescription drug costs are coming down in America, and this administration has led in breaking records for the amount of generic drug approvals at the

FDA, bringing down cost.

This year, for the first time in a long time, prescription drugs overall have decreased. And to build on this process, Energy and Commerce, through the Health Subcommittee, should be encouraging our medical companies to invest in R&D that will save lives.

Product hopping fixes that are broad or ambiguous will discourage this. So as we move forward, I encourage this committee to be precise. If we are not, the government will hinder innovation, America will fall behind, and patients -- patients -- will be left waiting for the cures that they long for.

Nearly two-thirds of new drug approvals are for incremental innovations. They should be welcomed and protected, not demonized. On average, each new drug saves more than 11,000 lives each year. If we stop innovating, we risk dire consequences. Improvements from each new drug can also eliminate almost 20 billion in lost wages by preventing lost work due to illness. For every incremental dollar spent on new drugs, total medical spending decreases by more than $7.

Americans benefit from innovation, and our healthcare system saves money because of it. Again, the U.S. is leading the world in medical innovation, developing more lifesaving treatments and cures than any other nation in the world. Our committee has a

history of working in a bipartisan cooperation. Any proposal hopefully considered under regular order must encourage innovation and go after the clearly anti-competitive practices.

Thank you, and I yield back.

Ms. Schakowsky. The gentlelady yields back.

And in lieu of the full committee chairman, Mr. Pallone, the chair now recognizes Mrs. Dingell for 5 minutes for an opening statement.

Mrs. Dingell. Thank you, Madam Chair. Today we are examining an often-overlooked issue in the drug pricing debate known as product hopping or evergreening. As the Energy and Commerce Committee works together, that is important. That is what we should all be proud of, that we have in many cases, to provide relief to Americans from the high cost of prescription drugs. We can't leave any stone unturned in examining ways to address this issue.

All of us have heard from constituents who are forced to cut pills in half, choose between paying for medication and rent, or avoiding taking needed medicines entirely due to cost.

And we can't stop innovating and research, but we need to make sure -- I continue to be horrified for these young children. And we talk about insulin, which is one of the ones we have to talk about, but the inhaler that now costs $700, the EpiPen. People that can least afford it and don't have insurance are many

times the ones that need these medicines more than anybody.

And part of the reason these costs remain so high is due to the loopholes and tactics that some pharmaceutical companies use to delay competition from generic drug manufacturers. Competition is crucial to lowering prescription drug prices and improving America's access to lifesaving medication.

When generic drugs enter the market in the United States, prescription drug prices fall dramatically -- try up to 90 percent. And this is how a market should work, by rewarding the innovation and promoting competition, and then the American people benefit.

Unfortunately, we have been seeing increasing examples in recent years of pharmaceutical companies exploiting the current structure of our Nation's regulatory and patent system to block competition and keep drug prices high through practices like product hopping.

Product hopping or evergreening is the reformulation of a drug by a brand-name manufacturer to delay competition and protect protection for profit. This often just includes minor changes, like reformulating a capsule to a tablet, small changes in the dosing, or the strength of a branded drug, or other changes that have little effect or therapeutic value.

Timed correctly, and combined with tactics like removing the older version of the drug from market or aggressively

marketing the new version of the product, pharmaceutical companies can and do successfully block competing generic products from the market. And the reason that this happens is simple: a blockbuster drug can bring in hundreds of millions of dollars each year in sales while under patent protection.

In fact, a 2016 study found that these sorts of tactics to delay the generic competition cost Americans at least $5.4 billion annually. Currently, there is little recourse against this when it happens. The FTC's authority to address product copying is limited and unclear. And as a result, product copying and similar practices have proliferated in recent years.

It is my hope that today's witnesses will help us all learn more about product hopping, and yet their expertise and knowledge will point us toward a solution that addresses this problem. I want to thank them all for being here.

Inaction on this issue is not an option. High health care and prescription drug costs affect all of us, regardless of our background or party. I know just from having to buy more than 20 different prescriptions for John per month -- and I had two insurances and Medicare -- what that cost is. Think of the mother working two jobs with a child that has asthma and has to buy a $700 inhaler.

This is an issue where bipartisan action is necessary and needed. I know my colleagues share my concern, and it is my

sincere hope that this hearing forms the basis for future actions and reforms.

Thank you for being here, and I yield back.

Ms. Schakowsky. The gentlelady yields back, and now I recognize Mr. Walden, ranking member of the full committee, for 5 minutes for his opening statement.

Mr. Walden. Good morning, Madam Chair.

Ms. Schakowsky. Good morning.

Mr. Walden. Thank you for having this hearing. It is really important. We do look forward to the testimony from the witnesses. Obviously, this committee has a long history of going after these issues and stopping bad behaviors where we have led on surprise medical billing, having a discussion about that, and we passed that out of here unanimously.

We rewrote the full FDA user fee agreements trying to get generics to market sooner. We did that in a bipartisan unanimous way -- I think it passed -- and they were able to put 971 generics into market last year, record number in a single year, and so we believe in bringing competition to the market.

We have jointly worked together on Cures, 21st Century Cures. And, you know, there is more work to be done there going forward, but I think that was pretty much almost unanimous. There were a couple of holdouts I think in the House. But because investing in medical research and all that leads to drugs and new treatments

and precision medicine -- as my friend from Michigan said, these diseases, these problems, hit us regardless of background or party.

We were together in this committee on CREATES, stop bad behavior. Unfortunately, after I left our good committee of Energy and Commerce, it got wrapped up in partisan politics, and the poison pills added on the floor. Otherwise, it would have passed unanimously. The same on pay to delay and fixing that. It got wrapped up and made poison on the House floor.

And I guess as we deal with this issue and get into these individual problems, what troubles me this morning is we have now been told we are going to have a hearing in the committee next week, Wednesday, on legislation to completely rewrite how we get our drugs and what we pay for them and how the government operates.

And, tragically, Republicans have been completely excluded from any of those discussions. Completely. It has been done out of the Speaker's office behind closed doors. And I don't know if you have a copy of the bill, Mrs. Dingell, or Ms. Schakowsky, or anybody else. I don't. We have seen a summary. But it tells me, unfortunately, this has gotten shifted over to be a partisan political issue, not a solution for pharmaceutical costs gone wild.

And I would hope that before we notice hearings, and I would

hope before we take this up next Wednesday, that we would have a chance to read through the bill. I am deeply disappointed we were not asked to be part of any discussions leading up to it, and I know in some of the press clippings I have seen already some of you are not happy, and some of you maybe haven't seen the bill either. But that is no way to deal with both helping our consumers and making sure we don't trash innovation.

We have proven our ability on this committee, this great Energy and Commerce Committee, of coming together on these issues and letting the committee process work. But I think we have all seen in our parties over time, when things get crafted outside of our environs, they don't always get it right.

And then we are going to get jammed with a bill that we are going to have very little time to review, and then come back and I am told mark up and vote on. And I just beg you and plead with you, it doesn't have to be this way. It doesn't have to be this way.

To your point, Mrs. Dingell, these diseases, they affect us all. What you went through with John, what I went through with my parents and my wife's mother, who had severe rheumatoid arthritis. Poor thing passed away years ago, and she had to deal with this her entire life. And we have all been hit by it.

My wife used to carry EpiPens, and then they became so expensive her doc said, "Well, you can probably get away with

a little Benadryl." Our son, as a youth, had an inhaler because he had youthful asthma. Fortunately, he outgrew it.

We all went after EpiPen. We all went after these things. We can all go after really good public policy in this sector, too. But, please, let us be part of it. Let us be part of these discussions.

We have really bright, capable people, as you know, on this side, as you do on your side. Don't exclude us from the legislative process. Don't spring a hearing for next Wednesday and not even give us legislative text, just somebody's document on what it may be or not be.

That is not in the great traditions of this committee, and it is not in the best interests of public health and solving this problem we have. You have a President that is fully committed. I have never -- you can like or dislike Donald Trump; I have never seen a President more engaged on this issue about bringing down pharmaceutical drugs.

There is an opportunity to be had here to achieve grand results that will benefit our consumers, maintain innovation, keep America in the lead. And I hope that partisan politics do not snuff that out. And with that, I yield back.

Ms. Schakowsky. The gentleman yields back.

The chair would like to remind members that, pursuant to committee rules, all members' written opening statements shall

be made part of the record.

And now I would like to introduce our witnesses for today's hearing. Mr. Michael A. Carrier, distinguished professor at Rutgers Law School, and co-director of the Rutgers institute for Information Policy and Law.

We have Mr. David Mitchell, founder of Patients for Affordable Drugs and Patients for Affordable Drugs NOW.

We have Ms. Joanna Shepherd, professor of law at Emory University School of Law.

And Mr. Jeffrey Francis, senior vice president and general counsel of the Association for Accessible Medicines.

We want to thank our witnesses for joining us today. We look forward to hearing your testimony. And at this time, the chair will recognize each witness for 5 minutes to provide their opening statements.

Before we begin, I just want to explain or remind people about the lighting system. In front of you is a series of lights. That light will initially be green at the start of your opening statement. The light will turn yellow when you have 1 minute remaining. Please begin to wrap up your testimony at that point. And the light will turn red when your time expires.

So, Mr. Carrier, you may begin, and you are recognized for 5 minutes.

STATEMENTS OF MICHAEL A. CARRIER, DISTINGUISHED PROFESSOR, RUTGERS LAW SCHOOL, CO-DIRECTOR, RUTGERS INSTITUTE FOR INFORMATION POLICY AND LAW; DAVID MITCHELL, FOUNDER, PATIENTS FOR AFFORDABLE DRUGS, PATIENTS FOR AFFORDABLE DRUGS NOW; JOANNA M. SHEPHERD, PROFESSOR OF LAW, EMORY UNIVERSITY SCHOOL OF LAW; AND JEFF FRANCER, SENIOR VICE PRESIDENT AND GENERAL COUNSEL, ASSOCIATION FOR ACCESSIBLE MEDICINE

STATEMENT OF MICHAEL A. CARRIER

Mr. Carrier. Thank you, Chairwoman Schakowsky, and Ranking Member Rodgers. Thank you for holding this hearing. Drug companies play games to increase profits, and one of those games is product hopping. The product hopping that I am talking about today, if we deal with it, it is not going to touch innovation at all, but it will bring lifesaving medications into the hands of consumers.

My name is Michael Carrier. I am a distinguished professor at Rutgers Law School. I study this area. I have written 115 articles, 60 on pharmaceutical antitrust law. I am quoted in media and courts all the time.

The first point here is that generic competition is crucial. When a generic enters the market, the price can fall 90 percent overnight. And so that is a central part of the Hatch-Waxman Act. The Hatch-Waxman Act says that the generic can rely on the

brand firm's clinical studies because we want to have generics on the market. That does real good.

That is also why we have state substitution laws. Every state in the country has a substitution law that says you can automatically substitute a generic for a brand version, and that is crucial as well.

And the reason we need all of this is something called the price disconnect. There is no other industry where you don't have one party that makes the price-quality determination. You have the doctor that decides what drug to prescribe, and you have the patient or insurance company that pays for it. And with that disconnect, there is a lot of room for anti-competitive games.

Now, it is not the case that every single reformulation is a problem. And Ranking Member Rodgers, I completely agree with you that we cannot go after serious innovations. If you have something that initially is in the eye, and then you do it in the arm, that is a really good innovation. That won't be touched by any of the cases in the court system, by any legitimate legislation that your committee considers. That is a real change.

And, in fact, 80 percent of the changes take place at a time that we don't expect a generic to be on the market, because drug companies make changes all the time, and most of the changes are good. It is just those few bad apples, the few 1 or 2 percent

-- and that is all it has been in the cases, 1 percent of the cases. There is not going to be that much brought.

But in those cases, there is nothing new at all. There is no new customer. There is no competition with another brand firm. All that happens is that the change is made to keep the generic off the market. And so the legislation that is considered here really can be reasonable.

One of the concerns here is that every time that the brand company switches from one version of a drug to another, from a capsule to a tablet, or a 150-milligram dose to a 140-milligram dose. The generic has to go back to the drawing board, reformulate the drug, get FDA approval, be subject to patent litigation, so every single time it is kept off the market for years. And this has significant effects on consumers.

And so one study found that $28 billion worth of drugs was subject to product hopping. In my testimony, I mention several of them -- overpaying $1.7 billion for Namenda, hundreds of millions of dollars for other drugs. I talk about prices that are so high. Adasuve is $4,500. Put together the component parts yourself, it is $45. It really hurts consumers when they have to pay a lot more than they should be paying.

I mentioned the five cases that have gone on in the court system. Let me just mention one -- Suboxone. Suboxone deals with opioid dependency. It is a very important drug. Reckitt,

the brand manufacturer, switched from one version, the tablet, to another version, the film. The tablet was a better version. Consumers liked it better. It didn't have safety concerns. The film, a kid puts in their mouth and it dissolves instantly.

Nonetheless, the drug company said the old version is the unsafe one. Let's pull it off the market, even though it is actually safer. They jacked up the price for the old one, even though it was cheaper to make then the new one, and they knew that they would give up profits, but they just did this to keep the generic off the market.

And so there are some really concerning examples of what is going on here. Of course, we have to worry about innovation, but it is not the case that taking away antitrust liability would help innovation in a lot of these cases. As we have heard, the brand company withholds the innovation for years until the generic is about to enter the market and then it springs it on the market.

There are reasonable solutions here. The Senate Judiciary Committee passed a product hopping bill 22 to nothing, completely bipartisan, deals with hard switches in which the old drug is removed from the market, soft switches in which the old drug stays on the market, gives the drug companies every defense that they could want in terms of showing that it makes some sense at all for what they are doing. So there is reasonable bipartisan legislation to be had here.

So at the end of the day, drug companies call this life-cycle management. It is not. It is really just keeping the gravy train of trivial tweaks flowing. What this committee can do, can really not touch innovation at all, while making consumers' lives better.

Thank you.

[The prepared statement of Mr. Carrier follows:]

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

Ms. Schakowsky. Thank you very much, Mr. Carrier.

And now, Mr. Mitchell, you are recognized for 5 minutes.

STATEMENT OF DAVID MITCHELL

Mr. Mitchell. Chair Schakowsky, Ranking Member Rodgers, members of the committee, I am honored to be here.

I am David Mitchell. I am founder of Patients for Affordable Drugs. More importantly, I have an incurable blood cancer called multiple myeloma, and prescription drugs are keeping me alive. Every two weeks I spend half a day at a clinic getting an infusion of drugs that, unfortunately, are slowly failing.

So last night I started taking a new oral chemo drug. Together, my drugs carry an annual list price of $875,000 a year. I have relapsed twice. Eventually, I am going to run out of options. So the importance of innovation is not theoretical for me. It is literally life and death.

But my experience has taught me one irrefutable fact, and that is drugs don't work if people can't afford them. That is why today's hearing is so important.

Take AbbVie and the cholesterol drug TriCor, Catherine of Minneapolis told us "My price for TriCor went up hundreds of dollars per month. The pharmacist whispered to me that if the doctor had changed the order to 160-milligram tabs and I broke it in half for the 80-milligram dose, it would only have cost

me 40 bucks." Catherine didn't know it, but she was describing a classic case of product hopping.

But to address the problem of out-of-control prices, we really have to come to grips with some larger facts. Despite what drug companies tell us, sky-high prices are not about innovation. Multiple studies show there is no correlation between the costs of R&D and the price that is assigned to a drug. And taxpayers foot a huge portion of the bill for basic science that leads to new drugs.

Every single drug approved by the FDA from 2010 to 2016 was based on science funded by taxpayers through the NIH. Meanwhile, independent analyses show that 9 of 10 drug companies spend more on advertising and marketing than they do on R&D.

Why do drug companies charge so much? Because they can. Yes. As drug companies should make a profit when they develop innovative drugs, but we are way out of balance, and it is costing us all in our family finances, our health outcomes, and our lives.

So I want to suggest three things we could do to rebalance the actual risk of innovation with a fair price for patients. Reform patent law, including provisions to stop product hopping; end the days of monopoly pricing power without taxpayer negotiation; force transparency from drug middlemen.

Let's start with patent law. Brand drug companies are

abusing our system to extend their government granted monopolies and block competition. There is a whole array of tactics. Product hopping is just one.

The classic version has been described by Professor Carrier, so I won't go into that.

When faced with patent expiration and generic competition on its blockbuster drug Suboxone, the maker changed from a tablet to a film that dissolved under the tongue. Professor Carrier described it.

We heard from a California woman named Janice. She was supporting her son recovering from opioid use disorder. During this time, she paid over $250 a month for Suboxone. She was forced to take out a loan and depleted all of her savings to pay for this medication.

Now, there are bills in Congress this year that offer solutions. I would be glad to discuss them in the Q&A. Yes. In all that we do, we have to address -- in all that we do to address product hopping, we have to ensure that we reward genuine innovation and stop anti-competitive practices.

Next, we need direct Medicare price negotiations. We pay two to three times what other countries pay for the exact same drugs. One big reason is that they negotiate; we should, too.

And, finally, we need more transparency around PBMs. These

huge companies cut deals that determine how much patients pay, but it is all secret.

Right now, there is a fundamental question that drug companies want us to ask about drug prices. What are we willing to pay to save a life? And I can tell you, that is easy. When it is your child on the gurney who can't breathe, when it is your cancer, the answer is: anything.

But that is the wrong question. The right question is: what is the amount of money that drug companies should be making on these drugs?

With hundreds of clinical trials underway for exciting new cell and gene therapies that are coming to market at a half a million dollars or as much as $2.1 million, we cannot afford to pay just any price that drug companies demand. Neither American families nor our healthcare system can afford that.

I feel incredibly grateful to be here today, alive and representing patients from all across the country. I believe the moment is at hand that we can address this problem, and with bipartisan support we will.

Thank you for having me.

[The prepared statement of Mr. Mitchell follows:]

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

Ms. Schakowsky. We are glad you are here and alive as well. Thank you for your testimony.

And now I want to recognize Ms. Shepherd for her 5-minute statement. Thank you.

STATEMENT OF JOANNA M. SHEPHERD

Ms. Shepherd. Thank you. Chairwoman Schakowsky, Ranking Member Rodgers, and distinguished members of the subcommittee, thank you for the opportunity to testify today about product hopping and the pharmaceutical industry.

My name is Joanna Shepherd. I am a professor of law at Emory University, and I hold a Ph.D. in economics. My research focuses on various topics in law and economics, including competition and the healthcare industry.

Replacing older drugs for newer drugs is generally part of the normal competitive process. According to the World Health Organization, over 60 percent of drugs deemed necessary for fighting common diseases are the result of incremental innovations.

Most of this activity is pro-competitive. Consumers have access to more products, and newer products are likely to be safer and more effective. We should encourage drug companies both to invest in improving their products and to bring those drugs to market when they are available.

However, when certain conditions are met, some product hops may be anti-competitive, coercing consumers to switch drugs and depriving them of choice. It sounds like this committee is very interested in finding that balance where we are preventing these anti-competitive measures but also protecting innovation that is so vital to the consumers -- American and around-the-world consumers of pharmaceutical drugs.

In this testimony, I am going to focus on how to achieve that balance. My testimony is based on both court decisions and rulings in past cases, and also existing competition law. I will explain that a hard switch that eliminates consumer choice with no offsetting consumer benefit is likely an anti-competitive product hop.

Similarly, a soft switch that significantly interferes with consumer choice, to the point that it effectively eliminates it, with no offsetting consumer benefit, is likely anti-competitive as well.

So when, in a hard switch, is consumer choice eliminated? This happens when consumers are coerced into switching to the new product because there is no available alternatives to the original product. This would occur, for example, if an older drug is pulled from the market right before its patent expires, so that the generics waiting to enter the market could not use automatic substitution laws to penetrate the market of the older

drug. In this situation, consumers would effectively have no choice but to switch to the new drug.

In contrast, a hard switch would not eliminate consumer choice, if it occurred after generics had already penetrated the market. In this situation, patients would already be accustomed to take the generic versions of the drug, so replacing the older drug would not coerce them into switching from the generic they had already been taking.

In fact, in this case, the product switch would be pro-competitive because it would give consumers more choice. They would still have the generic version of the old drug, plus newer drugs available.

A hard switch would also not eliminate consumer choice if brand companies replaced a drug that had plenty of patent life remaining and no generics anywhere on the horizon. This switch would also not reduce consumer choice, because consumers would have had one drug to choose from before and one drug to choose from after.

These examples suggest there is a very specific window during which a hard switch can be presumed to be anti-competitive. For conventional small molecule drugs, this window likely starts around the time a generic files an acceptable ANDA containing a paragraph 4 challenge. The window ends approximately three or so months after generic entry because research shows that

within three months of generic entry, generics have captured about 70 percent of the brand drug's market share. So maybe you want to, you know, flex that a little bit, but it is around that time.

Outside of this window, however, a hard switch would generally not eliminate consumer choice.

Moving on to a soft switch, when is consumer choice significantly interfered with to the point that it is effectively eliminated? This happens when consumers have no practical alternative but to switch to the new product?

For example, if brand drug companies communicate fabricated safety concerns about an older product to doctors, as they did in the Suboxone case, then patients effectively would have no choice but to switch to the new drug.

Similarly, if a brand company destroys inventory of the older drug, the consumers would effectively have no choice. However, a soft switch would not significantly interfere with consumer choice, if the brand company engages in standard business practices that typically accompany the introduction of new products. These include reallocating marketing efforts, offering price discounts or samples, so patients will try the new product, or encouraging doctors in a legal way to direct patients to these new products.

While these practices may shift market share, they do nothing to eliminate the availability of the older drug or to coerce

patients into switching. Moreover, because the older drug remains freely available for doctors to prescribe, generics can continue to take advantage of automatic substitution laws.

So in a soft switch, the degree of interference to effectively eliminate consumer choice will typically require some other wrongful conduct that unfairly disadvantages the original product. If it does not unfairly disadvantage the original product, then patients and their doctors can choose which drug they prefer.

Finally, I will end with a word of caution. Legislation to define what activity constitutes anti-competitive product hopping could potentially reduce healthcare spending and spur innovation by clearing up current ambiguity in the case law.

However, if the legislation is too broad, in that it covers too many standard business practices, or too vague, and that drug companies can't predict what behavior will lead to significant litigation, then the legislation will end up reducing innovation. This can have long-term negative effects on consumer health and healthcare spending.

Thank you.

[The prepared statement of Ms. Shepherd follows:]

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

Ms. Schakowsky. Thank you very much.

And now let me welcome Mr. Francer. I pronounced your name wrong before, and I want to get it right. And you are recognized for 5 minutes.

STATEMENT OF JEFF FRANCER

Mr. Francer. Thank you, Chairwoman Schakowsky, Ranking Member Rodgers, members of the subcommittee. Thank you for holding this important hearing today and for the committee's sustained efforts to bring down prescription drug pricing.

As stated before, my name is Jeff Francer. I am the general counsel of the Association for Accessible Medicines. We are the Nation's leading trade association for manufacturers of FDA-approved generic and biosimilar medicines.

Competition through the introduction of generic and biosimilar methods is a proven solution to lowering the cost of prescription drugs for patients. However, the continued availability of generic medicines is in jeopardy. Current market realities, combined with anti-competitive tactics, threaten the long-term stability of generic and biosimilar manufacturers.

Increasingly, brand name drug companies are building patent thickets around their drugs, not just for the original innovation but for smaller changes that may not be deserving of decades-long monopolies. To cite just one example, Lantus, an insulin

treatment for diabetes, is protected by 49 patents; 95 percent of them were filed after the drug was approved. While Lantus was approved in the year 2000, it has patent protection out now to 2031.

This problem significantly impairs competition and, not surprisingly, increases drug costs for patients. One anti-competitive tactic that we are discussing today is called product hopping. As discussed previously, product hopping occurs when a brand drug company seeks to switch patients to a new version of its drug just before the original one becomes subject to competition.

In many cases, the switch is forced on patients because the brand name drug companies stop selling the original medicine, and this is called the hard switch. The main goal of such switches is not to protect our health. Instead, these switches are designed to extend the brand name drug company's monopoly pricing and to delay competition.

Several cases illustrate the potential anti-competitive effects of product hopping. Namenda is a treatment for Alzheimer's. Ahead of competition, the brand name drug company attempted to withdraw its immediate release formulation from the market. The company then tried to switch patients to its new extended release formula.

The drug company did so knowing that physicians would be

highly reluctant to switch patients back to the earlier formulation if lower cost generics were later approved, and the brand name company's own documents confirm this.

One of the drug company's employees stated, and I quote, "If we do the hard switch, convert patients and care givers to once-a-day therapy versus twice a day, it is very difficult for generics to then reverse commute back."

Another troubling example that we have discussed is Suboxone. In the middle of one of our worst public health epidemics, the brand name drug company delayed patient access to a more affordable version of this opioid treatment. Put simply, product hopping tactics employed by some brand name companies delay generic and biosimilar competition, and this keeps drug prices in the United States the highest in the world.

Here is why. First, product hopping impairs automatic substitution. Under many state laws, a generic can automatically be substituted for the brand name drug at the pharmacy counter if it is therapeutically equivalent to the brand.

By changing the dosage form or the strength of the brand drug, pharmaceutical companies ensure that generic companies will not be therapeutically equivalent and, therefore, not substitutable.

Second, brand name drug companies are able to delay patient access to lower cost medicine by patenting minor modifications.

To address these anti-competitive tactics, AAM supports legislative changes to strengthen competition. Any legislation should be carefully calibrated and not overly broad, as we just discussed.

AAM is supportive of innovation, and we recognize that many changes to existing medicines result in meaningful health benefits.

In closing, AAM encourages the committee to consider several options, including ensuring a date certain for generic and biosimilar competition, accelerating the biosimilar patent dance in the BPCIA, harmonizing Hatch-Waxman with the America Invents Act, requiring more timely FDA action on biosimilar labeling carveouts, and ensuring that generics and biosimilars are fully available to patients.

I describe each of these solutions in more detail in my written testimony, and AAM would be glad to work with the committee on each of them.

And, in closing, I thank you for the opportunity to testify, and I also just learned this morning that today is Mr. Mitchell's 20th wedding anniversary. And I wanted to say for the record, Happy Anniversary.

[Applause.]

Mr. Mitchell. Thank you.

[The prepared statement of Mr. Francer follows:]

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Ms. Schakowsky. Thanks for updating us about that. Congratulations.

So we have concluded witness opening statements, and at this time we will move to member questions. Each member will have 5 minutes to ask questions of the witnesses, and I will start by recognizing myself for 5 minutes.

It is clear from the testimony that we have heard today that Congress has an opportunity to act to combat the gaming tactics of Big Pharma. And I just wanted to say that I do appreciate what seems to be the unanimity of carefully crafting legislation, and that is what I am currently trying to do to prohibit the actions that will soon be considered by the -- these actions considered by the subcommittee.

The legislation has a two-fold purpose. First, it will provide the Federal Trade Commission with authority to take action against a manufacturer engaged in product hopping; and, two, to seek remedies for these tactics, like the collection of unjust profits that a drug manufacturer gained as a result of inappropriate product hopping.

And, second, my bill will allow for greater transparency in drug pricing. The bill will, let's see -- well, the goal of this list is to provide the American taxpayers with the transparency that they deserve and to provide physicians with a public database to research drug information because -- before

decisions to prescribe them to their patients over generics.

So, Mr. Carrier, does the FDA currently maintain a list of products that are substantially similar, other than a minor change in formulation?

Mr. Carrier. No, it does not.

Ms. Schakowsky. Is there currently a straightforward online resource that physicians can rely on to corroborate the things that Pharma sales representatives are telling them about the drugs?

Mr. Carrier. No. I am not aware of anything like that.

Ms. Schakowsky. Is there a common resource that patients could use to confirm whether they need a reformulated brand drug over a generic?

Mr. Carrier. No, there is not.

Ms. Schakowsky. Thank you.

Mr. Mitchell, again, I want to thank you so much for coming and sharing both your personal story and the story of so many others. You said that you started on a new chemo drug just last night. How much does that drug cost, and what is your out-of-pocket cost?

Mr. Mitchell. This drug is called Pomalyst. Twenty-one capsules in this bottle that I take 21 days off, and then seven days -- 21 days and then 7 days off, about $17,200 list. My out of pocket under Part D is going to be north of $13,000 a year

for this drug. That is one drug that I take.

Ms. Schakowsky. My goodness. Can you tell us why transparency around product hopping and reformulations would be helpful for you as a patient and for your physicians?

Mr. Mitchell. When a company does what has been described here by the experts on both of my sides, it can result in a product that does not delivery any improvement for me, clinically or therapeutically, may not reduce side effects, may do nothing to help me.

So having that database that you have described available from my physician, or from myself, to be able to go online and find out, is this the same drug? Did it really change? Does it deliver any incremental benefit? Would be very helpful in sizing up choice-making, and my ability to have a conversation with my physician about whether that is the right drug for me.

Ms. Schakowsky. I wonder if you wanted to add anything, why you believe evergreening is among the most critical of the issues for patients.

Mr. Mitchell. As I said in my opening statement, innovation is critical important to me. It is not a theoretical matter. I need them to invent new drugs or I am going to die sooner than I hope to.

So when drug companies can evergreen, extend life inappropriately on an existing product, or build a patent thicket

around their product, so we can't get a new drug, a generic drug to market, when they can extend the life and profitability of old drugs, they do not spend their money to invest in new drugs.

So, for me, having them have to compete and having them have their period of time under Hatch-Waxman or under the ACA or under the Orphan Drug Act run out, in terms of their patent and exclusivity, so that they need to invest in new drugs, helps me.

Ms. Schakowsky. Thank you so much.

I now want to recognize Mrs. Rodgers, subcommittee ranking member, for 5 minutes to ask questions.

Mrs. Rodgers. Thank you, Madam Chair. And to our panel, I want to say thank you. I completely agree that we should be holding companies accountable for anti-competitive behavior. I believe that this Congress should pass legislation to increase transparency and accountability of PBMs, the middlemen within this whole system.

I also want to associate myself with Representative Greg Walden's opening statement. The fact that next week we are having a hearing on a major bill to address the cost of prescription drugs in America that we haven't even seen yet I believe is making a point, not solving a problem.

This committee has a rich history of working together to solve problems. And to my colleagues, Republicans and Democrats,

I really ask us all to dig deep. It seems like we are becoming very good at playing partisan politics. Republicans blame the Democrats, and the Democrats blame the Republicans. I am personally weary of it. And in the meantime, people despair.

You know, I am giving a lot of thought to the increased suicides we are seeing in America. People are despairing. And as we fail to act on behalf of the people that elected us, we are failing the people of this country. We should be giving people hope. Hope. Hope for so many who are sick, who are combating diseases or live with a disability, the hope comes through research and it comes through breakthroughs. It is not going to come through a bill that is passed by one party that goes nowhere.

So this committee worked in recent years to advance -- well, bipartisan -- to advance the FDA Reauthorization Act, which provided FDA with new tools and pathways to bring generic brands to market.

And we heard today how important this is. This administration has proved -- has successfully approved 781 generic drugs in 2018, which was a 90 percent increase from just 4 years prior.

So, Mr. Francer, I wanted to ask just -- would you address what you think this -- how much of an impact this is having as far as increasing the competition. That is important to holding

these companies accountable.

Mr. Francer. Yes. Thank you very much for the question. Generics and biosimilars can bring enormous savings to patients like David Mitchell and all of us. They brought about $300 billion in savings through the whole health system last year when you compare the brand price versus the generic price.

The turnover in competition is critical to allow that, and of course the innovative drug has to have the ability to have a return on its investment. That said, I wanted to call your attention to an increasing problem whereby Medicare Part D plans increasingly aren't even covering the generics when they are launched, and that is something that we have to make sure that when there is this turnover to competition patients and taxpayers can get the savings there.

Mrs. Rodgers. Absolutely. Thank you. Thank you for that. That is helpful.

Dr. Shepherd, understanding that we have seen and know how important competition is, how can we balance the important need for innovation and drug improvements with ensuring generics can continue to compete?

Ms. Shepherd. I think that balance is very important. I think it would involve, you know, obviously, defining what is anti-competitive conduct, and that being the activity that the legislation addresses, and that potential remedies would address,

but also being extremely clear about what that is and what would not be considered anti-competitive, so that any legislation is not too broad that it covers standard business practices or is not so vague that pharmaceutical companies who are often making investment decisions and R&D 10 or so years before they would ever have a ruling on whether or not their activity is anti-competitive, they can actually predict what they are doing and if it makes sense to invest hundreds of millions of dollars in a new drug because they can reliably predict that it will not be considered anti-competitive under legislation.

Mrs. Rodgers. We understand that replacing older drugs with newer, better products is not, alone, anti-competitive, but may deter competition in the future. When do such actions become anti-competitive?

Ms. Shepherd. I think for a hard switch, I think that the window is very important. So are there generics imminently about to enter or have they just recently entered but they haven't gained hold yet? I think that is important.

And the soft switch, I think what is really important is, is there other wrongful conduct like falsely disparaging the old product in the Suboxone case, or some other sort of wrongful conduct? It can't just be that introducing a new product and leaving the old product on the market is anti-competitive. It has to be more.

Mrs. Rodgers. Thank you. Thank you very much.

I yield back.

Ms. Schakowsky. Let me just say to our ranking member, I feel that on this subcommittee where we have a very broad jurisdiction we have been able to pass some important bills, like we did last week. And I hope going forward, as with this piece of legislation, that we can work together on that. I think there is a lot of unanimity among our witnesses today, and I think that can be true of us as well.

So I am hoping to maintain an atmosphere on all of the bills -- of bipartisanship on all of the bills that we deal with.

So the chair now recognizes Congresswoman Castor for 5 minutes.

Ms. Castor. Well, thank you, Chairwoman Schakowsky. Thank you for organizing this hearing on how drug companies are gaming the system. Consumers know this. I hear it all the time from the families who I represent back home in Florida. They are paying astronomical amounts of money for their prescription drugs, and it is unconscionable in America that drug prices are so high that it is driving some families into bankruptcy and into debt.

In many cases, these drug prices are artificially high. Drug companies are gaming the system, and as our witnesses have illuminated -- and I want to thank you all for your illuminating

testimony -- brand name drug companies engage in this outrageous monopolistic practice known as product hopping. Product hopping occurs when one pharmaceutical company's drug is about to lose its government guaranteed exclusivity, so the company introduces a slightly different drug with the purpose of keeping much cheaper drugs -- generic drugs -- out of the market.

And this practice has gotten so harmful that the Federal Trade Commission and the courts have stepped in to stop it, and now we need to develop some legislative remedies as well.

Manufacturers are doing this in order to delay or altogether frustrate competition against their products, and consumers are paying the price.

Let's talk about a real-world example, the drug Namenda that was used to treat -- that is used to treat dementia associated with Alzheimer's. A recent court found that Forest Laboratories, the manufacturer, had engaged in both a soft switch and a hard switch to thwart generic competition.

The case revealed that Forest acknowledged that it would convert patients and care givers to a once-a-day therapy versus a twice-a-day therapy if it made a hard switch, and most troublingly, that they knew this. It is very difficult, then, when a generic is introduced to get the patients to convert back.

So the market analysis uncovered that in the Namenda proceedings Forest Labs' own data showed that a soft switch in

their case would switch only 30 percent of patients to the newer, more expensive product, but the hard switch would move 80 to 100 percent of patients.

Forest Labs, in this case, actively and brazenly sought to undermine generic uptake. In reality, this meant that Forest Labs unfairly profited off of Alzheimer's patients. This is what is going on, and this is unconscionable.

So I want to ask our witnesses for their help. Mr. Carrier, could you please describe the kind of behavior that constitutes a hard switch again and maybe give us another example?

Mr. Carrier. Sure. So a hard switch is when the drug company removes the old version from the market, and so there are several cases that involve -- it is the Doryx case, the acne drug in the Third Circuit, involved the brand company pulling the old version off the market. The hard switch, the old one is gone. The soft switch, the old one technically remains on the market.

Ms. Castor. So, Dr. Shepherd, you had -- in your testimony to us, you highlighted a possible remedy, possible fix for this. Is there a downside for consumers if a hard switch approval is delayed until after the generic is introduced on the market?

Ms. Shepherd. No. There is not a downside for -- if it is just after the window and generics have been able to come in, there shouldn't be much of a downside for consumers.

Ms. Castor. And there is nothing in the law that regulates that now.

Ms. Shepherd. No.

Ms. Castor. Is that right?

Ms. Shepherd. Yes.

Ms. Castor. So, Chair Schakowsky, I would recommend that for your bill as you develop it. That seems to be one answer.

Mr. Carrier, do you agree?

Mr. Carrier. So I have offered in my scholarship a generic window that is very important, because if the brand company makes a change at a time that you don't expect the generic to be on the market, I say it should be automatically legal. And so my window is a bit different than Professor Shepherd's, but I do want to give the brand every benefit of the doubt when there is no generic about to enter the market.

Ms. Castor. Thank you very much. I yield back.

Ms. Schakowsky. The chair recognizes Mr. Latta for 5 minutes.

Mr. Latta. Well, thank you, Madam Chair. And thanks very much for holding today's hearing, and thanks very much to our witnesses for being with us today. And no one can deny that one of the greatest concerns that the American public out there has is the price of prescription drugs. I have long believed that

this Congress must take action and work in a bipartisan fashion to address the rising cost of prescription drugs.

At the same time, we should be supporting, not hampering, efforts that seek to improve the treatment of diseases and health issues.

If I could start my questions with you, Dr. Shepherd. In your testimony, you go into great detail about explaining the difference between the hard switching and soft switching of products. And on the hard switches, you mention an exception for when a new product is safer or significantly more effective.

Would you go in more detail about this exception or give any examples of when companies have developed a new product and compelled consumers to seek it out by pulling the old product?

Ms. Shepherd. Sure. So I would include, you know, either a product that is clearly safer or significantly more effective as allowing a switch that would otherwise be within this window that we all seem to agree, you know, should be important. And, you know, there is numerous examples of products that have been pulled and new ones put on, whether or not there is some sort of FDA finding that some small component is not as safe as was originally believed, and so the new drug is made with new compositions that are found to be safer.

And there is even other kinds of examples where things that

we may originally think of as very small formulaic tweaks that shouldn't matter end up mattering a lot. So, for example, current antimalarial drugs, the tweaks that were made to it included combining two drugs, so patients take one drug instead of two, extending the shelf life, and making a new pill that is dissolvable in water.

And each of those sound so simple, and like clearly somebody is trying to take advantage of something, but they end up mattering so much. I mean, shelf life matters in tropical climates. When a drug can be dissolved in water, that means infants can take it, who are most vulnerable to malaria. And combining two drugs into one is really important to reaching people where there is an issue of cost and availability of drugs.

And so we just need to be careful about what we define as improvement in efficacy because in different situations some things can matter a lot, but they wouldn't in others.

Mr. Latta. Let me follow up with another question for you. You also stated that there are dangers with introducing legislation to regulate this issue because it could reduce the innovation and increase spending.

Do you see a benefit in allowing the courts to continue to interpret the statutes that are already on the books, or in determining anti-competitive behavior and practices instead of adopting any new legislation?

Ms. Shepherd. I think new legislation could certainly make things a little bit more clear. I mean, there is a lot of similarity between the only two Circuit Court decisions we have on this issue, but there is also some disagreement, and I think there is uncertainty in the industry. So I think that legislation that minimizes this uncertainty would definitely be helpful to both innovation and to consumers.

Mr. Latta. And, again, what are some of those unintended consequences that are out there that can arise if Congress, instead of the courts, might be the ones trying to regulate the soft switching of the products?

Ms. Shepherd. Well, unintended consequences, I think if the legislation was too broad, and so by its language caught up behavior that could lead to true product improvement and not just these kind of sham innovations that we seem to all agree, you know, is an issue. So I think overly broad legislation would be a problem.

And also, if it I guess codifies ambiguity, that would be a problem as well, because that actually could even increase the vagueness in the current law from what we have today if the legislation is too kind of vague about what is anti-competitive and what isn't.

Mr. Latta. Well, thank you.

Madam Chair, I know the clock hadn't started when I started

my questioning, and so I am going to yield back the balance of whatever time is remaining.

Ms. Schakowsky. I am now recognizing Mr. Van Hollen -- O'Halleran, sorry -- I will get these names right -- for 5 minutes. Sorry.

Mr. O'Halleran. Thank you, Madam Chairwoman, and Ranking Member McMorris Rodgers, for holding this hearing on this incredibly important topic, one that I hear a lot about from individuals, from families in the 1st Congressional District of Arizona.

I have attended 24 town halls this year alone, and the exorbitant cost of health care, particularly prescription drugs, is the number one issue I hear about from constituents. I am pleased that Chairman Pallone and Chairwoman Schakowsky are committed to advancing legislation that would address this serious issue.

As we consider proposals this month that aim to lower the cost of prescription drugs, I believe it is important that we adopt an approach that encourages innovation and competition while ensuring that the cost savings are appropriately passed down to the consumers.

After hearing your testimony today, I have a number of questions here. But you basically have helped confuse the issue, not because of you but because of the seriousness of this issue

and how the system is put together. I think this would be a great time for about an 8-hour session with all four of you, but we can't do that today.

So what I would like to do is go down the table. I am concerned about the case law and how we could affect it or not affect it if we don't do it. I am concerned about the direction we are going in. It is obvious just negotiating drug prices is not the bottom line of what we have to accomplish here in Congress, that we have to identify how the system cannot be worked and manipulated to counter any price changes.

And so if I can get your opinions and ideas and concepts, I would like to start out with Mr. Carrier.

Mr. Carrier. This is one of the most important drug issues that you all can address. I have no faith that courts are going to get it right when they keep focusing their analysis on choice and coercion and saying, oh, consumers have a choice because there are two products on the market. That is what the courts have done.

In the Walgreens case, in the Asacol case, they said consumers have a choice because there are two products on the market. This is not about consumer choice when you have a price disconnect. There is one party that selects the drug. There is another party that pays for it. So by making clear that a soft switch can present anti-competitive harm, that is a real

benefit that this committee can do.

Mr. O'Halleran. Mr. Mitchell?

Mr. Mitchell. Thank you. I think that Congress passed Hatch-Waxman to balance the need for innovation and allowing markets and competition to lower the price after a period of exclusivity. When drug companies try and bend or abuse that framework, then we are not getting the benefits of the Hatch-Waxman framework.

So when a practice by a brand drug company that is essentially bringing a drug to market with no clinical or therapeutic improvement for patients, when they bring that to market, in order to defeat generic competition, and especially to defeat state substitution laws, which were put in place to make Hatch-Waxman have more of an engine, then that would be a time when the courts should be told this is a clear case of abuse.

Mr. O'Halleran. Ms. Shepherd?

Ms. Shepherd. Yeah. I would make two points. I think that the window is very important. We all seem to agree that, you know, the circumvention of the automatic substitution laws is a big part of the problem, and so there is a window in which that is important. And so limiting any sort of kind of presumption of anti-competitive behavior to that window I think would eliminate a lot of the problems that we are concerned with.

And then, second, on the soft switch, I think that is where

there is the real risk of catching too many behaviors that we would just consider normal business behaviors. And so I think defining what needs to be present in a soft switch, what kind of wrongful conduct are we considering as presumptively anti-competitive. I think that would be very important as well.

Mr. O'Halleran. Mr. Francer?

Mr. Francer. Yeah. As the whole committee is looking for solutions, I would also look towards, how do we make the patent system more effective and less of a blockade? This committee passed the BPCIA, which was the Biosimilars Pathway, and we are seeing that dozens and dozens of patents are really blocking the availability of these drugs, which are essentially the generic versions of these very expensive biotech drugs.

I would try to accelerate the patent dance that occurs and try to deal with the costly litigation, which is slowing down these approvals and their ability to get on the market.

Mr. O'Halleran. Thank you.

And thank you, Madam Chair. I yield.

Mr. Soto. [Presiding] The gentleman yields back.

The chair recognizes Mr. Bucshon.

Mr. Bucshon. Thank you. I appreciate that. I was a surgeon before I was in Congress, so this is kind of very -- I have a very strong interest in this. First, I want to say I associate myself with Ranking Member Walden's statement, and I

would implore us to bring bipartisan bills passed unanimously out of this committee to bring down drug prices to the floor for a vote.

And we see today we have an introduction of a very partisan big government bill as it relates to drug pricing, so it may be clear -- it is kind of clear to me, at least at the leadership level on the majority side, that there may not be much interest in actually getting something signed into law but to play politics primarily against the President.

That said, you know, I am interested in bipartisan solutions, and I think everyone on this subcommittee and the Health Subcommittee are. I am very proud of this committee and the fact that we have worked in a bipartisan way for many, many years on very tough issues and found common ground, and I think we can on drug pricing issues also.

As has been mentioned by both sides, this is a front burner issue for everyone that I represent. When I talk to people out there, healthcare costs, specifically drug prices, is one of their top issues for an American family sitting around the kitchen table looking at their budget.

And so I am hopeful and optimistic that we can address it. And I appreciate all of your testimony today. I found a lot of harmony in the testimony across everyone. I think there are nuanced differences in the approach to maybe address the problem,

but they are not that far apart, which I think gives us a great opportunity in this subcommittee to really find common ground to address it.

A couple of things. Dr. Shepherd, minor changes -- "minor changes" to existing drugs that can't be justified by innovation and drives up cost to consumers, do you think that -- you know, first of all, do you agree that that is happening a lot?

And also, who is best positioned to determine what constitutes a minor change? Because everything here and what we do, and in your legal profession, the language matters, right? So who is best positioned to assess what minor changes might be and what the benefit or detriment to the consumer is?

Ms. Shepherd. Sure, sure. Well, I guess I will answer your last question first. I mean, I would say it is absolutely the market. You know, there is a lot of drugs we can look at. I will -- two examples I might say would be NSAIDs and antidepressants -- that there is a lot of different drugs on the market. They are often just slightly tweaked versions of each other, but what we find, what doctors find, is that different patients, for whatever body chemistry, you know, reasons, react very differently to different drugs.

And we may -- you know, I could imagine if there is a court ruling early on, they may think, oh no, this is just a minor tweak; it is not worth it. Therefore, you know, we could presume that

there is anti-competitive behavior associated with it.

But it oftentimes time for the market to realize that different people do react very differently to whether it is these important drugs or it is contraceptives or things like that. Different things have different effects, and the markets and the doctors and the consumers are in the best position to judge that.

Mr. Bucshon. I mean, statin agents as an example.

Ms. Shepherd. Yes.

Mr. Bucshon. I take a statin agent. I have tried every one of them except the one that I am on, and couldn't take the others.

Ms. Shepherd. Right.

Mr. Bucshon. And many of them are very similar.

Ms. Shepherd. Yes.

Mr. Bucshon. But slightly different.

Ms. Shepherd. Right.

Mr. Bucshon. Mr. Carrier, do you want to comment on that?

Mr. Carrier. Sure. So I don't think courts should be in the business of determining if a change is minor or not.

Mr. Bucshon. Okay.

Mr. Carrier. And I don't think anyone believes that. On the other hand, you can see, if the change is about the same -- so think Suboxone. They switch from a tablet to a film, and when they go to the FDA and say, "Please approve my film," they never

did any studies for film. They said, "Oh, rely on the tablet studies, and they are basically the same."

So sometimes it is part of an overall effort where you badmouth your own product, you jack up the price, you do everything else; that comes to the fore. But I don't think a court, in any of this legislation, has to decide if it is a minor change or not.

Mr. Bucshon. Yeah. I mean, that change specifically could be that if you take an oral version, your gastrointestinal tract doesn't tolerate it well versus if you take a mucosal membrane absorption product, that you can tolerate it. But what you are saying is is they should be able to show that, and then that is a justifiable substantial improvement in the product, and that is what you are kind of saying.

Mr. Carrier. Absolutely. Yes.

Mr. Bucshon. Okay. I yield back. Thank you.

Mr. Soto. The gentleman yields back.

The chair recognizes Ms. Blunt Rochester.

Ms. Blunt Rochester. Thank you, Mr. Chairman. And thank you to Chairwoman Schakowsky and Ranking Member Rodgers for holding this hearing, and thank you to the witnesses for a very important hearing.

You know, we have this theme about gaming the system, and throughout Energy and Commerce has really been looking at this

whole issue of drug pricing and trying to figure out why these prices are so high.

And I think one of the things that you said, Mr. Mitchell, for me stuck out as a thing that I am holding in the back of my mind throughout this hearing, and that is you said, "Drugs don't work if people can't afford them." I mean, that is the bottom line, and that is what I hear from my constituents. If you can't afford them, what is the point?

And so we thank you for your testimony. We thank you for sharing your story. You represent a lot of people in our country that are grappling every day.

I would like to start my questions with Mr. Carrier. You talked about the price-disconnect and the fact that the drug marketplace is different than other marketplaces. It is not like automobile, you know, marketing or anything like that. And that this difference makes it especially susceptible to clever advertising manipulations.

What about this marketplace makes it susceptible to the manipulations and other anti-competitive practices?

Mr. Carrier. Thank you for the question. The problem here is that there is no other industry where you don't have a single party making the determination of price and quality. So in any other market -- let's say the paperclip market -- a new paperclip comes on the market, and it is 10 percent better than the old

paperclip.

Is it worth the increase in price? Let's say it is 25 percent more price. When you walk into the store, you can make that decision? Well, it has improved, but it costs this much more. So, therefore, I will or will not buy it. You don't have that in the pharmaceutical industry because the doctors are the ones subject to all of the advertising and the doctors don't have to think about cost when they prescribe it.

It is the patient or the insurer that has to do it. And so that is why doctors are subject to all of this advertising. It really makes a difference. There are empirical studies out there that show that when doctors are subject to all of this advertising they are more likely to prescribe the drug, and that is why it is a real problem here. It is not really about coercion or choice. It is about a really price-disconnected market.

Ms. Blunt Rochester. And to follow up on the chairwoman's question on transparency, would greater transparency for reformulations improve innovation? And how?

Mr. Carrier. I think so. So let's say that you have the FDA that has to list all of the reformulations. So you are drug company. You change your product. You list it on the FDA's website. You show what is different about it. You show that you engaged in really interesting clinical trials that come up with a whole bunch of improvements. That is something that is

worth knowing. We don't have that now. Transparency could help.

Ms. Blunt Rochester. Great. And I want to also shift a little bit to, one thing I know for sure is that drug patents and approvals are incredibly complex, and it is clear that some actors have taken advantage of the system to drive up these prices and ultimately reduce access to affordable health care for Americans.

This question is to the panel. How do the physicians and individuals find out about these reformulations? That is number 1.

And then, are there ways that we can use the available resources to improve physician education or even consumer awareness? And maybe we will start with Mr. Francer.

Mr. Francer. Sure. Well, I think it can be very difficult, actually, to find out about some of the changes, which is why some of the suggestions for improved transparency would be helpful. I think often physicians are finding out from communications directly from the drug company. You can find out some of them from the FDA website. But as was discussed before, it can be very difficult to learn about some of them.

Ms. Blunt Rochester. Mr. Mitchell?

Mr. Mitchell. Clearly, physicians are learning through medical journals, but they are also learning from detailers who are coming from pharmaceutical companies to explain why a given

drug is superior. Likewise, I know a lot of people with diseases at this point, chronic or acute, and they go out and try and research.

And so they will look around to see if there is something that helps them understand, is this drug in fact superior? What are the side effects that come with it? And so having a database where you could go look, especially in situations where there are minor changes taking place, would be helpful.

Ms. Blunt Rochester. Right, right. Anyone else from the panel?

Ms. Shepherd. I agree.

Mr. Carrier. Yeah. So drug companies are the ones that tell the doctors, and that is why they have so much power here.

Ms. Blunt Rochester. Gotcha. Back to the awareness piece, I think that you said people are basically doing it on their own and really with no help from the government. I have one more question, but I will submit it for the record. Again, thank you so much for your time and for your testimony.

And just on the hope piece, this committee passed out of committee after markup before the recess 25 -- I think 25, 24, bipartisan bills, and many people didn't hear about that. And so if I want to put one other thing on the record, there are things that we are doing together, and I think this is an area where we all feel there is a need to help the American people.

Thank you so much. I yield back.

Mr. Soto. The gentlelady yields back.

The chair now recognizes Mr. Carter for 5 minutes.

Mr. Carter. Well, thank you very much, and I appreciate every one of you being here. This is an extremely important subject, something that we have been concentrating on on this full committee, both in Health Subcommittee and on this subcommittee as well, and certainly something the American people need help with.

And no one knows that better in Congress than I do, because currently I am the only pharmacist serving in Congress. So I have lived this. I have been the one on the other side of the counter who has had to tell the patients how much their medication is. So this is extremely important, as you can imagine, to me.

Mr. Francer, I want to start with you and ask you, I am happy to be talking about the anti-competitive behaviors that are used. But I think we would be making a mistake if we didn't look at the whole piece of the puzzle, and I want to do that.

You discuss in your written testimony the problems around rebates. In fact, you said, "Recent analysis found that Medicare drug plans are increasingly shifting generic drugs from tiers with lower co-payments for patients to brand tiers with higher co-payments and co-insurance." And this is the way that these PBMs are doing this, and this is the way that it is increasing

costs, particularly to the patients, increasing their co-payments.

Can you just explain how these rebate agreements work very briefly?

Mr. Francer. Yeah. And thank you very much for the question. This is a case in which the system is failing patients. When you go to the pharmacy counter and meet with, you know, your former colleagues, you know, you expect that if you are going to get the generic version it is going to be pretty cheap. And it has taken a long time for it to get that way, but finally there is competition.

We, in our industry, have been surprised by recent findings that more and more the generics are being put on these higher co-pay tiers, so that it could actually be more expensive to the patient at the pharmacy counter to get the generic than the brand. I think this is something that the committee should look at, whether it is for Medicare, and then to look at the whole system.

Mr. Carter. You are exactly right. I mean, I was appalled at times to see that a generic would be on a higher tier than a brand name would. And I knew the reason why is the pharmacist. I knew it was because the PBM was getting a higher rebate. No other reason except for that, and that is something that it is hard to articulate to someone who doesn't necessarily understand it.

Now, most of the members of this committee get it and understand it. A lot of the members of the E&C Committee understand it. But once you get outside of that, there are very few who do, and it is hard to explain that and getting in the weeds enough to where we can explain it.

How widespread do you think this is?

Mr. Francer. Well, we are finding actually more and more. We are going to be releasing a paper next week that goes into more detail on this, but it is becoming an increasing problem. Number 1, the generic just not being covered at launch. And, number 2, this placement on tiers.

So I am happy to provide that for the record and to give you more information.

Mr. Carter. Good, good. So what about biosimilars? We had Dr. Gottlieb, Dr. Scott Gottlieb, when he was with the -- when he was the director -- commissioner of the Food and Drug Administration, he had suggested that this was one of the problems and that the abuse of the rebate system was blocking out a lot of affordable biosimilars.

Would you agree that that is happening there as well?

Mr. Francer. Well, there is a fairly well-known case in which there is litigation between Pfizer, which is trying to put a biosimilar on the market, and Johnson & Johnson, which has the innovative drug. And evidently the rebate situation has

essentially made it extraordinarily difficult for the biosimilar to get on the market.

Again, this is a failure of the system. This isn't the way it is supposed to work.

Mr. Carter. How can we fix it?

Mr. Francer. Well, I think in that case, we have to make sure that you treat biosimilars in a way that incentivizes their uptake, whether it is sharing the savings with the physicians or whether it is making sure that they are on the preferred tier.

There are a lot of different types of solutions, and we would be happy to work with you on it.

Mr. Carter. You know, I get so frustrated because we meet with Medicare and we meet with the staff, and we explain it to them, and they say, "Yeah, we know. We know."

You know and you are not doing anything about it.

"Well, if we do something about it, they will just do something else in another area." It is like squeezing a balloon. It is just going to go somewhere else.

You know, I really get passionate about this and really get upset about it, as you can imagine, because when you -- I have spent over 30 years as the one on the other side of the counter having to explain this to people. I am the one who had to see the mother in tears because she couldn't afford the medication

for her child.

I am the one that saw the senior citizens who were trying to decide, literally -- and I am not exaggerating -- trying to decide whether they were going to buy groceries or buy their medication.

What is happening now with the pharmacy benefit managers, the PBMs, the lack of transparency in the drug supply chain, is criminal. And until we get the resolve in Congress to do something about it, it is going to continue on.

Thank you, Madam Chair, and I yield.

Mr. Soto. The gentleman yields back.

The chair now recognizes Mr. McNerney for 5 minutes.

Mr. McNerney. I thank the chair, and I appreciate my colleague from Georgia's passion on this issue. And I appreciate the testimony. It has been very illuminating, so I appreciate that.

Each of you has acknowledged how product hopping impacts generic uptick and the market generally. The lack of competition in the market directly affects prices that consumers pay for their drugs. And to that point, Professor Carrie has shared some data from some well-known product hops, and I appreciate that, Professor.

The FTC has acknowledged that product hopping is an abuse of the regulatory system, and that it hurts consumers, and the

FTC has acted in cases to enforce some of the most egregious practices. I would like to learn more about what the FTC has done and how Congress can ensure that the FTC has the authority it needs to stop product hopping.

So I am going to start with Professor Carrier. Can you explain what enforcement authority the FTC currently has to address product hopping?

Mr. Carrier. So the FTC can go after these cases in court under its jurisdiction, and it has used that authority in the pay-for-delay settlement area. It has barely used it with product hopping. There is a 50 million piece of the Suboxone billion dollar settlement that was product hopping. That is the first time the FTC dealt with it, but legislation that you would consider it potentially and that the Senate Judiciary Committee consider it, will be incredibly important.

The FTC does not use its authority a lot. Six times in 20 years is the only time it has brought a pay-for-delay case. But in the most egregious cases, it could be incredibly important.

Mr. McNerney. Very good. Thank you. What additional measures should we consider to further clarify their authorities?

Mr. Carrier. So one other thing that you could do is to ask the FTC to do a report on product hopping.

Mr. McNerney. That was my next question. Should they do a report?

[Laughter.]

Mr. Carrier. Absolutely. And so one of the difficulties here is that it is a nuanced subject. And when you hear about a soft switch, you think, oh, maybe it is okay because there are two products on the market. Let's get evidence on how soft switches can be bad. Let's get evidence on how these concerning switches make no economic sense whatsoever. There is a test to apply. It makes no sense, other than keeping the generic off the market.

The FTC is uniquely situated to get all of this information. And just to go back for one second to Representative Carter's question, PBMs are a part of the problem here. They should be solving the price quality issue, and they are not. And we can still deal with this while still dealing with PBMs.

Mr. McNerney. Thank you.

Professor Shepherd, would you like to make a comment on this?

Ms. Shepherd. No. No, I would agree with that. I mean, I think that some -- you know, there has been some kind of like small reports, but I do think a larger study of the problem would help us get our head around how many times are there an innovation that we might consider incremental that are happening within this window, have no other offsetting benefit, and we can presume them to be anti-competitive. So I would agree that --

Mr. McNerney. Well, it is interesting. Professor Carrier

just said there is only six times that they have prosecuted product hopping. What singles out those six cases that made the FTC decide to go after them?

Mr. Carrier. So it really -- so six pay-for-delay cases, the FTC has been on the front lines of this for 20 years. They really choose the most egregious examples. And so these are the worst ones, like in the Cephalon case where the brand company paid the generics $300 million, just half the market, use that period of time to switch the market from the old version to the new version. By the way, product hopping and settlements work together a lot of the time. They really picked the most egregious example.

So for anyone worried about innovation, if we are giving authority to the FTC, look to pay-for-delay settlements. They have had this authority for 20 years. They bring one case every 3 years. This is not going to be an avalanche of innovation-hurting activity.

Mr. McNerney. So do you think the FTC just lacks resources, or --

Mr. Carrier. Yes. I think that these cases are big cases. You have the largest firms on the other side. Antitrust litigation goes on for years. The FTC certainly could use more resources.

Mr. McNerney. Thank you.

Dr. Francer, or Mr. Francer, do you believe that sensible legislation can be crafted that would use market forces to bring drug prices in the U.S. in line with the average international market price?

Mr. Francer. Well, I think that what we are talking about today, there is actually a lot of consensus on this panel to let competition work. And I am hopeful that the committee will continue to work in that way.

Mr. McNerney. All right. I am going to yield back, Mr. Chairman. Thank you.

Mr. Soto. Mr. McNerney yields back.

The chair recognizes Mr. Gianforte for 5 minutes.

Mr. Gianforte. Thank you, Mr. Chairman.

Skyrocketing costs of prescription drugs are making it more difficult for Montanans to prosper. I am committed to finding commonsense solutions to this problem. Competition is incredibly important, as we have discussed here today, in any marketplace. And I am glad that we have passed many bills out of committee to increase generic competition for generic drugs.

I am also encouraged by the work of the Trump administration that they have been doing in this area. The FDA has approved more generics than ever before, and it is driving down costs of medications.

We need to find commonsense solutions that make drugs less

expensive, increase transparency where it is needed, and put patients first.

I want to focus on biosimilars. They hold enormous potential to lower prescription drug prices and enhance patient access to lifesaving cures. I am working with Representative Schrader to help bring down biosimilars -- more biosimilars to market and get them in the hands of patients.

That is our bill. The Biosim Act will temporarily increase the reimbursement for biosimilar drugs for the average price of the drug plus 6 percent, increase it to the average price plus 8 percent, to help utilization.

I know the FDA has approved 24 biosimilars since 2015, but only nine are in the hands of patients now. That is a problem; we want to fix it.

Mr. Francer, what are the barriers to getting more biosimilars in patients' hands?

Mr. Francer. Yeah. Thank you for the question. I just want to give you one example. The drug Humira, this is a drug that is an incredible treatment. It was approved in 2002, and so it had its 12 years of exclusivity. That was over in 2014.

Its compound patent expired in 2016, yet they have 136 patents surrounding competition for this drug. And the drug takes in more revenue every year than all of the NFL teams combined. We need to do something about our patent system and

making sure that drugs don't have a limitless monopoly to have competition.

Mr. Gianforte. Okay. Thank you.

Ms. Shepherd, in your testimony, you suggest that whether product hopping is anti-competitive is highly situational dependent. Can you please explain what you mean by that?

Ms. Shepherd. Sure. You know, with the hard switch, it depends on when the switch is actually happening. Certainly, if a drug company removes their drug from market years after there has been generics in the market, it is not going to affect the availability of these generics to patients, or if they remove their product years before there is a generic even on the horizon, it is presumably just an improvement that they find necessary. And it is not impeding competition in any way.

And then with the soft switch, I think it depends so much on what is the behavior that is associated with it. Just introducing a new product, leaving the old one on the market, and even advertising the new product, you know, very aggressively. That is not -- there is nothing anti-competitive about that. There is plenty of choice. Both products are on the market. Automatic substitution laws work. It is when there is some other clearly wrongful conduct that accompanies a soft switch that it would be anti-competitive.

Mr. Gianforte. So if we want to introduce a bill that

prevents anti-competitive product hopping, how can we ensure that we are not capturing legitimate actions and get swept up with the anti-competitive stuff?

Ms. Shepherd. Well, again, you know, I think on the hard switch, defining the window is important. I think on the soft switch, just being extremely clear about, what is the behavior that will unfairly disadvantage the older product. And when we look at most court decisions, they have often -- and the FTC, in addition, has commented on this -- that it typically will require some other sort of wrongful conduct that accompanies the soft switch.

Mr. Gianforte. Yeah. Could you give a couple of examples of past product improvements that could have been considered illegal under an overly broad approach to anti-hopping.

Ms. Shepherd. Sure. Well, I mean, when we look at -- you know, I mentioned the antimalarials earlier. But when we look at the history of oral contraceptives, birth control pills, they have -- over the last multiple decades they have slowly come down in dosage.

Now, a lot of people would say a slight tweak in dosage, that is just an unimportant little improvement that doesn't offer real benefits, but over time those add up. And, in fact, we have, you know, statements from the -- hold on one second -- the National

Research Council that says the cumulative effect of incremental innovation is often more transformational than a first in class or radical innovation.

And so, you know, we just need to be careful. When these small improvements may one at a time look not so important, they do add up to being very important.

Mr. Gianforte. Okay. I want to thank the panel for your testimony today. I appreciate your helping with this. It is critically important that we get prescription drug prices down, so I appreciate it.

And with that, I yield back.

Ms. Schakowsky. [Presiding] The gentleman yields back.

Thank you, Mr. Soto, for being in the chair. You are next for 5 minutes.

Mr. Soto. My pleasure, Madam Chair.

First, I just want to get a clarification, because I have been a little confused about it. Is evergreening and product hopping the same thing? Or is it two different things? Mr. Carrier, my fellow Scarlet Knight, it would be great to hear from you first.

Mr. Carrier. So evergreening is used more loosely to refer to not only product hopping but patent thickening as well. So I would focus on product hopping as the switch from one version to another that really makes no good reason, whereas evergreening

is more the life cycle management practice that drug companies use in many places.

Mr. Soto. Thank you for that. I wanted to -- obviously, this committee has worked on pay-for-delay, updating the Orange and Purple Books. We are now looking at product hopping and evergreening.

Is there any other unfair deceptive trade practices to extend patents that exist right now that we haven't covered yet? And we will start with you and we will go across to hear from everybody. Mr. Carrier.

Mr. Carrier. So I would like to continue the discussion on biosimilars. There are not enough biosimilars on the market today, and there are so many hurdles, not just the patent thicket that Mr. Francer talked about, but also the rebates that he talked about, the cost of developing the drug, and disparagement.

Biologic companies are disparaging biosimilars, saying, "Oh, you could take this, but you might die," or something like that when under the statute you are not allowed to do that. And so that is one other thing to keep in mind.

And, again, everything else that you have dealt with on sample denials, pay for delay, and citizen petitions I would say as well are very important.

And the final piece is the PBM piece. Representative Carter made a great point that PBMs are not putting drugs on the

formularies because they are better drugs. They are putting drugs on the formularies because they are getting a big payout from the brand company.

And sometimes we hear, "Well, we can't do anything about brand companies because it is the PBM problem. We can't do anything about PBMs because it is a brand company problem." Do both. You can do both. You can solve everything we have talked about this morning, and you can also deal with the PBMs, and those are complimentary approaches.

Mr. Soto. Mr. Mitchell, any additional unfair deceptive trade practices that we haven't covered in our initial list?

Mr. Mitchell. I will just pick up on what Professor Carrier just said. It is outrageous for me, as a patient, that I can't know if the preferred drug on a formulary is there because it is the most effective drug, the least expensive drug among equally effective options, or if it is simply there because the brand drug company paid the PBM a big rebate, a kickback, which you give safe harbor to under law. That is not a good way to run a railroad. That is not a good way to do health care for people.

So when Mr. Carrier says, "You could do both," this is a brand problem and a PBM problem. Fix it, so I can depend that the PBM is taking care of me and not and not his profit needs.

Mr. Soto. Ms. Shepherd, any additional gamesmanship happening to extend patents that either you would like to

elaborate on or that we haven't discussed yet?

Ms. Shepherd. No. I think Professor Carrier made the point about the citizens' petitions and the sample availability, but I would also reiterate, I have done quite a bit of work on the PBM rebate issue as well. And so that is creating this just kind of absurd incentive within the market that a lot of people don't understand how responsible those rebates are for the actual list price increases we are seeing.

Mr. Soto. Thank you. And Mr. Francer.

Mr. Francer. So agree with what Professor Shepherd just mentioned, and the only one I would add is find a way to move up the biosimilar litigation, so that it can happen earlier and so that it is not blocking availability.

Mr. Soto. Now it would be great to hear from you all about a new bill that was just filed today to allow Medicare and the HHS Secretary to negotiate drug prices. It would be great to hear a show of hands. How many people -- how many of you believe that if we allow the HHS Secretary to negotiate Medicare drug prices that that would lower prices for the market overall? Raise your hand. Okay.

Secondly, if we focused on 250 of the most used, most expensive drugs, do you think that is a good start to lowering drug prices? Raise your hand if you agree with that statement. Okay.

And, finally, it would be great to hear from you, Mr. Carrier. I know you mentioned a little bit of -- a lot of these issues, but if you -- how key is it for Medicare to be able to negotiate a lot of these prices?

Mr. Carrier. So I have not studied this issue as much as the others, but I do think it is important to negotiate.

Mr. Soto. Okay. And Mr. Mitchell?

Mr. Mitchell. Well, we pay two to three times in this country what people pay in other countries. And the principal reason is that every other country in the world negotiates directly with drug companies; we don't. If PBMs were doing such a good job on my behalf negotiating for Part D, for example, why am I paying so much more than those other countries? So we think that just in the same way that the Federal Government negotiates for everything it buys -- aircraft carriers, copying paper -- that we should be negotiating drug prices as well and using our purchasing power to help American people get a better deal.

Mr. Soto. Thank you. My time has expired.

Ms. Schakowsky. Thank you.

Mr. Guthrie, you are recognized for 5 minutes for questions.

Mr. Guthrie. Appreciate it very much. I wish I had been here for this full discussion. But there is another committee meeting -- subcommittee meeting downstairs, and the chair and I just -- she was just down there as well, so sorry for not being

here for the full discussion. But I am the ranking member of the Oversight and Investigations Committee, which is meeting, not today, but we are currently examining the increases in insulin prices, particularly the list price versus the -- list price versus the discount, what people, what the pharmaceuticals or the insurance company actually pays.

And we looked at that one because it is not -- it has been around for 100 years. It is not part of the innovation, big innovation. There is great innovation in diabetes. But what is going on in health care, we are getting incredible innovations in pharmaceuticals. You mentioned Humira. You mentioned -- and I know that is a little dated, but you can cure Hepatitis C with a pill now. I know it is a procedure we can cure sickle cell anemia.

So we look at just the health care, in general. So my concern is we -- and I really pushed with Chair DeGette to go look at insulin because we need to get to the bottom of it. But what I am concerned about -- and, Ms. Shepherd, I think some of your looks and research you look into this -- is as we move forward -- and some are going to say, "We don't care about the unintended consequences. We are paying too much money."

But the unintended consequences would be to kill innovation that we have. I think some of the other countries do negotiate for drug prices, but they also limit formularies. And so we can

have that tradeoff as the Congressional Budget Office has said. If you want cheaper prices on Medicare Part D, the only way you are going to get it cheaper is if you limited formularies, even if you negotiate, which means limit what people can have in choice.

So I guess my question I am getting to is, how do we find the appropriate balance, Ms. Shepherd, between the need for innovation and the need for the competition to bring the prices down? Can we have both?

Ms. Shepherd. I think we can. I mean, you know, each side might have to give a bit, but I think it is possible. I think it depends on just crafting extremely clear legislation that makes it clear what is and what is not anti-competitive, making sure you are not capturing any improvements that could be innovative.

Mr. Guthrie. So what would be the ambiguities in some--I know in your testimony you talk about ambiguities in law could limit innovation. So what are some of the ambiguities that you would want to see clear in a piece of legislation that --

Ms. Shepherd. Sure.

Mr. Guthrie. You were right where you were going. I just want to --

Ms. Shepherd. Yeah, yeah, yeah.

Mr. Guthrie. -- my next question.

Ms. Shepherd. So, for example, if let's say in regards to a soft switch, the legislation says "any soft switch that unfairly

disadvantages the old product." Like I have no idea what that means. And, you know, disadvantage, I mean, I think most new product innovations disadvantage in some way older products because there is more competition on the market.

Unfairly? That is not a term we see described anywhere to really judge what that would be. And so I would just caution the subcommittee to think very clearly, maybe with precise examples or some real way to kind of -- to judge what would constitute an unfair disadvantage rather than just throwing it out with a bunch of "mays" instead of "wills," so that nobody really knows what it is.

Mr. Guthrie. Okay. Should the number of generics that already enter the market be a factor in determining whether or not removal of the brand product is anti-competitive?

Ms. Shepherd. No. That is not really -- as long as one generic is on the market, automatic substitution laws are working. And more generics, all that is going to do is -- will bring down the price, and that is important But as long as there is one on the market, there is nothing stopping more from coming into the market.

So that is kind of irrelevant from whether or not the automatic substitution laws have kicked in and have started working.

Mr. Guthrie. Okay. Mr. Mitchell, you had a comment?

Mr. Mitchell. Yes, sir. I think one of the things that is important there is, was it a hard switch? Because if they pulled the old product, then there is nothing for a doctor to write me a prescription for that is substitutable? And so that is the kind of, you know, specific act that you guys could clarify on.

Mr. Guthrie. Okay. Yeah, Mr. Carrier?

Mr. Carrier. And just to make even clearer, the no economic sense test is the most conservative test in antitrust law. It says, "Drug company, you win, as long as you have one reason other than keeping the generic market." Much more deferential than the rule of reason. That unifies hard switches and soft switches.

In the five cases that have been litigated, there has been no reason. Why pull a billion dollar drug off the market? Makes no sense. No economic sense. Unifies hard and soft switches and does not touch innovation.

Mr. Guthrie. Thanks. Thanks.

Mr. Francer, do you have any comment on that? You are the -- and Ms. Shepherd?

Ms. Shepherd. Yeah. On that comment, I think that the no economic sense, I think that is very difficult to operationalize for various reasons. You know, pharmaceutical companies have a lot of overhead. They do a lot of R&D that isn't designated to a specific drug. It is spread out across a lot of drugs.

And so the no economic sense test is going to require a pharmaceutical company to produce what are the specific costs of this drug, and what are the specific benefits. It is very difficult for them to do.

In addition, I just wonder if it doesn't -- it is not going to encourage gaming. I mean, that would give pharmaceutical companies the incentive to spend less on R&D -- not what we want them to do -- in order for the benefits to be more likely to exceed the cost. And so it just -- I worry about how that could be operationalized.

Mr. Carrier. And just to respond, if you look at the litigated cases, these are not close calls. I know there was a paper written a few days ago criticizing my test, but the cases that have been litigated involve TriCor, a $200 million drug pulled off the market; Nexium, a $4 billion drug; $1.5 billion in Namenda. These are not close cases. The companies are pulling off blockbuster drugs, and there is no sense whatsoever that this makes any sense at all.

Mr. Guthrie. Okay. Thank you.

My time has expired, and I will yield back. Thank you.

Ms. Schakowsky. Thank you. Well, all time for questioning has expired. I certainly want to thank all of our -- oh, I am so sorry. I yield 5 minutes to Mr. Sarbanes. Forgive me.

Mr. Sarbanes. Thank you. Thank you, Madam Chair. Thank

you for the opportunity to waive onto the committee today on a very, very important topic.

Mr. Mitchell, I wanted to ask you some questions. First, thanks for your testimony, and thanks for sharing your personal story and then channeling that into the effective advocacy that you have offered --

Mr. Mitchell. Thank you.

Mr. Sarbanes. -- on so many different venues. You have been pushing on this issue of lower drug prices for a long time, and you are frustrated, I am sure, as I am, by the lack of progress that we have made in terms of addressing the prices of drugs and producing meaningful drug legislation that can push back on industry and prevent these anti-competitive practices that have been detailed today, including product hopping and other things of that nature.

Tell me what you think is creating the barriers up here in Congress when it comes to passing and enacting legislation that would make a meaningful difference with respect to bringing down the cost of drugs for patients.

Mr. Mitchell. I believe that there is one and a half drug company lobbyist for every one of you in Congress right now.

Mr. Sarbanes. I think it is three, actually.

Mr. Mitchell. I believe that by definition -- and the economists flanking me can correct me if I am wrong -- by

definition, monopoly industries have unlimited resources to sustain the monopoly with political power. That monopoly power is being mobilized forcefully to block anything that will effectively lower the list prices of prescription drugs.

And, remember, we can talk about PBMs, we can talk about hospital markups, we can talk about markups by doctors. The headwaters of this problem is the list prices that are set by the drug companies. Nobody sets list prices except the drug companies. If we lower list, everybody who is making a percentage markup downstream will make less money, and it can go back to lower prices for people like me.

So those are the barriers I think that are chief in the way -- chiefly in the way of reform.

Mr. Sarbanes. Well, I agree with you, you won't be surprised to hear, 100 percent on that. I have kind of made myself a student of how the special interest ecosystem has developed here in Washington. Nobody has manipulated that more effectively than the pharmaceutical industry in the ways that you just described.

According to the Center for Responsive Politics, that industry spent more on lobbying last year than any other industry -- $280 million -- and in the 2018 election cycle donated over $41 million to federal candidates and federal committees.

You just made the point about the number of lobbyists that are deployed here on behalf of the industry, some 1,400 lobbyists

last year, according to the Center for Responsive Politics. So we are actually being -- we are actually being teamed at 3 to 1 ratio, which is even more than you suggested, and it is all about protecting the bottom line.

Mr. Mitchell. Well, if I may add, the scare tactics really offend me as a patient. You know, socialism, I am not going to get the drugs I need. There will be no innovation. I am going to die. There is room to lower drug prices. The pharmaceutical industry has profits that run in excess of two times the S&P 500.

There was a piece today in Axios that said that they are getting 20 percent of the profits in the healthcare system based on 20 percent of their revenues. Fifty percent of the profits, I am sorry, based on 20 percent of the revenues. There is money in the system to lower drug prices, allow us to have innovation, especially given that taxpayers pay so much of the money for innovation, to get lower drug prices. It is not going to make the world collapse on us as patients.

But they are shameless in the ways that they go out and lie and try and scare people, that if we actually lower drug prices, so people don't have to die because they can't afford their insulin, that somehow more people are going to die.

Mr. Sarbanes. Well, I appreciate that. I think you are right on the money. And, you know, it is hard sometimes to completely diagnose how this influence-peddling system works up

here. I think it is a combination of conscious active decision-making on the part of industries like the pharmaceutical industry, to protect the bottom line and to maximize their profits. And they make those judgments along the way.

But I also think what operates here is this kind of self-perpetuating system of influence, which makes it hard, even for the more enlightened people within some of these industries and companies, who might want to approach things in a different way, to break free of that model. It just keeps churning and churning and churning.

And it is up to us here who are the ones at whom those efforts are being directed day in and day out to take action to diminish undue influence that comes from these special interests, and lift up and expand the influence of the average person out there. And if we can do that, we will be able to address many of the issues I think that you all have brought to us today.

So thank you for your testimony, and I yield back to the chair.

Ms. Schakowsky. Thank you, Mr. Sarbanes.

So, once again, let me just thank our witnesses for participating in this hearing. I think we learned a lot today, especially the kinds of things that we should watch for as we work on legislation. And certainly we learned about the expertise at hand on this panel when we do so.

I hope my colleagues will all work with me to address this issue of gaming the system, and do it right. The time I believe to act is now.

I remind remembers that, pursuant to committee rules, that they have 10 business days to submit additional questions for the record, to be answered we hope by the witnesses who have appeared, and prompt replies to any of the questions that you may receive.

And now I request unanimous consent to enter the following into the record, other informational material. And without further objection. A research paper by Timothy J. Muris of George Mason University, a journal article published in the Journal of Law and Bioscience titled "May your Drug Price be Evergreen," and a journal article titled "Product Hopping: A New Framework."

[The information follows:]

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

Ms. Schakowsky. And with that, the Subcommittee on Consumer Protection and Commerce is adjourned. Thank you.

[Whereupon, at 12:27 p.m., the subcommittee was adjourned.]