

**PROFITS OVER CONSUMERS: EXPOSING HOW
PHARMACEUTICAL COMPANIES GAME THE SYS-
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HEARING
BEFORE THE
SUBCOMMITTEE ON CONSUMER PROTECTION AND
COMMERCE
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
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SUBMITTED MATERIAL

Research of Generic Drugs, Used Textbooks, and the Limits of Liability for Product Improvements, by Timothy J. Muris and Jonathan E. Nuechterlein, George Mason University, submitted by Ms. Schakowsky¹

Article of December 2018, “May your drug price be evergreen”, by Robin Feldman, published in the Journal of Law and the Biosciences, submitted by Ms. Schakowsky²

Article “Product Hopping: A New Framework”, by Michael A. Carrier and Steve D. Shadown, submitted by Ms. Schakowsky³

¹ Research paper by Timothy J. Muris, George Mason University is available at <https://docs.house.gov/meetings/IF/IF17/20190919/109970/HHRG-116-IF17-20190919-SD003.pdf>.

² Article on “May your drug price be evergreen” is available at <https://docs.house.gov/meetings/IF/IF17/20190919/109970/HHRG-116-IF17-20190919-SD004.pdf>.

³ Article on “Product Hopping: A New Framework” is available at <https://docs.house.gov/meetings/IF/IF17/20190919/109970/HHRG-116-IF17-20190919-SD005.pdf>.

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, DC.

The subcommittee met, pursuant to call, at 10:30 a.m., in room 2322 Rayburn House Office Building, Hon. Jan Schakowsky (chairwoman of the subcommittee) presiding.

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

Also present: Representative. Sarbanes

Staff present: Jeffrey C. Carroll, Staff Director; Evan Gilbert, Press Secretary; Lisa Goldman, Senior Counsel; Alex Hoehn-Saric, Chief Counsel, Communications and Protection; Megan Howard, FDA Detailee; Jerry Leverich, Senior Counsel; Dan Miller, Senior Policy Analyst; 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, Consumer Protection and Commerce; Tim Kurth, Minority Deputy Chief Counsel, Communications and Technology; 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.

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

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

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 anticompetitive 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 three 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 types 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 prepared statement of Ms. Schakowsky follows:]

PREPARED STATEMENT OF HON. JAN SCHAKOWSKY

Throughout today's hearing, you will hear many different terms used to describe the problem we are trying to address: "product hopping," "hard switches," "soft switches," and "evergreening."

But whatever the word or phrase, the bottom line is: drug manufacturers are gaming the system to make more money at consumers' expense.

Big Pharma says that high prices and exclusivity are essential to innovation.

But competition is actually most central to innovation—and the opposite of what Big Pharma wants.

Experts suggest that about 78% 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 by recycling old medicines into new forms.

The problem goes beyond several bad actors you will hear about over and over again today—Humira, Revlimid, Suboxone, Namenda, Prilosec.

Of the 100 best-selling drugs, about 70% had their protection extended at least once, and 50% have had their protections extended more than once.

Many companies are actually withholding new and beneficial discoveries about their drugs from the consumers until they can use this innovation to block competition.

Mr. Carrier's testimony provided 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 three years, until generic competition for their twice-daily drug was imminent, before releasing it.

Big Pharma actually blocked the innovation they claim to treasure—innovation that could have helped patients—until it 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 actions that drug manufacturers take in their commercial practices.

FDA is responsible for protecting public health by ensuring the safety, efficacy, and security of biological products, including drugs.

FDA does not construe patent 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 anti-competitive product hopping, it does not have explicit authority to challenge anticompetitive hard and soft switches.

Americans should not have to hope 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—or find that the generic has decided to settle with the brand company for a hefty Pay-for-Delay sum.

I look forward to learning from our witnesses today, as I craft legislation to protect consumers from Big Pharma's evergreening tactics.

Such legislation will set a precedent that I hope will

- force courts to recognize the consumer harms in evergreening,
- and discourage manufacturers from engaging in their anticompetitive practices to begin with.

We owe it to the American people to stop these practices, and I will do everything in my power to do so.

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

**OPENING STATEMENT OF HON. CATHY McMORRIS RODGERS,
A REPRESENTATIVE IN CONGRESS FROM THE STATE OF
WASHINGTON**

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 re-

search, 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 at 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 life-saving 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 costs. 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 to breaking records for the amount of generic drug approvals at the FDA, bringing down costs.

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.

[The prepared statement of Mrs. Rodgers follow:]

PREPARED STATEMENT OF HON. CATHY McMORRIS RODGERS

Good morning and welcome to the Consumer Protection and Commerce Subcommittee where today we focus on a healthcare competition issue: product hopping.

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 their life-saving treatments.

Product hopping occurs when a drug company attempts to switch patients from their 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 the 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 costs.

We should be focused 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 exactly what we want.

It gives patients access to more medications and treatments, and often times a safer and more effective way to heal.

For instance, there's a treatment for a degenerative muscular disease that required delivery through a needle into the eye.

The company later developed a method for the arm.

I don't know anyone who would prefer a shot in their eye.

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's not how it should be.

Increasing access to affordable treatments and prescription drugs usually is a bipartisan issue.

Energy and Commerce unanimously passed several bills this year tackling drug pricing only to have them packaged into a partisan messaging bill on the floor.

Fortunately, the Trump Administration has led on this front and is breaking records for the amount of generic drug approvals at the FDA.

This year, for the first time in a long time, prescription drug prices have decreased overall.

To build on this progress, 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.

We must be precise.

If we aren't, the government will hinder innovation, America will fall behind world-wide, and patients will be waiting for the cures they need.

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.

Plus, for every incremental dollar spent on new drugs, total medical spending decreases by more than seven dollars.

Americans benefit from innovation and our healthcare system saves money because of it.

Again, the U.S. has led the world in medical innovation, developing more life-saving treatments and cures than any other nation.

Our Committee has a history of bipartisan cooperation in building America as the global leader and no one here wants to reverse progress we've made because of the 21st Century Cures Act.

Any proposal—hopefully considered under regular order in our Health subcommittee—must encourage this innovation and go after clearly anticompetitive 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.

OPENING STATEMENT OF HON. DEBBIE DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

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 researching, 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, the strength of a branded drug, other changes that have little effect or therapeutic value.

Timed correctly, and combined with tactics like removing the older version of the drug from the 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, 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 healthcare 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.

[The prepared statement of Ms. Dingell follow:]

PREPARED STATEMENT OF HON. DEBBIE DINGELL

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 to provide relief to Americans from the high cost of prescription drugs, we must leave no 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.

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 Americans' access to lifesaving medication. When generic drugs enter the market in the United States, prescription drug prices fall dramatically, by up to 90 percent.

This is how a market should work—by rewarding innovation and promoting competition, the American people benefit.

Unfortunately, we have seen 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 their profits.

This often includes minor changes, like reformulating a capsule to a tablet, small changes in the dosing or 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.

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 generic competition cost Americans at least \$5.4 billion annually.

Currently, there is little recourse against these types of abuses. The FTC's authority to address product hopping is limited and unclear. As a result, product hopping and similar practices have proliferated in recent years.

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

Inaction on this issue is not an option. High healthcare and prescription drug costs affect all of us, regardless of background or party. 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 action and reforms.

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.

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

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; 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. They were able to put 971 generics into market last year, record number in a single year, 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 were 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, 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 is 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. The 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 the 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 great results that will benefit our consumers, maintain innovation, and keep America in the lead. And I hope that partisan politics do not snuff that out. And with that, I yield back.

[The prepared statement of Mr. Walden follow:]

PREPARED STATEMENT OF HON. GREG WALDEN

Good morning, Today's hearing is focused on the pharmaceutical industry and the practice known as product hopping.

There's no question that Americans pay too much for their healthcare, including the cost of prescription drugs. Over the past few years, we have made significant efforts to lower the cost of prescription drugs for consumers by advancing key priorities that are now law, including the 21st Century Cures Act, and a reauthorization of the generic drug user fee program in the FDA Reauthorization Act. And it is already working—last year FDA approved a record number of generic drugs, driving competition and giving consumers more choices. Republicans will continue to push for legislation that promotes competition, lowers the out-of-pocket cost for consumers, and establishes transparency and accountability in drug pricing.

But we should also acknowledge the investment required by the industry to remain the global leader in developing innovative and essential treatments and the effort and ingenuity necessary to counter evolutions occurring in the diseases themselves.

On average, it costs companies more than \$2.5 billion to bring a new drug to market, but only about 20 percent of the marketed drugs ever earn enough to recoup those costs. And once the patent exclusivity period is over, brand companies face the likely loss of roughly 80–90 percent of their sales to generic versions of their drug.

In large part, this is due to state substitution laws. Every state has a substitution law that requires or allows pharmacists to offer a generic drug when a patient presents a prescription for a brand drug. However, if the brand drug and generic drug are not the same, such substitution laws do not apply.

For example, if a drug is not bioequivalent—meaning it is able to be absorbed into the body at the same rate or therapeutically equivalent—meaning it has the same active ingredient, form, dosage, strength, and safety profile, then state substitution laws do not apply. Some argue that brand drug makers engage in product hopping to usurp these state substitution laws and ensure patients use their brand drug.

Product hopping occurs when brand pharmaceutical companies attempt to switch customers from an older version of a drug to a newer version. Typically, the newer drug has a longer patent exclusivity life which helps pharmaceutical companies maintain their market position and ultimately recoup the cost of developing new drugs.

There are two types of product hopping: a hard switch and a soft switch. In a hard switch, a brand company completely withdraws their product from the market to enter a new product. A soft switch occurs when a brand company keeps their older product on the market but shifts marketing efforts to the new drug.

Courts have been clear that a product withdrawal or improvement alone is not anticompetitive. Rather whether product hopping is anticompetitive or not relies heavily on the specific facts and circumstances of any given incident and requires some additional wrongful conduct.

To be clear, innovating and replacing older drugs is part of the normal competitive process that companies engage in routinely. We must be cautious about disincentivizing innovation. We know that brand drug companies incrementally improve their drugs all the time and that we see great societal benefits from such improvements. Most innovation by drug makers involves the development of next generation improvements, which may include new products that expand therapeutic classes, or increase available dosing options, or remedy physiological interactions of known medicines, or improve other properties of existing medications. These are good things. We benefit from them. In fact, according to the World Health Organiza-

tion, more than 60 percent of all drugs deemed necessary for combatting prevalent diseases are the result of incremental innovation.

Today's discussion is important, and I am thankful to the panel and to those that traveled to be here with us today.

Before I yield, I would like to say there is a form of product hopping I do support—and that is a product hop to a legislative hearing on autonomous vehicles or a hearing on privacy, so I'll just say I associate myself with Mrs. Rodgers' remarks in that regard. We know there is bipartisan support for those two initiatives, and I know the subcommittee members are eager to work on them.

I look forward to hearing more from you all. Thank you. 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 E. MITCHELL, FOUNDER, PATIENTS FOR AFFORDABLE DRUGS, PATIENTS FOR AFFORDABLE DRUGS NOW; JOANNA M. SHEPHERD, PROFESSOR OF LAW, EMORY UNIVERSITY SCHOOL OF LAW; AND JEFFREY K. 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 really 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 one or two percent—and that is all it has been in the cases, one 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 a 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, and 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 were subject to product hopping. In my testimony, I mention several of them—overpaying \$1.7 billion for Namenda, and 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 manu-

facturer, 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. In the film a kid, puts it 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 than 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:]



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Michael A. Carrier

House Energy & Commerce Committee (Subcommittee on Consumer Protection and Commerce)
Hearing on “Profits over Consumers: Exposing How Pharmaceutical Companies Game the System”
September 19, 2019

I. Introduction

- A. Drug companies play games to increase profits
- B. One game is “product hopping,” making minor changes to keep generics off market
- C. This game cannot be justified by innovation and keeps high-priced drugs out of hands of U.S. consumers

II. My Background

- A. Have studied pharmaceutical antitrust law as co-author of leading IP/antitrust treatise; author of more than 115 articles (60 on pharmaceutical antitrust law); author of “amicus” briefs on behalf of hundreds of professors; and one frequently cited in media (1900+ times) and courts (including Supreme Court)

III. Generic Competition

- A. Generic competition crucial to affordable drugs; price can fall 90%
- B. Regulatory regime encourages competition:
 - 1. Hatch-Waxman Act allows generics to rely on brands’ safety/effectiveness studies
 - a) Drafters sought to ensure provision of “low-cost, generic drugs for millions of Americans” and recognized that generic competition would save consumers and government millions of dollars each year¹
 - 2. State substitution laws, in effect in all 50 states today, allow (and in some cases require) pharmacists to fill prescriptions for brand drugs with generic versions
 - a) Pharmacists play crucial role, as they are more price-sensitive than doctors, make greater margins on generics, and compete with other pharmacies on price
 - 3. Substitution laws needed because of “price disconnect” (doctors prescribe, but not pay for, drug while consumers/insurers pay for, but not select, drug)

IV. Product Hopping

- A. Product hopping occurs through different types of reformulations:
 - 1. Use new forms: e.g., antidepressant Prozac and cholesterol treatment TriCor (capsule to tablet); anxiety-treating Buspar (tablet to capsule)
 - 2. Add/remove compounds: e.g., heartburn-treating Prilosec to Nexium, allergy medication Claritin to Clarinex, antidepressant Celexa to Lexapro, heartburn medication Prevacid to Kapidex
 - 3. Combine previously separate compositions: e.g., migraine-treatment Treximet, high-blood-pressure medications Azor, Caduet, Exforge
- B. Reformulations often appropriate – 80% take place outside “Generic Window” when competition expected²
 - 1. But some switches made just to keep generic off market
- C. Product hopping combines 2 actions:
 - 1. Reformulating product so generic version can’t be substituted and
 - 2. Encouraging doctors to write prescriptions for reformulated product
 - 3. * No innovation reason: brand does not *expand* prescription base; just *migrates* base to block generics
- D. Product hopping does *not* include:
 - 1. Promoting both products without encouraging switch
 - 2. Introducing reformulations to fill out product line or satisfy demand
 - 3. Expanding prescription base by competing with other branded products or growing market
- E. Every time brand changes drug slightly, generic cannot be substituted
 - 1. Substitution requires “AB rating”: generic “therapeutically equivalent” to brand (same active ingredient, form, dosage, strength, safety/efficacy profile) and “bioequivalent” (absorbed into body at same rate)³
 - 2. Product hopping exploits this regulation – minor changes (capsule to tablet, 10-mg to 12-mg dose) prevents generic from obtaining AB rating needed for substitution
 - 3. Generic must then start all over again: reformulate drug, get FDA approval, and fight new set of patents (litigation, automatic 30-month stay)

¹ 130 CONG. REC. 24,410, 24,427, 24,456 (1984).

² Steve Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L. J. 1, 26-27 (2009).

³ FDA, *Orange Book Preface*, <https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface>.



- F. Harms from both “hard switches” (original drug pulled from market) and “soft switches” (original drug remains)
- G. Greater harms when brand switches before generic enters market (promotion/marketing more effective in convincing doctors to prescribe reformulated version)

V. Harms: General

- A. Product hopping has massive effect on consumers
 1. Most recent (2009) empirical analysis found \$28 billion worth of drugs subject to product hopping, including Advair, Allegra, Augmentin, Caduet, Clarinex, Kapidex, Lexapro, Nexium, Prozac, Risperdal⁴
 - a) For \$1 billion blockbuster drug, consumers pay extra \$765 million each year from delayed competition⁵
 2. Consumers have overpaid \$1.7 billion for Namenda, \$200 million for Effexor, \$700 million/year for TriCor, and (according to legal complaints) \$11.5 billion for Nexium and \$650 million annually for Suboxone⁶
 3. Brand firms have charged significantly more each month for drugs like Adasuve (\$4500 vs. \$45), Zytiga (\$10,000 vs. \$3,300), and Treximet (\$695 vs. \$21)⁷
 4. Consumers unable to afford high prices cut pills in half, choose between paying for drugs and food/rent, and do not take needed medicines

VI. Harms: Examples

- A. Cholesterol-treating TriCor: capsule to tablet
 1. Abbott switched from capsule to tablet, (slightly) lowered drug’s strength, bought back drugs, stopped selling capsules, and changed code for capsules in national drug database to “obsolete.”⁸ Then it did all this again.
 2. *Made no sense*: Abbott discouraged doctors from prescribing \$200-million drug, incurring costs to make switch...despite projections showing no new sales or profits⁹
- B. Heartburn-treating Prilosec to Nexium
 1. Almost no difference between drugs, but AstraZeneca aggressively promoted Nexium to doctors while stopping promotion of Prilosec, switching market to receive additional 13 years of patent protection¹⁰
 2. *Made no sense*: Stopped marketing most profitable (\$4 billion) drug...even though sales increased less than for other drugs in class, and expert told doctors they “should be embarrassed” if prescribe “same drug” Nexium¹¹
- C. Opioid-dependence-treating Suboxone: tablets to sublingual (under-the-tongue) film
 1. Reckitt publicly announced removal of tablets for safety reasons (even though tablets safer), waited 6 months to remove, disparaged (and raised price of) Suboxone tablets, and promoted Suboxone film to doctors¹²
 2. *Made no sense*: Raising price of tablets (even though film more expensive) was costly, as was warning of false safety concerns, for result of...“substantially reduced profit margins” on \$700 million in annual sales!¹³
- D. Acne-treating Doryx: capsule to tablet
 1. Warner Chilcott stopped selling capsules, removed capsules from website, “auto-referenced” tablets, informed wholesalers/retailers/dealers that capsules replaced by tablets, and bought back and destroyed capsules¹⁴
 2. *Made no sense*: Capsules earned at least \$50 million in revenues; reformulated version “more costly and difficult” to manufacture, with brand...“not expect[ing]... increased sales or profits.”¹⁵
- E. Alzheimer’s-treating Namenda: IR (2x/day) to XR (1x/day)
 1. To obtain 14 more years of patent protection, Forest stopped actively marketing IR, significantly promoted XR, sold XR at discount, announced discontinuance of IR, and published letters urging switch to XR¹⁶

⁴ Steve Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L. J. 1 (2009).

⁵ FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010),

<http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf> (multiple generics take 90% of sales at average 85% discount).

⁶ 787 F.3d 638, 661 (Namenda); <http://theconversation.com/explainer-evergreening-and-how-big-pharma-keeps-drug-prices-high-33623> (Effexor); <https://www.motherjones.com/kevin-drum/2012/04/how-keep-healthcare-costs-high-one-easy-lesson/> (TriCor); 2007 WL 1480480 (Nexium); https://www.hilliardshadowenlaw.com/images/uploads/banner/Suboxone-2015.04.13-149_-_End-Payor-Plaintiffs_Second_Amended_Complaint.pdf (Suboxone).

⁷ <https://www.consumerreports.org/drug-prices/product-hopping-drives-up-drug-prices-but-you-can-still-save-on-your-meds/> (Adasuve); <https://consumer.healthday.com/cancer-information-5/prostate-cancer-news-106/a-light-breakfast-might-cut-cost-of-pricey-prostate-cancer-drug-732344.html> & <https://www.drugs.com/price-guide/abiraterone-oral-tablet-250-mg> (Zytiga); https://www.washingtonpost.com/national/health-science/nine-tips-for-paying-less-for-doctor-visits-drugs-and-medical-treatments/2018/03/16/f5862014-1b09-11e8-ac5a-16e60c4605f3_story.html (Treximet).

⁸ *Abbott Labs. v. Teva*, 432 F. Supp. 2d 408, 415-18 (D. Del. 2006).

⁹ Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 223 (2016).

¹⁰ *Walgreen v. AstraZeneca Pharmaceuticals*, 534 F. Supp. 2d 146, 148-49 (D.D.C. 2008).

¹¹ Carrier & Shadowen, at 224.

¹² *In re Suboxone Antitrust Litigation*, 64 F. Supp. 3d 665, 674 (E.D. Pa. 2014).

¹³ *Id.*

¹⁴ *Mylan Pharmaceuticals v. Warner Chilcott*, 838 F.3d 421, 429-31 (3d Cir. 2016).

¹⁵ Carrier & Shadowen, at 227.



2. *Made no sense*: Forest pulled one of its best-selling drugs (\$1.5 billion in annual sales) to suffer... “20% franchise disruption” and loss of “tens if not hundreds of millions of dollars”!¹⁷

VII. Harms: Innovation

- A. No empirical evidence has shown innovation would be deterred by applying antitrust analysis to product hopping
- B. Brand firms often withhold incremental innovations from market to use later as part of product hop:
 1. *Tricor*: Abbott delayed seeking new indication for original product, reserving it for reformulation, even though “data necessary to get the new indication was available much earlier.”¹⁸
 2. *Neurontin*: Warner-Lambert conceded that “principal reason[] for not seeking FDA approval” for off-label uses was that it “wanted to reserve them for a later promotional campaign for its reformulated product.”¹⁹
 3. *Namenda*: Forest waited until generic competition for twice-daily Namenda imminent before introducing once-daily version (even though obtained FDA approval three years earlier!)²⁰
 4. If value of “innovation” to consumers was greater than value to brand of delaying generic, would immediately introduce innovation to reap increased gains
- C. Not valuable innovation when product hopping makes sense only by harming generic
 1. *Namenda* court found that defendants “presented no evidence to support their argument that antitrust scrutiny of the pharmaceutical industry will meaningfully deter innovation.”²¹
 2. *Namenda* court also noted that “immunizing product hopping from antitrust scrutiny may deter significant innovation” by encouraging brands to “switch[] the market to trivial or minor product reformulations rather than investing in the [R&D] necessary to develop riskier, but medically significant innovations.”²²
 3. In recent years, drug companies have increasingly sought “ancillary patents on chemical variants, alternative formulations, methods of use, and relatively minor aspects of the drug.”²³

VIII. Solutions

- A. In June, Senate Judiciary Committee passed (by 22-0 vote) the Affordable Prescriptions for Patients Act of 2019
 1. Gives FTC power under Section 5 to challenge anticompetitive hard and soft switches
 - a) Hard switch = (1) withdraw drug or destroy inventory and impede competition + (2) sell follow-on drug
 - b) Soft switch = (1) unfairly disadvantage original and impede competition + (2) sell follow-on drug
 - c) Drug company can offer justifications based on showing (1) would have taken actions regardless of effect on competition and (2) had safety, supply-disruption, or procompetitive reasons for switch
 - d) Deferential analysis accepts all legitimate reasons in context of conservative (“no economic sense”) test
 2. One benefit: Ensure courts recognize harms of soft switches when only reason for change is to harm generic
 - a) *Walgreen’s* court ignored price disconnect in finding no allegation AstraZeneca “eliminated any consumer choices” but claiming it “added choices,” with superiority determinations “left to the marketplace.”²⁴
 - b) *Dorix* court focused on competitor rather than consumer (even though company “made . . . ‘hops’ primarily to ‘delay generic market entry’”).²⁵
- B. FDA
 1. Allow “therapeutic substitutability” (at FDA and states) unless safety/effectiveness concerns
 - a) Require bioequivalence but not mandate same route of administration, dosage form, or strength
- C. FTC Report
 1. Provide report (see S. 771 § 406 (115th Cong.)) covering types of product hops, timing, patents/exclusivities, cost to consumers/insurance, and effect on brand profits and generics

IX. Conclusion

- A. Drug companies call product hopping “life-cycle management” but just keeps gravy train of trivial tweaks running
- B. Congress can play crucial role, encouraging legitimate innovation and helping consumers afford prescription drugs

¹⁶ *New York ex rel. Schneiderman v. Actavis*, 787 F.3d 638, 648 (2d Cir. 2015).

¹⁷ Carrier & Shadowen, at 228.

¹⁸ Steve Shadowen et al., *Bringing Market Discipline to Pharmaceutical Product Reformulations*, 42 IIC 698, 710 (2011) (data “used to get approval for the new indication had been developed in studies for the original product”).

¹⁹ *Id.* (noting that Warner-Lambert “was concerned” that generics “would undermine sales” of the new drug).

²⁰ 787 F.3d at 647.

²¹ *Id.* at 659.

²² *Id.*

²³ C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 JOURNAL OF EMPIRICAL LEGAL STUDIES 613, 615 (2011).

²⁴ 534 F. Supp. 2d at 151.

²⁵ 838 F.3d at 431.

Ms. SCHAKOWSKY. Thank you very much, Mr. Carrier.
And now, Mr. Mitchell, you are recognized for 5 minutes.

STATEMENT OF DAVID E. 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 to 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 nine of ten 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:]

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

before the

**U.S. House of Representatives Subcommittee on Consumer Protection and Commerce
of the**

House Committee on Energy and Commerce

for a hearing on

Protecting Consumers from Pharmaceutical Market Gaming Tactics

September 19, 2019

Chairwoman Schakowsky, Ranking Member McMorris Rodgers, Members of the Committee. I am honored to be here today.

Section I. Background and Introduction

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

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

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

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

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

Cancer had literally broken my back.

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

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

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

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

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

Section II. The Cost of Drugs

From 2011-2016, prescription drug spending in the U.S. grew by 28%, which was more than 2.5 times inflation during that period.¹ Forty-two percent of cancer patients deplete their entire net worth within the first 2 years of treatment — in part due to high drug prices.² And drug spending growth is projected to accelerate by 31% by 2023.³

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

In fact, a recent poll from the Kaiser Family Foundation found that 70% of Americans say lowering prescription drug prices should be Congress' top health care priority. Respondents

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

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

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

ranked it ahead of addressing surprise billing and ensuring protections for people with pre-existing conditions.⁴ People are hurting.

This makes my story far from unique.

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

This week, I started taking a second generation version of that same drug. It has gone up in price by 65% over the past six years. My out-of-pocket cost for the first fill was \$2,758 and I expect my total annual out of pocket to be more than \$13,000 per year — just for that one drug.

Revlimid is an old drug — it was approved by the FDA in 2005 — and the principal reason it is so expensive is because its maker, Celgene, has gamed the system and refused to sell samples to generic companies trying to bring a competitor to market.^{7, 8}

But Celgene isn’t the only drug manufacturer gaming our patent system. Drug corporations often change drugs incrementally and patent the new product, which extends corporations’ monopoly pricing power. For example, a company might move from a tablet to a capsule and apply for a new patent. Patents should not be issued for drugs that are not inventive. And gaming of the system to extend patents and block competition should not be permitted under U.S. law.

Here’s how product hopping impacts patients.

Janice is from California. Her son was struggling to recover from opioid use disorder and needed Suboxone, a drug that has been subject to product hopping. She paid for it, but the roughly \$60 per week was a strain on her family’s budget. She was forced to take out a loan and depleted all of her savings to pay for this medication. “This medicine has been extremely helpful for him,” she says. “Addiction is a deadly disease and I’m glad there is a medication that helps to combat it, but it shouldn’t be this costly.”

She is right.

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

⁵ <https://www.kff.org/report-section/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019-tables/>

⁶ <https://www.kff.org/report-section/medicare-beneficiaries-out-of-pocket-health-care-spending-as-a-share-of-income-now-and-projections-for-the-future-report/>

⁷ <https://www.centerwatch.com/drug-information/fda-approved-drugs/drug/889/revlimid-jenaldomide>

⁸ <https://www.bloomberg.com/news/articles/2018-05-17/u-s-names-drugmakers-gaming-safety-system-to-shield-profits>

Janice's story highlights a drug that has been subject to one of the most egregious examples of product hopping. When faced with patent expiration and generic competition on its blockbuster drug, Reckitt Benckiser switched from a Suboxone tablet to a film that dissolves under the tongue. The company released the film shortly before losing the monopoly on the Suboxone tablet, and then made every effort to switch patients to the film by raising the price of the tablet and flooding doctors' offices with samples of the new version.⁹ Then, citing safety claims later found to be fraudulent, they discontinued the older version, forcing all Suboxone patients onto their new patent-protected version.¹⁰ Reckitt Benckiser undertook this scheme while tens of thousands of Americans were dying annually from misuse and overdoses of opioids.¹¹

But it's not just product hopping on drugs for opioid use disorder or REMS abuses for cancer drugs. Other abuses of our system, like patent thickets, sham citizen petitions, and pay-for-delay deals serve to block competition and keep prices high.

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

Section III. It's Not About Innovation

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

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

This claim mangles the facts.

There is no direct correlation between R&D costs and the price of a drug. As policy expert Avik Roy wrote: "Proponents of high U.S. drug prices argue that high prices are necessary to support pharmaceutical innovation. But, with a modicum of scrutiny, the fatal flaws in this argument become immediately apparent."¹²

⁹ <https://www.thedailybeast.com/suboxone-creators-shocking-scheme-to-profit-off-of-heroin-addicts>

¹⁰ <https://www.ftc.gov/news-events/press-releases/2019/07/reckitt-benckiser-group-plc-pay-50-million-consumers-settling-ftc>

¹¹

<https://www.cdc.gov/drugoverdose/data/statedeaths.html#targetText=70%2C237%20drug%20overdose%20deaths%20occurred,driver%20of%20drug%20overdose%20deaths>

¹² <https://freopp.org/a-market-based-plan-for-affordable-prescription-drugs-931e31024e08>

Dr. Peter Bach, of Memorial Sloan Kettering Cancer Center, and his colleagues also examined this issue in depth. Their findings “counter the claim that the higher prices paid by U.S. patients and taxpayers are necessary to fund research and development.”¹³

Right now, drug companies make enormous profits — roughly two to three times the average of the S&P 500 — and spend most of it on expenses outside of R&D.¹⁴ Nine out of 10 big pharmaceutical companies spend more on marketing, sales, and overhead than on research.¹⁵

From 2013 to 2017, the five largest U.S.-based drug companies spent less than one-fifth of revenue on research and development on average.¹⁶ The same companies — Johnson & Johnson, Pfizer, Merck, AbbVie, and Amgen — spent about 70% more on sales, marketing, and administrative expenses than R&D in this same timeframe.¹⁷

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

U.S. taxpayers foot a huge and critical portion of the bill to develop new drugs. Based on a survey of PhRMA’s own member companies, one out of every three dollars spent on drug research comes from American taxpayers.^{18,19} Every single drug approved by the FDA from 2010-2016 was based on science funded by taxpayers through the NIH.²⁰

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

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

¹³ <https://www.healthaffairs.org/doi/10.1377/hblog20170307.059036/full/>

¹⁴ <https://www.gao.gov/products/GAO-18-40>

¹⁵ https://www.washingtonpost.com/news/wnk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.dc7e820c4172

¹⁶ Analysis of SEC Filings. Top 5 US-based companies by market cap as of November, 2018 (JNJ, PFE, MRK, ABBV, AMGN).

¹⁷ Analysis of SEC Filings. Top 5 US-based companies by market cap as of November, 2018 (JNJ, PFE, MRK, ABBV, AMGN).

¹⁸ <https://www.sciencemag.org/news/2018/09/nih-gets-2-billion-boost-final-2019-spending-bill>

¹⁹ <https://www.phrma.org/advocacy/research-development>

²⁰ <https://www.pnas.org/content/115/10/2329>

- NIH could reinstate its reasonable pricing provision in Cooperative Research and Development Agreements (CRADA) and Exclusive Licensing Agreements. This provision was removed by the NIH in 1995.²¹
- Congress could create an outside entity to support NIH and ensure price is addressed when technology is transferred from the NIH to the private sector.

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

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

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

Section IV. Immediate Legislative Solutions

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

Let's start with patent law.

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

Between 2005 and 2015, at least 74% of the new drug patents issued were for drugs already on the market.²²

Of the roughly 100 best-selling drugs, nearly 80% obtained an additional patent to extend their monopoly period.²³

²¹ <https://www.nytimes.com/1995/04/12/us/us-gives-up-right-to-control-drug-prices.html>

²² <https://www.bloomberg.com/news/articles/2017-11-01/most-new-drug-patents-are-for-old-remedies-research-shows>

²³ https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3061567

These tactics have led to longer exclusivity than our laws intended. The median length of post-approval market exclusivity for small-molecule drugs was not five years or even the seven years allowed for orphan drugs. It was 12.5 years.²⁴

Today, I will focus on one specific strategy used to extend monopolies — product hopping. One of the best definitions of product hopping I have read is this:

“Product hopping, also called ‘forced switching’ or ‘evergreening,’ involves a brand-name company switching the market for a drug, prior to its patent expiration date, to a reformulated version that has a later-expiring patent, but which offers little or no therapeutic advantage. The newer version, for example, could have a slightly different tablet or capsule dose or a slow-release formulation (given once a day rather than twice daily). In conjunction with this change, the company spends heavily to convince doctors and/or patients to switch to the new drug and may even withdraw the (often profitable) older drug from the market before its patent expiration date. When the generic version of the drug becomes available, pharmacists cannot substitute it for the new (branded) version because state laws allow drug substitution only if the dosage strength and other characteristics remain the same.”²⁵

As we approach product hopping from a patient perspective, *the key challenge is to act in a manner that encourages and protects real innovation that delivers meaningful clinical and therapeutic benefits while stopping product hops designed only to thwart competition and keep prices high.*

We support product evolution that improves effectiveness or reduces toxicities of a drug. I take a drug that causes painful peripheral neuropathy — loss of feeling in my feet. If a reformulated drug were to reduce this type of side effect, it would be a positive and innovative change for patients and could merit a patent extension when, for example, the mechanism meets the standards of non-obviousness required for a new patent.

But when drug companies offer a new product that does not provide clinical or therapeutic benefit, there should be no extended patent life.

After a drug company makes incremental or non-innovative changes, it often performs a “soft switch” or a “hard switch” to transfer its market share from the old drug to the new.

²⁴ FN-Wang B, Liu J, Kesselheim AS. Variations in time of market exclusivity among top-selling prescription drugs in the United States. *JAMA Internal Medicine* 2015;175(4):635-637.

²⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915805/>

A soft switch occurs when a drug company aggressively markets the new drug to physicians and patients; it is often accompanied by a price hike in the older drug. A hard switch occurs when a manufacturer stops selling the older version of the drug altogether.

Under both instances, drug makers often flood doctors' offices with free samples of the "new" version for which there isn't a ready generic equivalent.

One reason soft and hard switches are effective in maintaining a drug company's monopoly over a drug can be found in state substitution laws — which are essential policies to encourage and speed market uptake and penetration for generics.

“States have also made it easier for generics to reach the market through their enactment of drug product selection (DPS) laws. Such laws, in effect in all fifty states today, are designed to lower consumer prices. The laws allow (and in some cases require) pharmacists—absent a doctor's contrary instructions—to fill prescriptions for brand-name drugs with generic versions.”²⁶

In the soft switch, the promotion is aimed at getting consumers to request and physicians to write prescriptions for the new version of the drug, thus limiting and/or preventing substitution. In the hard switch, given the importance of substitution laws in driving up generic market share, the new generic is doomed because there is no longer a brand drug for which to substitute.

Clearly, these practices are designed to circumvent the intent of Hatch-Waxman and state substitution laws. How does this play out for patients? Simply stated: We have less choice and pay higher prices.

Two drugs been involved in high-profile product hopping cases are Suboxone and Tricor. Here's what patients have told us about both.

Samantha from West Virginia wrote: “I have been in recovery for over ten years now. The cost of Suboxone is outrageous — especially since, from the time I began taking it until now, the price is still as high or higher. It's ridiculous! It's easier for people to misuse narcotics (the cost is less). The cost for Suboxone is about \$800 [for a 90-day supply].”

Beatel from Minnesota told us: “When I changed to Medicare at 65, my price for 40mg of Tricor went to \$1,800/month. The pharmacist whispered to me, ‘If the doctor changed the order to 160mg tabs and I broke it in half for the 80mg dose, it would cost me \$40.’”

²⁶ <https://scholarship.law.nd.edu/ndlr/vol92/iss1/4/>

The drug company still had the patent on the 40mg tab. The patent for the 160mg tab had expired...same drug."

The encouraging news is that multiple bills are presently making their way through Congress that would help address product hopping abuses:

- *REMEDY Act (S. 1209/H.R. 3812)*: This bill is led by Senators Durbin (D-IL) and Cassidy (R-LA) on the Senate side and Representatives McKinley (WV-01) and Welch (VT-At Large) on the House side. REMEDY allows generic manufacturers to enter the market more easily once the substantive patent and all exclusivities have expired and reduces incentives to litigate patent infringement on non-substantive patents. This would allow generic manufacturers to bring drugs to market sooner.
- *Terminating the Extension of Rights Misappropriated (TERM) Act of 2019 (H.R. 3199)*: This bill, led by Representatives Jeffries (NY-08) and Collins (GA-09), would nullify all patents for a drug once the first patent expires, unless the drug maker can demonstrate with a preponderance of evidence that a new patent covers an invention that is "patentably distinct". This bill would limit the ability of pharmaceutical companies to extend their monopoly exclusivities by product hopping.
- *Affordable Prescriptions for Patients Act (S. 1416)* This bill is led by Senators Cornyn (R-TX) and Blumenthal (D-CT), and establishes product hopping as an anti-competitive behavior in violation of antitrust law. Under the bill, product hopping is defined as when a manufacturer obtains approval of an application for a change, modification, or reformulation of an already existing and approved drug that makes generics that were previously substitutable for the drug no longer substitutable. Exceptions to the bill are generally any evidence that the competitive benefits outweigh the anticompetitive.

Members of this committee are supportive of numerous other bipartisan bills to address patent abuses and anti-competitive industry practices. I thank Committee members for their work. We have lent our support to the following bipartisan bills making their way through the House and Senate to address these abuses:

- **Pay-for-delay Deals:** Brand name drug companies pay off generic companies that plan to bring a competitor to market. In exchange for this payment (or something of value that could be another commercial consideration), the generic manufacturer delays its product's entry into the market. This practice is addressed by H.R. 2375, the *Preserve Access to Affordable Generics and Biosimilars Act*, sponsored by Representatives Nadler (NY-10) and Collins (GA-09).

- **REMS abuses:** Brand drug companies use a safety program called Risk Evaluation and Mitigation Strategies (REMS) as a pretext for not selling drug samples to generic companies, which need the brand product in order to develop an equivalent and lower-priced competitor. The U.S. government could save \$3.9 billion²⁷ by stopping this abuse, which the FDA has called “unfair and exploitative.”²⁸ The bipartisan CREATES Act (H.R. 965) tackles this issue by providing an avenue for generic companies to sue brand name companies for samples. In the House, CREATES is led by Representatives Cicilline (RI-01), Sensenbrenner (WI-05), Nadler (NY-10), Collins (GA-09), Welch (VT-At Large), and McKinley (WV-01).
- **Patent-thickets:** Brand drug companies often file dozens of new patents on old drugs in order to force a generic company to file suit against each of them, delaying a generic competitor from coming to market. For example, AbbVie secured more than 100 patents on Humira and is currently blocking a competitor in the U.S.²⁹ The *Affordable Prescriptions for Patients Act (S.1416)*, sponsored by Senators Cornyn (R-TX) and Blumenthal (D-CT) provides authority to challenge patent thickening behavior as anti-competitive.
- **Sham citizen petitions:** Brand-name drug makers were behind 92% of all citizen petitions filed between 2011 and 2015 — all aimed at blocking cheaper generic drugs. The FDA threw out nine of every 10 of those petitions.³⁰ Congress should stop the use of sham citizen petitions. Both the *Ensuring Timely Access to Generics Act of 2019* (H.R. 2455), sponsored by Representatives Joyce (PA-13) and Brindisi (NY-22), and *Stop STALLING Act* (H.R. 2374), led by Representative Jeffries (NY-08) and others, add scrutiny and accountability to the citizen petition process.
- **Transparency and price hikes:** Drug prices cannot be properly addressed without achieving transparency on the part of pharmaceutical manufacturers. The *Fair Drug Pricing Act (H.R. 2296)* requires manufacturers to report and justify certain price hikes. This bill, sponsored by Representatives Schakowsky (IL-09) and Rooney (FL-19), passed out of House Energy and Commerce Committee as part of the *METRIC Act*.

Next, we need Medicare price negotiations.

Over the past five years, AbbVie, the company that makes the top selling drug in the world, Humira, has more than doubled the price here in the United States. But in Europe, Abbvie sells

²⁷ <https://www.cbo.gov/publication/54479>

²⁸ <https://www.fda.gov/news-events/speeches-fda-officials/remarks-fdc-workshop-understanding-competition-prescription-drug-markets-entry-and-supply-chain>

²⁹ <https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug>

³⁰ <https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1956&context=aulr>

the exact same drug for 80% less.³¹ On average, Americans pay twice as much for prescription drugs as other nations.³²

Why does the rest of the world get affordable drugs while Americans pay outrageous prices?

One big reason is that other countries negotiate directly with drug companies. We should, too. Given the prices we pay, it is clear that relying on pharmacy benefit managers to negotiate is not working. We know that not only from the experience of other nations, but also from the Veterans Administration (VA). The VA negotiates and Medicare Part D could have saved \$14.4 billion in 2016 alone by negotiating as the VA did.³³

Medicare negotiations can take several approaches; the VA approach is just one. The framework recently reported on from leadership in the House of Representatives would ensure that Americans benefit from lower drug prices whether covered by a government plan or private insurance. Importantly, it incorporates bipartisan elements like international reference pricing and inflation caps. We look forward to reviewing the bill when it is introduced.

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

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

Moreover, rebates are sometimes used to stymie competition. Professor Robin Feldman explains “the system contains odd and perverse incentives, with the result that higher-priced drugs can receive more favorable health-plan coverage, channeling patients toward more expensive drugs.”³⁴ Lower-priced alternatives may be unable to gain traction in the market because of a huge, legal kickback given for use of the more expensive brand — costing patients, consumers and taxpayers.

Secret rebates are bad policy. This is economics 101: Competition — the free market — can't work effectively without transparency.

Section V. Conclusion

³¹ <https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html>

³² <https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/>

³³ <https://www.statnews.com/pharmalot/2019/01/14/medicare-drug-prices-veterans-affairs/>

³⁴ https://www.washingtonpost.com/outlook/2018/11/26/why-prescription-drug-prices-have-skyrocketed/?utm_term=.f9e74687f9af

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

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

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

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

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

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

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

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

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

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

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 are 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 taking 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 file an acceptable ANDA containing a paragraph four 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:]

TESTIMONY OF JOANNA SHEPHERD,
PROFESSOR OF LAW AT EMORY UNIVERSITY

BEFORE THE SUBCOMMITTEE ON CONSUMER PROTECTION AND COMMERCE,
U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY AND COMMERCE

HEARING ON *PROFITS OVER CONSUMERS: EXPOSING HOW PHARMACEUTICAL COMPANIES GAME THE
SYSTEM*

SEPTEMBER 19, 2019

Chairwoman Schakowsky, Ranking Member Rodgers, and distinguished members of the Subcommittee, thank you for the opportunity to testify about product hopping in the pharmaceutical industry.

My name is Joanna Shepherd. I am a Professor of Law at Emory University. I hold a Ph.D. in Economics and was formerly an Economics Professor. My research focuses on various topics in law and economics, including the healthcare industry and empirical analyses of the civil justice system. I have published broadly in law reviews, legal journals and peer-reviewed economics journals, and I am the author of two books. My research has been cited by numerous courts, including the U.S. Supreme Court. I have previously testified before the House Judiciary Committee, and before the National Academy of Sciences and several state legislative committees.

I. EXECUTIVE SUMMARY

Product hopping is a phrase used in certain quarters to describe brand drug companies' attempts to switch customers from an older version of a drug to a newer version. Typically, the newer drug has a longer patent life, thus extending the brand company's market exclusivity and profits. A product hopping switch can be either a "hard switch" or "soft switch." In a hard switch, a brand company completely withdraws an older drug from the market while introducing a new drug, whereas in a soft switch, the brand company keeps the older product on the market, but shifts marketing efforts to the new drug.

Whether product hopping is anticompetitive is highly situation dependent. Replacing older drugs for newer drugs is generally part of the normal competitive process that companies engage in as they produce innovative new products. This replacement is usually procompetitive in that it provides newer and better choices for consumers. However, when certain conditions are met, some hard and soft switches may be anticompetitive, coercing consumers to switch drugs and

depriving them of choice. This testimony will explain when brand drug company's market replacement of an older product for a newer product constitutes anticompetitive product hopping. A hard switch that eliminates consumer choice with no offsetting consumer benefit is likely an anticompetitive product hop. A soft switch that significantly interferes with consumer choice to the point that it effectively eliminates it, with no offsetting consumer benefit, is likely anticompetitive.

The next section of this testimony explains the incentives for product hopping created by legislation that applies to the drug market, patent law, and state substitution laws. The third section discusses the only two Circuit court cases that have analyzed whether product hopping claims violate federal antitrust law. In the fourth section, I describe the conditions that must be present for both a hard switch and a soft switch to be anticompetitive. The fifth and last section of this testimony explains that if enacted legislation is too broad or overly vague, instead of benefitting consumers it could harm them by reducing innovation and increasing health care spending.

II. THE LEGAL AND INDUSTRY FRAMEWORK THAT INCENTIVIZES PRODUCT SWITCHING

In this section, I describe the incentives for product hopping created by patent law and state substitution laws.

Patent law incentivizes brand-name pharmaceutical companies to make new drugs by granting an exclusive patent period during which the brand company can charge higher prices. The ability to charge higher prices during the patent period is critical because it allows the company to recoup the exorbitant costs of bringing a drug to market and provides a powerful profit incentive to innovate. Data indicate that the average brand drug takes over 10 years and \$2.6 billion to make it through the arduous FDA approval process.¹ Moreover, only 10 percent of drugs that begin clinical trials are eventually approved by the FDA.² For the majority of brand manufacturers, this

¹ Joseph A. DiMasi, Director of Economic Analysis, Tufts Center for the Study of Drug Development, Briefing: Cost of Developing a New Drug (Nov. 18, 2014), http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18_2014.pdf. An older study by the same authors found that it cost over \$1 billion to bring a drug to market. Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 *MANAGERIAL & DECISION ECON.* 469 (2007).

² Michael Hay et al., *Clinical Development Success Rates for Investigational Drugs*, 32 *NATURE BIOTECHNOLOGY* 40, 40-41 (2014). The study used data from 2003-2011 and included both new drug applications and biologic license applications. *Id.* at 40.

means that they will never recoup their research and development costs; in fact, 80 percent of marketed brand drugs never earn enough sales to cover these costs.³

In contrast to the FDA approval process for new drugs, generics face a much cheaper and quicker process. The Hatch-Waxman Act in 1984⁴ created the Abbreviated New Drug Application (“ANDA”) process that greatly truncates the approval process for generic drugs that can demonstrate bioequivalence with the corresponding brand drug.⁵ Generics that establish bioequivalence can rely on *previously submitted* brand-name safety and efficacy data, and skip the most expensive portion of the FDA approval process for brand drugs—the clinical trials.⁶ As a result of the ANDA process, it only costs generics \$1 to \$2 million to bring a drug to market. By contrast, it costs an average of \$2.6 billion to bring a new branded drug to market because of the costs of research, development and the FDA approval process.⁷

Moreover, as their patent period expires, brand companies face the likely loss of 80-90 percent of their sales to generic versions of the drug under state substitution laws. These laws allow or even require pharmacists to automatically substitute a generic equivalent drug when a patient presents a prescription for a brand drug. As a result, state substitution laws enable generics to “free-ride” off their brand name counterparts. Brand name manufacturers engage in extensive marketing efforts, often spending hundreds of millions of dollars to promote their drugs to physicians⁸ and the general public.⁹ When generic drugs are automatically substituted for brand drugs under state substitution laws, the generic companies reap the benefits of years of the brand companies’ marketing efforts without bearing the costs. Generic companies typically spend very

³ News Release, U.S. Food & Drug Admin., FDA Approves Ofev to Treat Idiopathic Pulmonary Fibrosis (Oct. 15, 2014) <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm418994.htm>.

⁴ Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355(2012)).

⁵ See Holly Soehnge, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers*, 58 FOOD & DRUG L.J. 51, 53 (2003).

⁶ 21 U.S.C. § 355(j).

⁷ OFFICE OF THE ASSISTANT SEC’Y FOR PLANNING & EVALUATION, U.S. DEP’T OF HEALTH & HUMAN SERVS., EXPANDING THE USE OF GENERIC DRUGS (Dec. 1, 2010), <http://aspe.hhs.gov/basic-report/expanding-use-generic-drugs#11>; Henry Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, 8 GEO. PUB. POLICY REV. 7, 13 (2003) (noting that “[g]eneric firms can file an Abbreviated New Drug Application (ANDA), a process that takes only a few years and typically costs a few million dollars.”).

⁸ Estimates suggests that pharmaceutical companies spend almost \$100,000 in marketing efforts for every 11 practicing physicians in the United States. Abigail Zuger, *Fever Pitch: Getting Doctors To Prescribe Is Big Business*, N.Y. TIMES, Jan. 11, 1999, at A1.

⁹ Brand companies spent between \$103 million and \$249 million on the top-10 most heavily advertised drugs in 2014 alone. See Beth Snyder Bulik, *The Top-10 Most Advertised Prescription Drug Brands*, FIERCEPHARMAMARKETING (2015), <http://www.fiercepharmamarketing.com/special-reports/top-10-most-advertised-prescription-drug-brands>

little on advertising. Instead, they free-ride on the marketing efforts of brand companies and rely on automatic substitution laws for a large chunk of their sales.

Brand companies, understanding that automatic substitution laws grant generics a regulatory windfall, often have no incentive to develop new indications for existing drugs or to continue marketing their drugs after the patent period expires and generics enter the market. To do so would essentially be handing over 80-90 percent of their sales directly to generic competitors. And a perverse consequence of the laws is that the more effective the brands are at promoting their drug to prescribers, the more money generics make when pharmacists substitute the brand for the generic.

As a result of a patchwork of multiple statutes, brand companies have the incentive to shift their marketing efforts to a new patent-protected drug which can serve as a substitute for the drug about to go off patent. To acquire a patent and FDA approval, the new drug must be different and innovative; for example, new versions may be extended-release drugs that improve patient compliance and reduce the likelihood of adverse events, scored versions of tablets that allow for increased dosing flexibility, or variations in dosage strengths that allow the drug to be used to treat new indications. The brand companies hope that if they can establish a market for their new drug, which may inevitably shift many of the consumers away from the original drug, they can preserve their profitability. While patients benefit from the development of these new drugs, critics note that they will keep at least some of the brand companies' sales out of the hands of generic entrants. Thus, incentives under patent law—incentives to innovate in order to obtain the exclusionary patent period—motivate brand companies to create new drugs instead of handing over the majority of their sales to the generic companies. As the FTC has explained, these new drugs can, in turn, benefit consumers: “The threat posed to existing brand drugs by generic competition can incentivize the brand company facing a dramatic loss of sales to develop new and innovative drugs that benefit consumers.”¹⁰

III. PRODUCT-HOPPING DECISIONS IN CIRCUIT COURTS

Because product hopping, at least in its extreme forms, naturally frustrates generic manufacturers that can no longer free-ride off of the marketing efforts of brand companies, courts have seen some litigation in this area. The next section discusses the only two Circuit Court cases that have issued decisions on product hopping.

¹⁰ Brief for Federal Trade Commission as Amicus Curiae, *Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Limited Company*, No. 12-3824, 2012 WL 7649225, (E.D. Pa. Dec. 3, 2012).

A. *New York v. Actavis*

In May 2015, *New York v. Actavis* became the first appellate case to address pharmaceutical product hopping.¹¹ In the case, the state of New York claimed that brand drug company Forest Laboratories, a subsidiary of Actavis, had initiated a hard switch to remove Alzheimer drug Namenda IR from the market and replace it with Namenda XR. The difference between the XR and IR versions was in dosage form; IR was a twice-daily drug but XR was a once-daily extended release drug. Initially the company sold both IR and XR, but tried to “soft switch” consumers to XR. Forest spent substantial sums promoting XR to doctors, caregivers, patients, and pharmacists.¹² The company also sold XR at a discounted rate, making it “considerably less expensive” than IR, and gave rebates to health plans so that patients would not have higher co-pays for XR compared to IR.¹³ At the same time, Forest ceased actively marketing IR. However, as the end of the IR patent approached, the company announced plans to discontinue selling IR altogether—a hard switch.

However, before Forest could withdraw Namenda IR, the district court issued a preliminary injunction requiring Forest to continue selling the superseded IR until one month after generics entered the market. The Second Circuit upheld the injunction in *New York v. Actavis*, concluding that Forest’s planned replacement of Namenda IR with Namenda XR violated Section 2 of the Sherman Act.¹⁴ The Court decided that, while Forest’s soft switch still gave consumers the ability to choose between the drugs, the planned hard switch eliminated this choice. It determined that Forest’s product switch would produce anticompetitive and exclusionary effects on competition, creating a “dangerous probability” that Defendants would maintain their monopoly power after generics entered the market.¹⁵

Certainly, neither product withdrawal nor product improvement alone is anticompetitive. But under *Berkey Photo*, when a monopolist *combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, and to impede competition, its actions are anticompetitive under the Sherman Act . . . Here, Defendants’ hard switch—the combination of introducing Namenda XR into the market and effectively withdrawing Namenda IR—forced Alzheimer’s patients who depend on memantine therapy to switch to XR (to which generic IR is not therapeutically

¹¹ *New York v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015).

¹² *Id.* at 648.

¹³ *Id.*

¹⁴ *Id.* at 653.

¹⁵ *Id.* at 655.

equivalent) and would likely impede generic competition by precluding generic substitution through state drug substitution laws.¹⁶

B. Mylan v. Warner Chilcott

In September of 2016, *Mylan Pharmaceuticals v. Warner Chilcott* became the second and only other appellate case to analyze whether product hopping claims violate federal antitrust law.¹⁷ In *Mylan*, the generic plaintiff argued that brand drug company Warner Chilcott engaged in a series of product hops of acne drug Doryx by introducing reformulations that merely modified the drug's form, dosage or score.¹⁸ With each change, Warner Chilcott eventually ceased promoting the prior formulations and ultimately withdrew them from the market, but generally not before Mylan began selling a generic version. The plaintiffs alleged that these reformulations were intended to create obstacles for generic manufacturers benefiting from automatic substitution laws because each change required generic manufacturers to re-apply for AB-rating to allow them to continue to benefit from state substitution laws.¹⁹

The Third Circuit concluded that Warner Chilcott had not violated Section 2 of the Sherman Act, primarily because it lacked the requisite monopoly power in the relevant market under the rule of reason test. First, the court determined that because Warner Chilcott had only an 18 percent market share in the market of interchangeable oral tetracycline drugs (a much broader market than Plaintiffs argued was relevant), it did not have monopoly power nor was it likely to achieve monopoly power with its product hops.²⁰ The Court further concluded that Warner Chilcott's product hops were not anticompetitive because Mylan was not entirely blocked from the market; brand Doryx had been off patent with other generic competitors for many years and Mylan continued selling generic Doryx during the relevant time period. The court ultimately concluded that although "[d]efendants were motivated by an intent to compete with generics, the evidence nonetheless demonstrates that Defendants' product modifications had no anticompetitive effects on the market."²¹

C. Points of Agreement in Circuit Decisions

Although the 2nd Circuit in *Actavis* ruled for the generic plaintiff and the 3rd Circuit in *Mylan* ruled for the brand defendant, there are several issues on which the Courts seem to agree.

¹⁶ *Id.* at 653-54.

¹⁷ *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421 (3d Cir. 2016)

¹⁸ *Id.* at 430.

¹⁹ *Id.*

²⁰ *Id.* at 436-438.

²¹ *Id.* at 439.

First, the brand drug must have monopoly power. In *Actavis*, the defendant clearly had monopoly power, at least narrowly conceived, because the Namenda products were the only dementia drugs based on memantine. In contrast, in *Mylan*, there were several drugs on the market with the same active ingredients as Doryx that doctors, insurers, and the FDA considered to be fully interchangeable. Although both courts view monopoly power as essential, they differ in defining the market in which the power must exist. The 2nd Circuit defined the relevant market as the brand drug and its generic equivalents only, whereas the 3rd Circuit defined the market more broadly to include interchangeable products in the same therapeutic class.

Second, patent cliffs are important. In *Actavis*, the fact that the Namenda IR patent was imminently expiring when Forest announced the hard switch was critical to the 2nd Circuit's decision that the switch was for the purpose of eliminating generic competition. The 3rd Circuit agreed that an expiring patent may have resulted in a different outcome in *Mylan*: "Here, there were no patent cliffs on the horizon, and the evidence demonstrates that there were plenty of other competitors already in the oral tetracycline market."²²

Third, brand company's reasons (or lack thereof) for engaging in the switch are important. Both courts agree that it would raise suspicions if the brand defendant has no reason for switching drugs other than impeding generic competition. The 2nd Circuit in *Namenda* concluded that "[a]ll of Defendants' procompetitive justifications for withdrawing IR are pretextual."²³ In *Mylan*, the third circuit believed that the defendants offered strong evidence of non-pretextual purposes for their various product changes, but asserted that "we do not rule out the possibility that certain insignificant design or formula changes, combined with other coercive conduct, could present a closer call with respect to establishing liability in future cases."²⁴

Fourth, the nature of the switch is important, with hard switches much more likely to be deemed anticompetitive. In *Mylan*, the 3rd Circuit ruled in favor of the brand defendant because Warner Chilcott did not engage in a hard switch: "[w]hile product hopping under certain circumstances may be viewed as anticompetitive conduct, this is not one of those cases. . . . Mylan was not foreclosed from the market."²⁵ In *Actavis*, the 2nd Circuit implied that they would have concluded differently if Forest had only engaged in a soft switch:

Defendants argue that courts should not distinguish between hard and soft switches. But this argument ignores one of Berkey Photo's basic tenets: the market can determine whether one product is superior to another only 'so long as the free choice of consumers is

²² *Id.* at 440.

²³ *New York v. Actavis PLC*, 787 F.3d 638, 658 (2d Cir. 2015).

²⁴ *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 440 (3d Cir. 2016)

²⁵ *Id.* At 438.

preserved.’ Had Defendants allowed Namenda IR to remain available until generic entry, doctors and Alzheimer’s patients could have decided whether the benefits of switching to once-daily Namenda XR would outweigh the benefits of adhering to twice-daily therapy using less-expensive generic IR (or perhaps lower-priced Namenda IR). By removing Namenda IR from the market prior to generic IR entry, Defendants sought to deprive consumers of that choice.²⁶

IV. WHEN IS PRODUCT HOPPING ANTICOMPETITIVE: CONSIDERATIONS FOR FUTURE LEGISLATION

Brand drug companies incrementally improve their drugs all the time. According to the World Health Organization, over 60 percent of drugs deemed necessary for combating prevalent diseases are the result of incremental innovations.²⁷ Most of this activity is procompetitive in that it provides newer and better drug choices for consumers. So, when does a brand drug company’s market replacement of an older product for a newer product constitute anticompetitive product hopping? Below I discuss the elements that would make both a hard switch and, in some cases, a soft switch anticompetitive.

A. Hard Switch

In *Actavis*, the 2nd Circuit stated that “[c]ertainly, neither product withdrawal nor product improvement alone is anticompetitive.”²⁸ Indeed, removing an older drug from the market and replacing it with a newer, more effective drug is generally procompetitive. We should encourage drug companies to remove older products when there is a newer product that is clearly safer or more effective. And perhaps even more importantly, we should encourage drug companies to invest in innovating and improving their products.

However, if the hard switch eliminates consumer choice with no offsetting consumer benefit, then it is likely an anticompetitive product hop.

²⁶ *New York v. Actavis PLC*, 787 F.3d 638, 654-655 (2d Cir. 2015).

²⁷ J. Cohen, L. Cabanilla, & J. Sosnov, *Role of Follow-On Drugs and Indications on the WHO Essential Drug List*, 31 J. CLINICAL PHARMACY & THERAPEUTICS 6, (2006).

²⁸ *New York v. Actavis PLC*, 787 F.3d 638, 653-654 (2d Cir. 2015).

1. *Eliminates Consumer Choice*

A hard switch eliminates consumer choice when it coerces the consumers into switching to the new product because there are no available alternatives to the original product. For example, this would occur if an older drug was pulled from the market right before its patent expired 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 no longer have the choice of the older drug. They would also effectively have no choice of the generic drugs once they entered the market. As the 2nd Circuit explained in *Actavis*, because generics do little marketing on their own, “competition through state drug substitution laws is the only cost-efficient means of competing available to generic manufacturers”.²⁹

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 taking the generic versions of the older drug, so replacing the older drug with a newer drug would not coerce them into switching from the generic drug they had been taking. In fact, in this case, the product switch would be procompetitive because it would give consumers more choice. As the 2nd Circuit explained in *Actavis*, there is no consumer coercion if “generics had already entered the market at the time of defendants’ product reformulation.”³⁰ Similarly, a hard switch would not eliminate consumer choice if a brand company replaced a drug with plenty of patent life remaining and no generics on the horizon. This switch would not reduce the drugs that consumers could choose from; they had one drug to choose before the switch and one drug to choose after the switch.

These examples suggest that there is a window during which a hard switch can be presumed to be anticompetitive but, outside of that window, it is extremely unlikely that the product replacement eliminates consumer choice. For conventional, small-molecule drugs this window starts around the time a generic company files an acceptable ANDA containing a Paragraph IV challenge to the drug as this indicates that there is a generic competitor that could potentially enter the market. The window should end when the generic drug has penetrated the market. According to existing research, generics are able to capture over 70 percent of the brand drug’s market share within only 3 months of their market entry.³¹ Thus, the relevant window should end sometime around 3 months after generic entry. Outside of this window, whether before the Paragraph IV

²⁹ *New York v. Actavis PLC*, 787 F.3d 638, 656 (2d Cir. 2015).

³⁰ *New York v. Actavis PLC*, 787 F.3d 638, at 652 n.23 (2d Cir. 2015).

³¹ Henry Grabowski, Genia Long, & Richard Mortimer, *Recent Trends in Brand-Name and Generic Drug Competition*, 17 J. MED ECON. 207 (2014).

challenge or after generics have penetrated the market, a hard switch will generally not eliminate consumer choice.³²

2. Consumer Benefit

Nevertheless, drug manufacturers that initiate a hard switch during this presumptively anticompetitive window should be able to justify the action if the new product is safer or significantly more effective. Not allowing this exception would deter drug companies from investing in and introducing clearly superior products, which would ultimately harm consumers.

Indeed, allowing defendants to justify their otherwise anticompetitive conduct is consistent with the rule-of-reason test that has generally been applied to antitrust claims by the Supreme Court over the last 100 years.³³ Under this framework, once a plaintiff establishes that the defendant's conduct is anticompetitive, the defendant may offer non-pretextual procompetitive justifications to defend its conduct.

B. Soft Switch

In general, the market introduction of a new or improved product while leaving an older product on the market is procompetitive. Consumers have access to more products, and the new product is likely to be safer or more effective in some way. We should encourage drug companies both to invest in improving their products and to bring those drugs to market when they are available. Consequently, regulation of soft switches should be done with caution.

However, if a soft switch includes conduct that significantly interferes with consumer choice so that it effectively eliminates it, with no offsetting consumer benefit, then the soft switch is likely anticompetitive.

1. Significant Interference with Consumer Choice

A soft switch significantly interferes with consumer choice to the point of effectively eliminating it when customers have no practical alternative but to switch to the new product. For

³² It is possible that a generic could submit a Paragraph IV challenge but never come to market. In this situation, the brand company would be in limbo in this window indefinitely, even though replacing an older product with a newer product would not eliminate consumer choice. Thus, there should be an allowance that if no generics enter the market within a set amount of time, the brand company is not presumed to be in this anticompetitive window.

³³ *Standard Oil Co. v. United States*, 221 U.S. 1, 31 S. Ct. 502, 55 L. Ed. 619 (1911)

example, if a brand drug company keeps an older drug on the market but communicates unambiguously fabricated safety concerns to doctors while championing the newer alternative, then patients effectively have no choice but to switch to the new drug.³⁴ Similarly, if a brand company destroys inventory of the older drug to create a shortage so that prescribers stop prescribing it, then consumers would effectively have no choice.

However, a soft switch would not significantly interfere with consumer choice to the point of effectively eliminating it if the brand company engages in standard business practices that typically accompany the introduction of a new product. These standard practices include advertising that is consistent with FDA-approved labelling, reallocating marketing efforts to the newly-released product, offering price discounts or samples so patients will try the new product, or otherwise encouraging doctors and insurers to direct patients to the new product. While these practices may shift market share to the new drug, they do nothing to eliminate the availability of the older drug or 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.

Thus, a soft switch should only be presumptively anticompetitive if it so significantly interferes with consumer choice that it effectively coerces patients into switching. This degree of interference will typically require some other wrongful conduct, such as fabricating safety concerns or falsely disparaging a product, 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. As the 2nd Circuit explained in *Actavis*, “the market can determine whether one product is superior to another only ‘so long as the free choice of consumers is preserved.’”³⁵

2. *Consumer Benefit*

As with a hard switch, defendants that initiate a soft switch that significantly interferes with consumer choice should be able to justify the action if the new drug is safer or more effective. Not allowing this exception would deter drug companies from introducing superior products, which would ultimately harm consumers.

³⁴ See *In re: Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*, 64 F.Supp.3d 665, 681 (E. D. Pa. 2014).

³⁵ *New York v. Actavis PLC*, 787 F.3d 638, 654-655 (2d Cir. 2015) (citing to *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 (2d Cir. 1979)).

V. CONSEQUENCES OF OVERLY BROAD OR VAGUE LEGISLATION

Legislation defining anticompetitive product hopping should aim to facilitate generic entry and lower drug prices. However, if the enacted legislation is too broad or overly vague, it could instead harm consumers by reducing innovation and increasing health care spending.

First, overly broad legislation would deter important future innovations. Most innovation in the pharmaceutical industry involves development of next generation improvements, such as creating new products that expand therapeutic classes, increase available dosing options, remedy physiological interactions of known medicines, or improve other properties of existing medicines.³⁶ According to FDA data, two-thirds of new drug approvals are for these incremental innovations.³⁷ And according to the World Health Organization, over 60 percent of drugs deemed necessary for combating prevalent diseases are the result of incremental innovations.³⁸ Overly broad legislation would deter these important incremental innovations that are critical to improving health outcomes.

Second, legislation that is unclear about when the introduction of new products will be deemed anticompetitive product hopping will create significant uncertainty for brand innovators. This uncertainty may, in turn, lead to less innovation in the pharmaceutical industry. Brand drug companies are largely responsible for pharmaceutical innovation; in the last decade, they have spent over half a trillion dollars on R&D, and they currently account for over 90 percent of the spending on the clinical trials necessary to bring new drugs to market.³⁹ But if brand companies cannot reliably predict whether the introduction of new products will be considered anticompetitive, they will have less incentive to engage in costly R&D. The companies will not spend the billions of dollars⁴⁰ it typically costs to bring a new drug to market when they cannot be certain if, years down the road, the introduction of that new drug will lead to significant litigation,

³⁶ See, INT'L FED'N OF PHARMACEUTICAL MFRS. & ASS'NS, INCREMENTAL INNOVATION: ADAPTING TO PATIENT NEEDS, 11 fig.3 (Jan. 2013), http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_Incremental_Innovation_Feb_2013_Low-Res.pdf.

³⁷ NAT'L INST. FOR HEALTH CARE MGMT. RESEARCH & EDU. FOUND., CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION, 3 (2002).

³⁸ J. Cohen, L. Cabanilla, & J. Sosnov, *Role of Follow-On Drugs and Indications on the WHO Essential Drug List*, 31 J. CLINICAL PHARMACY & THERAPEUTICS 6, (2006).

³⁹ PhRMA, *2019 Profile Biopharmaceutical Research Industry 2* (2019), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/2019-Profile-Booklet_FINAL_NoBleeds.pdf. See generally, Kaitin, N. Bryant & L. Lasagna, *The Role of the Research-Based Pharmaceutical Industry in Medical Progress in the United States*, 33 J. OF CLINICAL PHARMACOLOGY 414 (1993), (92 percent of new drugs are discovered by private branded companies).

⁴⁰ Joseph A. DiMasi, Director of Economic Analysis, Tufts Center for the Study of Drug Development, Briefing: Cost of Developing a New Drug (Nov. 18, 2014), http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18_2014.pdf.

market-stopping injunctions or penalties. If product hopping legislation increases the uncertainty around the introduction of new products, innovation will suffer.⁴¹

The consequences of this reduced innovation will be felt by consumers. Research shows that pharmaceutical innovation has produced significant health benefits to consumers. Empirical estimates of the benefits of pharmaceutical innovation indicate that, on average, each new drug brought to market saves 11,200 life-years *each year*.⁴² Another study finds that the health improvements from each new drug can eliminate \$19 billion in lost wages by preventing lost work due to illness.⁴³ Moreover, because new effective drugs reduce medical spending on doctor visits, hospitalizations, and other medical procedures, data show that for every incremental \$1 spent on new drugs, total medical spending decreases by more than \$7.⁴⁴ Brand companies are largely responsible for pharmaceutical innovation. Thus, actions that reduce brand innovation will have long-term negative effects on consumer health and health care spending.

⁴¹ Frank R. Lichtenberg, Columbia University & National Bureau of Economic Research, Conference Presentation on The Economic Value of Medical Research, Pharmaceutical Innovation, Mortality Reduction, and Economic Growth (Dec. 2-3, 1999), <http://m.laskerfoundation.org/media/pdf/pharmaceuticalimrec.pdf>. (Empirical estimates of the benefits of pharmaceutical innovation indicate that each new drug brought to market saves 11,200 life-years *each year*).

⁴² Frank R. Lichtenberg, Columbia Univ., & Nat'l Bureau of Econ. Research, Conference Presentation on The Economic Value of Medical Research, Pharmaceutical Innovation, Mortality Reduction, and Economic Growth (Dec. 2-3, 1999), <http://m.laskerfoundation.org/media/pdf/pharmaceuticalimrec.pdf>.

⁴³ Craig Garthwaite, *The Economic Benefits of Pharmaceutical Innovations: The Case of Cox-2 Inhibitors*, 4 APPLIED ECON. 116 (2012).

⁴⁴ Frank R. Lichtenberg, *Benefits and Costs of Newer Drugs: An Update*, 28 MANAGERIAL & DECISION ECON. 485, 485 (2007).

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 JEFFREY K. 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 caregivers 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 carve-outs, 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.

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:]



Your Generics & Biosimilars Industry

Testimony of

Jeffrey K. Francer

Senior Vice President and General Counsel

Association for Accessible Medicines

Before the

Subcommittee on Consumer Protection and Commerce

of the House Committee on Energy and Commerce

“Profits Over Consumers:

Exposing How Pharmaceutical Companies Game the System”

September 19, 2019

Chairwoman Schakowsky, Ranking Member Rodgers, and Members of the Subcommittee:

Thank you for holding this important hearing, which could have great consequences on this Committee's critical work to lower drug prices and increase pharmaceutical price competition for America's patients. My name is Jeff Francer, and I am the general counsel of the Association for Accessible Medicines ("AAM"). AAM is the nation's leading trade association for manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines. Today, generic and biosimilar medicines comprise 90% of prescriptions in the United States at only 22% of total drug spending.¹ As of 2016, AAM's members provided more than 36,000 jobs at nearly 150 facilities and manufactured more than 61 billion doses of generic medicines in the United States every year. Our core mission is to improve lives by advancing timely access to more affordable generic and biosimilar medications.

I. INTRODUCTION

Increasing competition in the prescription drug market—especially with the introduction of more affordable generic and biosimilar medicines—has been the only meaningful way to deliver savings at the pharmacy counter for patients. Generic medicines play an integral role in health care and enhance patient access to life-saving treatments. Indeed, generic manufacturers have delivered savings of nearly \$2 trillion—including \$293 billion in 2018—to patients and the health care system in the last decade.²

Biosimilar medicines represent another critical step forward in reducing high drug prices. Biosimilars are safe, effective and lower-priced versions of costly brand-name biologics. By the year 2025, over 70 percent of drug approvals are expected to be biological products.³ Experts estimate that FDA-approved biosimilars could save more than \$54 billion over the next 10 years.⁴ In doing so, biosimilars will enable greater access to lifesaving cures for an estimated 1.2 million patients.⁵

However, the sustainability of a competitive generic market and the availability of generic medicines for patients is in jeopardy. Current market realities and anticompetitive tactics—combined with misguided policies—threaten the long-term stability of the generics and biosimilars markets. As AAM outlined in a February 2018 whitepaper, "Ensuring the Future of Accessible Medicines in the U.S.," generic and biosimilar manufacturers are facing an increasing set of challenges to getting new competitive and

¹ AAM, *2019 Generic Drug and Biosimilar Access Report in the U.S.*, April 2019.

² *Id.*

³ U.S. Pharmacist, *Biosimilars: Current Approvals and Pipeline Agents*, October 2016.

⁴ RAND, *Biosimilars Cost Savings in the United States*, October 2017.

⁵ The Biosimilars Council, *Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines*, August 2017.

more affordable medicines to market and to ensuring patient access to generic medicines on the market continues without interruption.⁶

One of the greatest barriers to increased prescription drug competition is abuse of the U.S. patent system. Increasingly, brand-name drug companies are building patent “thickets” around their drugs, not just for the original innovative research, but for much smaller changes that may not be deserving of decades-long monopolies. In some instances, brand-name drug companies are attempting to accumulate patents not because they are innovative, but rather to increase litigation and development costs for potential generic and biosimilar competitors. This problem significantly impairs competition and, not surprisingly, increases costs—patent thickets have cost patients and payers approximately \$7.6 billion in lost savings since 2015.⁷

Generic and biosimilar competition can also be delayed by another practice known as “product hopping.” Product hopping occurs when a brand-name drug company seeks to switch patients to a new version of a drug just before the original product becomes subject to generic competition. In many cases, the switch is forced on patients because the brand-name drug company stops selling the original product—a so-called “hard switch.” The main goal of such switches is not to improve patient health. Instead, these switches are designed to extend monopoly pricing, delay generic competition, and limit patient access to more affordable generic and biosimilar medicines.

Several cases illustrate the potential anticompetitive and anti-patient effects of product hopping. For example, in the case of Namenda®, the brand-name drug company planned to force Alzheimer’s patients to switch to its new extended-release (ER) formulation by withdrawing its immediate-release (IR) formulation from the market.⁸ The company knew that even if lower-cost IR generics were approved later, physicians would be highly reluctant to switch these vulnerable patients back to an IR formulation once they were stable on an ER formulation. The brand-name drug company’s documents confirm as much: as the company conceded at the time, “if we do the hard switch and . . . convert patients and caregivers to once-a-day therapy versus twice a day, **it’s very difficult for the generics to then reverse-commute back.**”⁹

The product hop in Suboxone® was equally harmful. There, the brand-name drug company sought to switch patients to a newly-formulated version by making allegedly false claims that it was safer than the older version and could better prevent accidental poisoning by children.¹⁰ This case is particularly egregious because it not only involves

⁶ AAM, *Ensuring the Future of Accessible Medicines in the U.S.: Avoiding Shortages & Ensuring Competition for America’s Patients*, February 2018.

⁷ Biosimilars Council, *Failure to Launch*, June 2019.

⁸ *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015).

⁹ *Id.* at 656 (emphasis added).

¹⁰ *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665 (E.D. Pa. 2014).

allegedly false claims regarding pediatric safety, but also because it delayed competition for a drug intended to treat opioid addiction in the middle of one of the worst health epidemics in U.S. history.

The impact of product hopping on generic and biosimilar competition can be significant. *First*, product hopping impairs automatic substitution, which is “the only cost-efficient means of competing available to generic manufacturers.”¹¹ Indeed, under many state laws, a generic drug can only be automatically substituted for a brand-name drug at the pharmacy counter if it is “therapeutically equivalent” to the brand. By changing the dosage form or strength of the branded drug, however, brand-name drug companies can ensure that generic versions of the original brand-name product will not be “therapeutically equivalent” and therefore not substitutable.¹² *Second*, because the new version typically will be protected by new patents, it will be protected from generic competition for years to come. By moving the goal posts every few years through product hopping, brand-name drug companies can potentially delay meaningful competition.

AAM supports legislation to curb anticompetitive brand tactics. However, any solution should be carefully calibrated to ensure it is not overbroad. AAM is supportive of innovation and recognizes that some changes to existing pharmaceutical products can result in substantial health benefits. Thus, it will be important for Congress to consider how to distinguish between “product hopping” that is anticompetitive from legitimate medical improvements.

In addition, the Committee should consider further legislative changes to strengthen competition in the pharmaceutical marketplace, including legislative changes to help eliminate anticompetitive patent thickets, including:

- Ensuring a date certain for generic and biosimilar competition;
- Accelerating the biosimilar “patent dance”;
- Harmonizing Hatch-Waxman with the America Invents Act (“AIA”);
- Requiring more timely FDA action on biosimilar labeling changes seeking to add a “carved out” indication or other condition of use; and
- Ensuring that new generic and biosimilar competition is available to patients through preferred formulary placement.

These suggested legislative changes are discussed more fully in AAM’s comments below.

¹¹ *Actavis*, 787 F.3d at 655-56.

¹² *Orange Book Preface: Approved Drug Products with Therapeutic Equivalence Evaluations*, 36th edition, Center for Drug Evaluation & Research, FDA, June 2016.

II. OVERVIEW: HOW PRODUCT HOPPING IMPAIRS GENERIC COMPETITION

A. Product Hopping Generally

Product hopping is a tactic used by some brand-name drug companies that takes advantage of the special rules governing approval and use of generic drugs. It occurs when a brand-name drug company reformulates a medicine—typically when its patents and exclusivity are about to expire—and then seeks to switch patients from the original to the reformulated medicine.¹³ The purpose is to move the bulk of the business from an older product that is about to face generic competition to a reformulated product that has additional patent protection and thus will not face generic competition for years. And the result is that patients end up paying higher prices because of the lack of any meaningful competition for the new medicine. Indeed, the district court in *Namenda*[®] estimated that “consumers would pay almost \$300 million more and third-party payors would pay almost \$1.4 billion more” if the *Namenda*[®] product hop had been successful.¹⁴

Product reformulations can take many forms. In some cases, the brand-name drug company makes a relatively simple change to the product’s dosage form such as switching from a tablet to a capsule. For example, the sponsors of *Prozac*[®], an antidepressant, and *Tricor*[®], a cholesterol treatment, switched from capsule to tablet dosage forms.¹⁵ In other cases, the brand-name company may slightly modify the active ingredient, as was done with the heartburn medicine *Nexium*[®], or combine two previously approved active ingredients into a single product, as was done with the migraine treatment *Treximet*[®].¹⁶

The method by which brand-name drug companies accomplish the switch also can take many forms, although they are typically categorized into “hard” versus “soft” switches. A “hard switch” occurs when the brand-name drug company withdraws the original product from the market so that patients have no choice but to switch to the newer, reformulated drug.¹⁷ A “soft switch” occurs when the brand-name drug company does not withdraw the original product from the market but takes other aggressive steps to encourage patients to switch to the new product, such as marketing only the new product, increasing the price of the original product, or imposing burdensome distribution requirements on the original product.¹⁸

¹³ Michael A. Carrier and Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 171-72, 2016.

¹⁴ *Actavis*, 787 F.3d at 661.

¹⁵ *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006).

¹⁶ *Walgreen Co. v. AstraZeneca Pharmaceuticals*, 534 F. Supp. 2d 146 (D.D.C. 2008).

¹⁷ Carrier, *supra* note 13, at 168.

¹⁸ *Id.*

Although brand-name drug companies often argue that these types of changes are made to improve the product and benefit patients, the changes are sometimes intended to sidestep meaningful generic competition just before it occurs. In this way, brand-name companies may take advantage of the unique regulatory regime governing the approval and use of generic drug products. Specifically, under the Hatch-Waxman Act, a generic drug may be approved if it is the “same” as a brand-name product in terms of, among other things, active ingredient, dosage form, route of administration, strength, and labeling, and if it is bioequivalent to the brand-name product—*i.e.*, performs the same way in the body.¹⁹ A generic that meets these rigorous approval requirements is deemed to be “therapeutically equivalent” to the brand. Under many state laws, a “therapeutically equivalent” generic drug can be substituted for the brand at the pharmacy counter.²⁰ This generic drug substitution, in fact, is the primary way generic drugs compete against brand-name drugs and result in significant savings to patients and the healthcare system.

Product hopping, however, flips this engine of competition on its head. By making minor changes to the original brand-name drug—such as switching from a tablet to a capsule—the brand-name drug company can ensure that a generic version of the original product will not be “therapeutically equivalent” to the reformulated product. By switching the market to the reformulated product right before FDA approves a generic of the original product, the brand-name drug company can ensure that generic uptake will be minimal. A few examples of how this tactic is used in practice may be helpful to explain to the Committee just how pernicious and anticompetitive this strategy can be.

B. Examples of Product Hopping

1. Namenda®

Namenda® was an extremely successful, immediate-release (IR) treatment for moderate-to-severe Alzheimer’s disease. When the drug neared the end of its patent protection, however, the sponsor sought to avoid this patent cliff by introducing a new, extended-release version called Namenda® XR in 2013 and working aggressively to switch patients from Namenda® IR to Namenda® XR.²¹ To accomplish this switch, the sponsor stopped actively marketing Namenda® IR, aggressively promoted Namenda® XR to healthcare providers and patients, and offered deep discounts for Namenda® XR to make it considerably less expensive than Namenda® IR.²² These “soft switch” tactics, however, did not work. Indeed, the brand-name drug company’s internal projections

¹⁹ *Id.* at 173-74.

²⁰ *See id.* at 186-87.

²¹ *Actavis*, 787 F.3d at 638, 642.

²² *Id.* at 648.

“estimated that only 30% of Namenda IR users would voluntarily switch” to Namenda® XR before generic entry.²³

In light of these data, the brand-name drug company moved to a “hard switch” in 2014, announcing that they would withdraw Namenda® IR from the market and urging healthcare providers to “discuss switching to Namenda® XR” with their patients.²⁴ Such a hard-switch would convert “80 to 100% of IR patients to XR prior to generic entry,” meaning that there would be “few to no prescriptions” left for which generics would be eligible to compete.²⁵ The brand-name drug company also requested that the Centers for Medicare and Medicaid Services (“CMS”) remove Namenda® IR from the Medicare formulary so that Medicare health plans would no longer cover it.²⁶

The brand-name drug company’s contemporaneous statements made clear that the purpose of the reformulation was to make it “very difficult” for generic competition. Indeed, the company’s own internal documents confirmed as much:

- “We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity.”
- “[W]hat we’re trying to do is make a cliff disappear and rather have a long—a prolonged decline. And we believe that by potentially doing a forced switch, we will hold on to a large share of our base users.”
- “[I]f we do the hard switch and we convert patients and caregivers to once-a-day therapy versus twice a day, it’s very difficult for the generics then to reverse-commute back.”²⁷

Ultimately, the State of New York filed suit to prevent the hard switch, which resulted in an injunction prohibiting the brand-name drug company from withdrawing Namenda® IR from the marketplace. That injunction was affirmed by the Second Circuit.²⁸

2. Suboxone®

Another troubling example of “product hopping” involves Suboxone®, a well-known

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.* at 655.

²⁶ *Id.*

²⁷ *Id.* at 657-58.

²⁸ *Id.* at 663.

treatment for opioid addiction. Suboxone® was originally approved in 2002 in a sublingual tablet dosage form. After its exclusivity expired, the brand-name drug company received approval for a new version of Suboxone® in a sublingual film dosage form. This new version had patent protection extending until 2023.²⁹

Once FDA approved the film version of Suboxone®, the brand-name drug company initiated an aggressive switch campaign to avoid impending generic competition, which included raising the price of the original tablet formulation even though the film formulation was more expensive to manufacture and package.³⁰ Moreover, the brand-name drug company made promotional claims that the new film version was safer because it carried a lower risk of accidental pediatric poisoning. The sponsor even went so far as to announce that would be withdrawing the original tablet formulation from the market because of these pediatric safety concerns and did so six months later.

These safety claims appear to have been false. Indeed, the risks to children may actually have been **higher** for the new film version of Suboxone® than the original tablet formulation.³¹ As a result of these allegedly false marketing claims, which were intended to further the sponsor's "product hopping" strategy, the sponsor has now been indicted by the Department of Justice for, among other things, mail fraud, wire fraud, health care fraud, and conspiracy. As the grand jury found, the brand-name drug company's "fraudulent scheme lasted for years and hindered patients' health care providers', and health care benefit programs' accurate assessment regarding opioid-addiction treatment in order to increase the company's profits."³²

3. Tricor®

Finally, the Tricor® case shows how brand-name drug companies can engage in multiple product hops. There, the brand-name drug company originally obtained approval of Tricor®, a cholesterol-lowering drug, in a capsule dosage form.³³ While generic drug approvals were blocked by exclusivity, the brand-name drug company sought and obtained approval of a new tablet dosage form in slightly different strengths. After approval, the company engaged in a variety of hard switch tactics, including:

- stopping all sales of Tricor® capsules;
- buying back existing inventory of those capsules from pharmacies; and

²⁹ *Suboxone*, 64 F. Supp. 3d at 674-75.

³⁰ *Id.* at 674.

³¹ *Id.*

³² *United States v. Indivior Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.)*, Case No. 1:19-cr-00016, Dkt. No. 3 (W.D. Va. 2019).

³³ *Abbott*, 432 F. Supp. 2d at 415-16.

- changing the National Drug Data File (“NDDF”) code to “obsolete.”³⁴

As a result of these tactics, generic substitution was no longer possible because the generic capsules were not therapeutically equivalent to the new Tricor® tablets.³⁵

Unsurprisingly, the brand-name drug company engaged in another round of product hopping later in Tricor®’s lifecycle. The brand-name drug company sought and obtained approval of slightly different strengths (145 mg and 48 mg instead of 160 mg and 54 mg), removed the prior strengths from the market, and once again changed the NDDF codes to obsolete.³⁶ Ultimately, the brand-name drug company apparently settled the product hopping claims for \$184 million.³⁷

C. Negative Implications of Product Hopping

These examples illustrate the potential anticompetitive problems created by product hopping. *First*, product hopping can eliminate automatic generic substitution. This is because even minor modifications to a medicine—such as changing from a capsule to a tablet—can affect substitutability. Brand-name drug companies know that a generic tablet cannot be automatically substituted for a capsule even if both products behave the same way in the body. Thus, they introduce new products just before the old product faces generic competition. This breaks the “therapeutic equivalence” link that allows for automatic generic substitution. As a result, a generic version of the original product cannot be automatically substituted at the pharmacy counter for the new product, therefore perpetuating the brand-name drug company’s monopoly and its monopoly pricing.

This lack of automatic substitution affects patients. Notably, generics made up only 2% of unit sales after the maker of Tricor® engaged in multiple product hops, including hard switch techniques.³⁸ Even when a brand-name drug company does not engage in a hard switch, generic entry remains difficult. Indeed, generics only compromised about 25% of unit sales after the brand-name drug company made a soft switch from Prilosec®

³⁴ *Id.* at 416.

³⁵ *Id.* at 414.

³⁶ *Id.* at 418.

³⁷ Nicole Callan, *Antitrust Liability for “Product Hopping”: A Look at Recent Decisions*, ABA Section of Antitrust Law, 2015.

³⁸ Transcript of Record at 534-35, *Teva Pharm. USA, Inc. v. Abbott Labs.*, 580 F. Supp. 2d 345 (D. Del. 2008); Carrier, *supra* note 13, at 217.

to Nexium®.³⁹ Had generic entry not been impeded by these product hops, generics would have likely captured approximately 85% of the market.⁴⁰

Second, product hopping can delay innovation. Significantly, the makers of Tricor® delayed seeking a new indication until after the reformulated product had been introduced, even though “[t]he data necessary to get the new indication was available much earlier.”⁴¹ Likewise, with Neurotonin®, the brand-name drug company admitted that a “principal reason [for not seeking FDA approval [for new indications] was that it wanted to reserve them for a later promotional campaign for its reformulated product.”⁴² And, in Namenda®, the brand-name drug company delayed introducing Namenda® XR until the eve of generic competition—even though it had actually received approval three years earlier.⁴³

Third, product hopping—in combination with other anticompetitive techniques—can substantially delay generic approvals. Indeed, in Suboxone®, generic approvals on the original tablet formulation were delayed for months after the brand-name drug company used citizen petitions to augment its product hopping scheme.⁴⁴ The pendency of the citizen petitions allowed the brand-name drug company to delay generic approval and, in the meantime, “convert the vast majority of Suboxone sales from the tablet to the film.”⁴⁵

III. OVERVIEW: HOW PATENT THICKETS HARM PATIENTS

As discussed above, product hopping can have significant consequences for manufacturers, patients, and taxpayers. Perhaps the greatest long-term obstacle to increased prescription drug competition, however, is patent abuse by some brand-name drug companies. While AAM’s member companies strongly support innovation, patent abuse is preventing them from delivering more affordable generic and biosimilar medicines to patients.⁴⁶

³⁹ Carrier, *supra* note 13, at 217.

⁴⁰ *Id.*

⁴¹ *Id.* at 202.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ End Payors’ Second Am. Compl. at 4, *In re: Suboxone Antitrust Litig.*, MDL No. 2:13-md-2445 (E.D. Pa. 2015).

⁴⁵ *Id.* at 5.

⁴⁶ AAM, *Ensuring the Future of Accessible Medicines in the U.S. – Ensuring Competition for America’s Patients*, February 2018.

Recent research confirms the extent of the problem and the increased costs borne by patients. Increasingly, brand-name drug companies are building impenetrable thickets of patents around their drugs. Indeed, at least 78 percent of the new patents in FDA's Orange Book are associated with **existing** drugs on the market.⁴⁷ And more than 70 percent of the roughly 100 best-selling drugs have had their patent protection "extended at least once, with almost 50% having [their patent protection] extended more than once."⁴⁸

The problem has only become more severe and pervasive. Indeed, the Institute for Medicines, Access, and Knowledge ("I-MAK") recently examined the top 12 brand-name drugs on the market and found that a total of 848 patents (71 per drug) shield these medicines from generic and biosimilar competition for an average of 38 years.⁴⁹ A few examples from the report demonstrate how patent thickets stifle competition and raise prescription drug prices:

- The world's top-selling brand-name drug, Humira® is now protected by more than 130 patents,⁵⁰ and it has become a more lucrative franchise than **the entire National Football League**.⁵¹ Perhaps unsurprisingly, the price of Humira® has increased 144 percent since 2012.⁵²
- One of the most prescribed cancer treatments, Revlimid®, is now protected by a patent thicket consisting of 96 patents that may provide for as much as 40 years of monopoly protection.⁵³ The price of Revlimid® has increased 79 percent since 2012.⁵⁴
- Diabetes patients who rely on the insulin treatment, Lantus®, may not see a generic or biosimilar alternative for 37 years because of the 49 patents that have been issued.⁵⁵ The price of Lantus® has increased 114 percent since 2012.⁵⁶

⁴⁷ Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J. L. & Biosciences 590, December 2018.

⁴⁸ *Id.* at 597.

⁴⁹ I-MAK, *Overpatented, Overpriced*, August 2018.

⁵⁰ *Id.*

⁵¹ Anna Rose Welch, *AbbVie's Humira Can Tackle the NFL – But Can It Handle Biosimilars*, Outsourced Pharma, February 2015.

⁵² I-MAK, *Overpatented, Overpriced*, August 2018.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

As these examples show, many brand-name drug companies are accumulating more and more non-innovative patents that are designed to increase litigation and development costs for potential generic and biosimilar competitors. Patients and taxpayers ultimately pay the price for these tactics—without effective generic and biosimilar competition, patients will continue to pay bloated monopoly pricing. Addressing patent abuse must be a top priority for Congress to effectively reduce prescription drug prices.

IV. POTENTIAL LEGISLATIVE SOLUTIONS

A. Product Hopping

AAM supports legislative solutions to address anticompetitive brand-name drug company gamesmanship tactics such as product hopping. AAM cautions, however, that the Committee should be careful to ensure that any legislative solutions are narrowly tailored. AAM recognizes the value of true innovation and does not believe that improvements to existing products that provide real value and health benefits to patients should be discouraged.

Instead, legislative solutions could focus on increasing scrutiny of the types of product hopping strategies that provide few, if any, benefits to patients and instead are intended primarily to avoid legitimate generic competition. Those strategies may include:

- Deleting NDDF codes;
- Destroying or buying back existing inventory;
- Increasing the price for the original drug without a legitimate business justification for doing so; or
- Withdrawing the original drug from the market for reasons unrelated to safety.

AAM would be happy to work with the Committee to formulate appropriate legislative strategies to address anticompetitive product hopping.

B. Ensuring a Date Certain for Generic and Biosimilar Competition

The high cost of prescription drugs is an immediate problem, and we urge the Committee to consider longer-term solutions as well. We suggest that the Committee focus on solutions to patent thickets, which now represent the most significant impediment to biosimilar competition.

One option to consider would be to provide biosimilar applicants with a date certain for market entry. During consideration of the Biologics Price Competition and Innovation Act ("BPCIA"), Eli Lilly expressly proposed this concept: if regulatory exclusivity were granted for a long enough period, Lilly would be willing to give up its ability to use its

patents to keep biosimilars off the market longer.⁵⁷ Yet in the final BPCIA, brand-name drug companies received 12 years of exclusivity—almost as long as the 14 years Lilly proposed, and much longer than any other form of exclusivity on the books—but gave up **none** of their ability to stave off competition through patents.

AAM recognizes the value of true innovation and wants to see the owners of properly issued patents receive compensation for the use of their invention. But in the context of today's patent thickets, each patent potentially becomes a weapon far out of proportion to the innovation it embodies. Each patent can be used to keep biosimilar competition off the market, either through a court order enforcing the patent through an injunction or by a company-crippling award of lost profits for the entire biologic franchise. The patent laws do not have to give such disproportionate power to incremental advancements in knowledge—say, to the 132nd patent in the thicket covering a single product, even assuming the other 131 are valid.

After a suitable monopoly period, Congress could choose to refocus any remaining patents on providing compensation to the inventor, perhaps through royalties, rather than by blocking competition. Working out the details of such a system would involve work and discussion by both the Committee and stakeholders. But if the Committee wants to have a lasting impact on the high prices that the current patent environment makes possible, it is time to begin such a discussion.

C. Accelerating the Biosimilar Patent Dance

We also suggest that the Committee consider ways to accelerate the BPCIA patent dance and therefore expedite patient access to more affordable biosimilar medicines. Under the current law, the BPCIA patent dance—which initiates the patent litigation process for biosimilars—cannot be commenced until after a biosimilar application has been accepted for review by FDA.⁵⁸ This means that a biosimilar company must wait years to test patents that may be invalid. As the Federal Circuit has recognized, this type of delay is inefficient and harms consumers. Indeed, "the public is best served by getting invalid patents declared invalid as early as possible."⁵⁹

Consistent with this strong policy, we propose a 1-2 year acceleration of the BPCIA patent dance. At the biosimilar manufacturer's option, it could start the patent dance after a Type 3 Biosimilar User Fee Amendment ("BsUFA") meeting with FDA. Importantly, a Type 3 BsUFA meeting does not occur until a biosimilar applicant submits a "comprehensive data package," including "[f]ull study reports for a clinical study or clinical

⁵⁷ John Wilkerson, *Lilly Proposed Forfeiting Biologics Patents if Exclusivity Sufficient*, Inside Health Policy, December 2008.

⁵⁸ 42 U.S.C. § 262(l)(2).

⁵⁹ *Hallco Mfg. Co. v. Foster*, 256 F.3d 1290, 1297 (Fed. Cir. 2001).

studies.”⁶⁰ Exchanging this “comprehensive data package” as part of the accelerated dance would help ensure that brand-name drug companies have sufficient information to meaningfully ascertain infringement claims and timely commence patent litigation. It also ensures that any subsequent patent litigation is sufficiently ripe and justiciable.

At bottom, the rationale for an accelerated patent dance is simple: an earlier start to the patent dance means that patent litigation ends earlier. And a more-timely conclusion to patent litigation ultimately expedites biosimilar market entry and patient access to more affordable alternatives. We are happy to work with the Committee to help develop this solution.

D. Harmonizing Hatch-Waxman with the AIA

We also suggest harmonizing Hatch-Waxman with the AIA. Presently, a thirty-month stay of approval may only be terminated by a district court decision.⁶¹ It cannot be terminated by a Patent Trial and Appeal Board (“PTAB”) final written decision—even if that decision invalidates all claims of all patents that created the thirty-month stay. That creates a potentially inequitable scenario: the PTO’s invalidation of all brand-name drug patents will still not lead to generic competition. To address this, we suggest updating the Hatch-Waxman Act by including provisions that would terminate a thirty-month stay based on a PTAB final written decision on all relevant patents and claims.

E. Biosimilar Carve-Ins

We also encourage the Committee to expand its efforts to speed biosimilar competition by addressing another significant barrier to biosimilar market entry: FDA’s treatment of biosimilar labeling “carve-ins.”

One way that biosimilar manufacturers navigate patent thickets is to “carve-out” patented indications or uses from their labeling and gain initial approval with “skinny labeling.” But biosimilar manufacturers may need to eventually carve those indications back in after they address patents through litigation or settlement. This “carve-in” process is critical for the success of biosimilars, as each carved-out use limits the potential market and savings for consumers.

Significantly, there is not an efficient process for adding uses back into the labeling of biosimilars once patent issues have been addressed. The FDA currently treats such applications as “Supplements with Clinical Data” under BsUFA and reviews them on a full 10-month clock. This protracted review period is inappropriate. It severely undermines the ability of biosimilar manufacturers to bring their products to market, costing consumers millions of dollars and hurting the industry for years to come.

⁶⁰ FDA Draft Guidance, *Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products*, June 2018.

⁶¹ 21 U.S.C. § 355(c)(3)(C); 21 U.S.C. § 355(j)(5)(B)(iii).

In January 2019, former FDA Commissioner Scott Gottlieb, M.D., said that FDA was “going to be putting out policy this year to explain how to carve back in indications ... We’re working on defining an efficient way to do that.”⁶² We suggest that the Committee encourage FDA to follow through on its commitment and reduce the review time for these specific type of supplements to no longer than 90 days. This policy will go a long way toward creating a healthy biosimilars market, improving consumer choice, and saving the healthcare system billions of dollars.

F. Preferred Formulary Placement

New generic competitors are particularly important to ensuring future prescription drug savings. That is why the FDA prioritizes its review of first generic competitors to a brand-name drug. Although the FDA has been approving generic drug applications at a record-setting pace, brand-name drug companies have pioneered the use of exclusionary rebates to block new generic or biosimilar competition.

As a result, new generic competitors are increasingly unavailable to patients because they are blocked by exclusionary brand drug rebate agreements or placed on formulary tiers with inappropriately high cost sharing. For instance, a recent analysis found that Medicare drug plans are increasingly shifting generic drugs from tiers with lower copayments for patients to brand tiers with higher copayments and coinsurance.⁶³ This means that seniors do not benefit from lower prices and lower out-of-pocket costs, and taxpayers continue to pay for high-priced brand-name drugs.

Policymakers can take immediate steps to ensure that patients receive the full benefit of lower-cost generic and biosimilar medicines by:

1. Ensuring Medicare Part D plans cover new, lower-priced generic products at launch;
2. Providing for placement of generic drugs on tiers designated as generic and separate from brand tiers; and
3. Creating a separate specialty drug tier to allow for formulary differentiation among specialty brands versus specialty generics and biosimilars.

These policies would support greater patient access to lower-cost generics and would immediately reduce seniors’ out-of-pocket costs by more than \$4 billion.⁶⁴ Ensuring such policies would help put an end to some brand-name drug company schemes that

⁶² Gottlieb, Scott, M.D., Keynote Address to the J.P. Morgan Healthcare Conference, January 2019.

⁶³ Avalere Health, *Effect of Potential Policy Change to Part D Generic Tiering on Patient Cost Sharing and Part D Plan Costs*, February 2019.

⁶⁴ *Id.*

undermine pharmaceutical competition and would generate immediate savings for America's patients and taxpayers.

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Thank you again for the opportunity to testify on this important issue. I look forward to answering your questions.

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; 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.

Again, Mr. Mitchell, 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 seven 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 deliver any improvement for me, clinically or therapeutically, may not reduce side effects, and 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? It 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 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 four 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 caregivers 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 now recognizes Mr. Latta for 5 minutes.

Mr. LATTI. 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 allow-

ing 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 healthcare, 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 improve-

ment 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. Yes. 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. Yes. 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 now 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. OK.

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. Yes. 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 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. OK. I yield back. Thank you.

Mr. SOTO. The gentleman yields back.

The Chair now 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 ten 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 Web site. 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 healthcare 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 Web site. 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. Yes. 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. Yes. 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 the pharmacist is. 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 Energy and Commerce 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, "Yes, 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 OK 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 three 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 now 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 life-saving 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 six percent, increase it to the average price plus eight 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. Yes. 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. OK. 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. Yes. 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 his-

tory 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. OK. 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 healthcare 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 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. OK.

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. OK.

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. OK. 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 healthcare, 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 healthcare, 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. Yes, yes, yes.

Mr. GUTHRIE [continuing]. 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. OK. 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. OK. 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. OK. Yes, 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. Yes. 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. OK. 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, and 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 the 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 three to one 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 Members that, pursuant to committee rules, that they have ten 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."

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.]

[Material submitted for inclusion in the record follows:]



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Michael A. Carrier

Response to Representative Schakowsky's Questions for the Record

**House Energy & Commerce Committee (Subcommittee on Consumer Protection and Commerce)
Hearing on "Profits Over Consumers: Exposing How Pharmaceutical Companies Game the System"**

October 22, 2019

I. Product Hopping

- A. Product hopping is game drug companies play to keep generics off market
- B. Product hopping combines two actions:
 - 1. Reformulating product so generic version can't be substituted and
 - 2. Encouraging doctors to write prescriptions for reformulated product
 - 3. * No innovation reason: brand does not *expand* prescription base; just *migrates* base to block generics
- C. Harms from both "hard switches" (original drug pulled from market) and "soft switches" (original drug remains)
 - 1. Greater harms when brand switches before generic enters market
 - a) Promotion/marketing more effective in convincing doctors to prescribe reformulated version
- D. Product hopping has massive effect on consumers
 - 1. Most recent (2009) empirical analysis found \$28 billion worth of drugs subject to product hopping, including Advair, Allegra, Augmentin, Caduet, Clarinex, Kapidex, Lexapro, Nexium, Prozac, Risperdal¹
 - a) For \$1 billion blockbuster drug, consumers pay extra \$765 million each year from delayed competition²
 - 2. Consumers unable to afford high prices cut pills in half, not take needed medicines
- E. Overlapping terms
 - 1. *Product hopping* is defined above
 - 2. *Patent thickening* refers to the acquisition of numerous patents to cover a single product
 - 3. *Evergreening* includes either of the above categories, as well as general "life-cycle management"

II. FTC Report: Necessity

- A. Need information on frequency (and types) of product hopping, effect on consumers
 - 1. This information is not collected by FDA, FTC, or other agencies
 - 2. Given prevalence of drug companies' arguments that product hopping justified by innovation, full array of evidence would be useful
- B. Need information on how soft switches can be anticompetitive, particularly since courts have not recognized harms
 - 1. *Walgreens*: soft switch did not "eliminate" choice but "added" it as "marketplace" determines "superior[ity]"³
 - 2. *Asacol*: soft switch is not a product hop because it leaves "consumer choice intact" and lacks the "key product withdrawal that undergirds a product-hopping claim"⁴
 - 3. *Namenda*: soft switch allows patients and doctors to "evaluate the products . . . on the merits" while "hard switch crosses the line from persuasion to coercion"⁵
 - 4. Each of these assertions ignores the "price disconnect" by which a doctor decides the drug to prescribe and a patient/insurer pays for the drug, leaving no single entity to make the price-quality tradeoff
- C. FTC has expertise in authoring pharmaceutical reports such as the influential ones addressing settlements (2002) and authorized generics (2011)

¹ Steve Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L. J. 1 (2009).

² FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010),

<http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf> (multiple generics take 90% of sales at average 85% discount).

³ *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008).

⁴ *In re Asacol Antitrust Litig.*, 233 F. Supp. 3d 247, 269-70 (D. Mass. 2017).

⁵ *New York ex rel. Schneiderman v. Actavis PLC ("Namenda")*, 787 F.3d 638, 654 (2d Cir. 2015).



III. FTC Report: Contents

- A. A model for what a report could contain appears in S. 771 § 406 (115th Cong.)
- B. Require FTC to submit report to Congress on extent to which
 - 1. brand/biologic firms engage in product hopping, which includes analysis of
 - a) timing of reformulated product's introduction in relation to generic's market entry,
 - b) types of changes made in reformulated product,
 - c) patents and market exclusivities awarded to reformulated product, and
 - d) various forms of product hopping brand/biologic firms employ
 - 2. brand/biologic firms assess profitability of new drug based on whether introduced before generic entry
 - 3. product hopping affects consumers (including total estimated annual cost of doctors prescribing reformulated drug instead of generic)
 - 4. product hopping affects insurance prices and availability (including cost increases and coverage reductions attributable to economic losses described in #3 above)
 - 5. product hopping affects brand/biologic profits, revenues, unit sales, and prices
 - 6. product hopping affects generic sales, profits, and prices
 - 7. brand/biologic firms withdraw⁶ original drugs or keep them on the market
 - a) This information is not included in S. 771 but is vital given how
 - i. soft switches could harm competition but
 - ii. courts (see *Walgreens*, *Asacol*, *Namenda*) do not recognize

IV. Conclusion

- A. Product hopping presents anticompetitive nuances that are not always acknowledged
- B. FTC can use its pharmaceutical expertise to discern and assess product hopping's competitive effects

⁶ This category includes discontinuing manufacturing, announcing withdrawal, and adding to the list of discontinued products.

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Additional Questions for the Record

**Subcommittee on Consumer Protection and Commerce
Hearing on
“Profits Over Consumers: Exposing How Pharmaceutical Companies Game the System”
September 9, 2019**

Ms. Joanna M. Shepherd, Professor of Law, Emory University School of Law

The Honorable Cathy McMorris Rodgers (R-WA)

1. When a brand company discontinues its branded drug, and takes it off the market for reasons unrelated to safety or efficacy, can a generic drug company file a generic drug application for such a discontinued drug and go to market?

Answer: Yes, a generic drug can come to market as long as the patent for the branded drug has expired.

2. When a brand company introduces a reformulated drug and discontinues the original drug, does that prevent a generic company from going to market with a generic copy of the original drug?

Answer: No, a generic drug can still come to market once the patent for the branded drug has expired.

- a. And would consumers (or their physician) then have a choice between the generic old product and the branded new product?

Answer: Yes, both the branded new product and the generic version of the older product would be on the market, so consumer and their physicians would have a choice.

3. Under existing legislative proposals, the only permissible justification for a hard switch is that the change to the product was made for reasons related to safety. However, this ignores the fact that important improvements may be made related to the efficacy of a drug. Do you believe that a manufacturer should be held liable for an antitrust violation if they develop a new product that is significantly more effective than the previous version of the drug and remove the less effective drug from the market? For example, if a manufacturer develops a new version of a drug that increases the cure rate for an otherwise fatal disease from 40% to 80% and then removes the less effective version from the market, do you not consider that a legitimate justification for switching the market to the new product?

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Answer: I consider this a legitimate justification because it will ensure that more patients are directed to more effective drugs.

4. If we seek to preclude drug makers from "unfairly disadvantaging" existing products, do you think this will result in fewer choices for consumers? If so, why?

Answer: Yes, the phrase "unfairly disadvantaging" is extremely vague and potentially very broad. Legislation that is too broad in that it covers too many standard business practices, or too vague in that drug companies can't predict what behavior will lead to significant litigation or penalties, will end up reducing innovation. This reduced innovation will mean that fewer products come to market, resulting in fewer choices for consumers.

5. In your testimony, you highlight that certain incentives established by patent law, motivate brand drug makers to innovate rather than hand their sales over to generic competition - which the FTC has actually recognized as benefitting consumers. Can you please explain?

Answer: As their patent period expires, brand companies face the likely loss of 80-90 percent of their sales to generic versions of the drug under state substitution laws. These laws allow or even require pharmacists to automatically substitute a generic equivalent drug when a patient presents a prescription for a brand drug. To avoid losing most of their sales to generic companies, brand companies have the incentive to shift their marketing efforts to a new patent-protected drug which can serve as a substitute for the drug about to go off patent. To acquire a patent and FDA approval, the new drug must be different and innovative. Thus, incentives under patent law—incentives to innovate in order to obtain the exclusionary patent period—motivate brand companies to create new drugs instead of handing over the majority of their sales to the generic companies. As the FTC has explained, these new drugs can, in turn, benefit consumers: "The threat posed to existing brand drugs by generic competition can incentivize the brand company facing a dramatic loss of sales to develop new and innovative drugs that benefit consumers."¹

6. Your testimony indicates that there is a window of time during which a hard switch can be presumed anticompetitive. Can you please explain when you believe that window should begin and end?

Answer: There is a window during which a hard switch can be presumed to be anticompetitive. For conventional, small-molecule drugs this window starts around the time a generic company files an acceptable ANDA containing a Paragraph IV challenge to the drug as this indicates that there is a generic competitor that could potentially enter the market. The window should end when the generic drug has penetrated the market. According to existing research, generics are able to capture

¹ Brief for Federal Trade Commission as Amicus Curiae, Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Limited Company, No. 12-3824, 2012 WL 7649225, (E.D. Pa. Dec. 3, 2012).

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over 70 percent of the brand drug's market share within only 3 months of their market entry. Thus, the relevant window should end sometime around 3 months after generic entry.

- a. If a manufacturer withdraws an older product from the market outside of the window, would this eliminate consumer choice?

Answer: No, outside of that window, it is extremely unlikely that the product replacement eliminates consumer choice. If a brand company replaces a drug with plenty of patent life remaining and no generics anywhere on the horizon, consumer choice is not eliminated because it does not reduce the drugs that consumers could choose from; they had one drug to choose before the switch and one drug to choose after the switch. Replacing a drug after generics have already penetrated the market also does not eliminate consumer choice because patients would already be accustomed to taking the generic versions of the older drug, so replacement would not coerce them into switching from the generic they had been taking.

- i. If not, should the action be presumed anticompetitive?

Answer: No.

7. As discussed in the hearing, patients have long benefited from improvements to existing drugs made by the original manufacturer. However, broad and vague legislation that would impose antitrust liability on original manufacturers is likely to chill incentives for such companies to invest in improvements to existing drugs. Accordingly, broad or vague legislation leaves only one option for manufacturers: to start drug development anew, which will slow development of life-saving medicines and increase the costs to produce medicines.

- a. Can you provide your view on the impact of decision-making within a pharmaceutical manufacturer in light of the economic burden and uncertainty this legislation may result in? In your view, is this legislation likely to drive up costs to consumers by eliminating the option for pharmaceutical manufacturers to improve on their innovation over time?

Answer: Vague legislation will create significant uncertainty for brand innovators. If brand companies cannot reliably predict whether the introduction of new products will be considered anticompetitive, they will have less incentive to engage in costly R&D. The companies will not spend the billions of dollars it typically costs to bring a new drug to market when they cannot be certain if, years down the road, the introduction of that new drug will lead to significant litigation, market-stopping injunctions or penalties.

This reduction in innovation is likely to drive up healthcare costs over time for two reasons. First, less innovation means that fewer products will come to market, and fewer products mean there is less competition to keep prices low. Second, newer and more effective drugs reduce medical spending on doctor visits, hospitalizations, and other medical procedures; data show that for every incremental \$1 spent on new drugs,

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total medical spending decreases by more than \$7. Thus, less drug innovation will likely result in increases in other healthcare spending.

8. Professor Carrier has recommended that Congress include an "economic sense" test as part of drug pricing legislation. Do you agree with an "economic sense" test approach or would you recommend Congress consider a more pinpointed standard? Please explain your reasoning.

Answer: I would not recommend the "no-economic-sense" test for several reasons. First, it asks the wrong conceptual question in situations where brand companies have introduced a new product to market—activity that is typically considered procompetitive. If this new product provides some therapeutic value for consumers, society should not care what impact the value-creating product has on the company's profits. Second, the "no-economic-sense" test would be very difficult to operationalize. For a brand company producing several products, many of the costs are jointly shared across multiple products, and it would be difficult or even impossible to allocate a share to an individual product. Finally, and most importantly, the "no-economic-sense" test would create terrible incentives. Because brand companies would face the risk of severe penalties if the investment they make in developing a new product outweighs the profit they earn, the companies would have the perverse incentive to either economize on their investments, which may curtail important research and development activities, or not invest in bringing new products to market at all. This could have significant impacts on drug innovation.

9. In your testimony, you note that a minor change to a follow-on product is often, in and of itself innovative? Can you elaborate on this point?

Answer: Most innovation in the pharmaceutical industry involves development of next generation improvements, such as creating new products that expand therapeutic classes, increase available dosing options, remedy physiological interactions of known medicines, or improve other properties of existing medicines. According to FDA data, two-thirds of new drug approvals are for these incremental innovations. And according to the World Health Organization, over 60 percent of drugs deemed necessary for combating prevalent diseases are the result of incremental innovations.

10. In the hearing, you noted that patients have benefited from adjusted or improved dosages in medicines that have occurred as a result of advancements and better understandings of the science over time. Yet if the soft switch language is too broad or vague, do you believe such legislation would chill investment in improved products? If so, what impact might the legislation have on specific patient populations that did not respond to the original product? How would you narrow the soft switch language to address this concern?

Answer: Soft-switch language that is too broad in that it covers too many standard business practices, or too vague in that drug companies can't predict what behavior will lead to

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significant litigation or penalties, will reduce investment in the development of next generation improvements. Reduced investment means that fewer improved products will come to market. This will harm patients that benefit from these improvements because they cannot tolerate the route of administration or dosage form of the original product or suffer side effects from the original product.

Legislation should clearly indicate that a soft switch will only be presumptively anticompetitive if it so significantly interferes with consumer choice that consumers have no practical alternative but to switch to the new product, with no offsetting consumer benefit. Legislation should also indicate that this degree of interference will typically require some other wrongful conduct, such as fabricating safety concerns or falsely disparaging a product

11. Absent specific actions by a manufacturer to prevent generic entry into the market, you suggest that innovation resulting in a follow-on product should not qualify as product hopping. Can you elaborate on the potential negative unintended consequences that would stifle innovations in medicine?

Answer: The introduction of a new or improved product that does not prevent generic entry is generally procompetitive. Consumers have access to more products, and the new product is likely to be safer or more effective in some way. We should encourage drug companies both to invest in improving their products and to bring those drugs to market when they are available. Overly broad legislation that defines too many standard business practices as anticompetitive will deter drug companies from investing in and introducing superior products. This decrease in innovation will result in reduced choice for consumers, which will have negative impact on consumer health and increase health care spending.

12. Do you believe "consumer coercion" or "lack of choice" should be added as a factor in the soft switch provision of the product hopping legislation? If so, can you provide specific examples that would trigger "consumer coercion" or "lack of choice" in a soft switch?

Answer: Yes, I believe that legislation should make clear that a soft switch is only presumptively anticompetitive if it involves wrongful conduct that so significantly interferes with consumer choice that it effectively eliminates it, with no offsetting consumer benefit.

A soft switch significantly interferes with consumer choice to the point of effectively eliminating it when customers have no practical alternative but to switch to the new product. For example, if a brand drug company keeps an older drug on the market but communicates unambiguously fabricated safety concerns to doctors while championing the newer alternative, then patients effectively have no choice but to switch to the new drug. Similarly, if a brand company destroys inventory of the older drug to create a shortage so that prescribers stop prescribing it, then consumers effectively have no choice.

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13. In the hearing, you stated that it should not be considered a "soft switch" to merely introduce a follow-on product and leave the original product on the market - that there must be other wrongful conduct. Can you explain what you meant by this statement? What "other wrongful conduct" should be required to trigger a soft switch?

Answer: Generally, the market introduction of a new or improved product while leaving an older product on the market is procompetitive: consumers have access to more products, and the new product is likely to be safer or more effective. However, if a soft switch includes wrongful conduct that gives consumers no practical alternative but to switch to the new product, then it has effectively eliminated consumer choice. For example, if a brand drug company keeps an older drug on the market but communicates unambiguously fabricated safety concerns to doctors while championing the newer alternative, then patients effectively have no choice but to switch to the new drug. Similarly, if a brand company destroys inventory of the older drug to create a shortage so that prescribers stop prescribing it, then consumers effectively have no choice.

14. As currently contemplated, product hopping legislation may also include a transparency component that would require manufacturers to disclose marketing plans and other strategic communications to both the FDA and the FTC. What trade secret concerns might occur with such disclosure requirements? Should Congress create an exception from such disclosure for confidential business information?

Answer: Congress should create an exception for the disclosure of confidential business information. Otherwise, the disclosure could result in confidential business information becoming available to competitors, which will likely weaken competition in the drug industry and increase drug prices. Federal antitrust agencies have long recognized that the disclosure of sensitive business information can lead to tacit collusion and higher prices: "the sharing of information related to a market in which the collaboration operates or in which the participants are actual or potential competitors may increase the likelihood of collusion on matters such as price."² Similarly, the FTC notes that the disclosure of price and cost information is particularly harmful to competition: "the sharing of information relating to price, output, costs, or strategic planning is more likely to raise competitive concerns than the sharing of information relating to less competitively sensitive variables."³

15. New products can increase competition through brand-to-brand competition. Can you describe how this can happen, and how certain proposals on "product hopping" may serve to disincentivize these innovations, and therefore decrease brand-to-brand competition?

² THE FEDERAL TRADE COMMISSION AND THE DEPARTMENT OF JUSTICE, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS §3.31(b) (2000), available at <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf>.

³ *Id.*

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Answer: Overly broad or overly vague legislation that reduces incentives to improve drug products and bring those drugs to market, will result in less brand innovation. The companies will not spend the billions of dollars it typically costs to bring a new drug to market when they cannot be certain if, years down the road, the introduction of that new drug will lead to significant litigation, market-stopping injunctions or penalties. Less innovation by brand companies means there will be fewer brand products brought to market to compete with other brand products.

16. Many of the witnesses have testified that "product hopping" undermines a generic or interchangeable biologic ability to be automatically substituted for the reference product. If this is the primary concern, is there a reason to include non-interchangeable biosimilars within scope of any purported "product hopping" bill? Wouldn't including biosimilars have a negative impact in innovation in the biologics space?

Answer: There is no reason to consider non-interchangeable biosimilars in product-hopping legislation. These non-interchangeable biosimilars cannot take advantage of automatic substitution laws, so whether an original drug is replaced by an improved version is irrelevant: the non-interchangeable biosimilar could not be substituted for either the original or the new drug.

17. Legislation pending in the Senate would give rise to a presumption of anticompetitive "product hopping" if a manufacturer introduced a "follow-on product" and took any action that "unfairly disadvantaged" the older product. You testified that any approach to "product hopping" must be precisely drafted to avoid negatively impacting innovation. Would this standard of "unfairly disadvantag[ing]" provide manufacturers with sufficient guidance on the types of activities that would be presumptively anti-competitive?

Answer: The phrase "unfairly disadvantaging" is extremely vague and gives no practical guidance on the types of activities that would be presumptively anticompetitive. Legislation that is unclear about when the introduction of new products will be deemed anticompetitive will create significant uncertainty for brand innovators. This uncertainty will lead to less innovation because brand companies will not engage in costly R&D if they cannot be certain whether, years down the road, the introduction of that new drug will lead to significant litigation, market-stopping injunctions or penalties.

18. The FTC already has significant authority to prohibit anticompetitive activity. What risks does industry-specific "product hopping" legislation have on reducing innovation in the biopharmaceutical space?

Answer: Legislation targeting the pharmaceutical industry that is overly broad or overly vague could harm consumers by reducing drug innovation. This reduced innovation will likely reduce consumer choice, negatively impact health outcomes, and increase overall health care spending.

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The Honorable Michael C. Burgess, M.D. (R-TX)

1. When a pharmaceutical company engages in a "soft-switch" - what is the impact on patients? Can you give an example of harm to a patient as a result of a "soft-switch"?

Answer: In general, the market introduction of a new or improved product while leaving an older product on the market is procompetitive: consumers have access to more products, and the new product is likely to be safer or more effective in some way. However, if a soft switch includes wrongful conduct that so significantly interferes with consumer choice that customers have no practical alternative but to switch to the new product, then the soft switch effectively eliminates consumer choice. In this situation, the patient may not have the ability to choose a product that would be better or safer for them.

2. As you mentioned in your testimony the determination whether product hopping is anticompetitive is dependent on the situation. It is the FTC's job to identify and challenge anticompetitive behavior and patent-gaming. What is the FTC currently doing to prevent anticompetitive patent practices?

Answer: Although the FTC is in the best position to explain what they are doing in this area, I know that they have been challenging anti-competitive product-hopping behavior. For example, in July, 2019, FTC announced a \$50 million settlement with Reckitt Benckiser Group over charges that the company violated antitrust laws through a deceptive scheme to thwart lower-priced generic competition to its branded drug Suboxone.⁴

3. In light of your antitrust and competition-focused studies, are the courts the best place to deal with anticompetitive determinations?

Answer: Courts have the advantage of analyzing each product replacement situation individually so that they can precisely determine when a replacement is anticompetitive. However, there is currently some inconsistency among court decisions and, as a result, a lack of clarity about when product replacements will be considered anticompetitive product hopping. As a result, legislation that is clear and not overly broad could provide important guidance on when the introduction of new products will be deemed anticompetitive.

4. What is the United States Patent and Trademark Office doing to monitor patents and prevent patent gaming?

⁴ Federal Trade Commission, Reckitt Benckiser Group plc to Pay \$50 Million to Consumers, Settling FTC Charges that the Company Illegally Maintained a Monopoly over the Opioid Addiction Treatment Suboxone (July 11, 2019), <https://www.ftc.gov/news-events/press-releases/2019/07/reckitt-benckiser-group-plc-pay-50-million-consumers-settling-ftc>.

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Answer: The USPTO is in the best position to explain what it is doing to ensure the quality of existing patents. However, USPTO Director Andrei Iancu has spoken publicly of his office's efforts to bring vigorous but balanced review of challenges to existing patents through the inter partes review process enacted as part of the America Invents Act.⁵

5. Your testimony notes that Congress "should be careful to ensure that any legislative solution be narrowly tailored" and that "improvements to existing products that provide real value and benefits to patients should be encouraged." Does he have concerns that existing legislative proposals may be overly broad and deter these important improvements?

Answer: Current proposals include the phrase "unfairly disadvantages" that is extremely vague and potentially very broad. Legislation that is too broad in that it covers too many standard business practices, or too vague in that drug companies can't predict what behavior will lead to significant litigation or penalties, will end up reducing innovation. This reduced innovation will mean that fewer products come to market, resulting in fewer choices for consumers.

6. Is "unfairly disadvantaged" an established principle in antitrust law? Is it dear what it means to you?

Answer: The phrase "unfairly disadvantaging" is extremely vague and gives no practical guidance on the types of activities that would be presumptively anticompetitive. Although the FTC and various courts have sometimes observed after-the-fact that anticompetitive behavior "unfairly disadvantages" competitors, the phrase is generally not used to proactively proscribe certain behaviors that will be deemed anticompetitive.

7. If we seek to preclude drug makers from "unfairly disadvantaging" existing products, do you think this will result in fewer choices for consumers?

Answer: Yes, because "unfairly disadvantage" is so vague a term, legislation that does not offer more clarity on when the introduction of new products will be deemed anticompetitive will create significant uncertainty for brand innovators. If brand companies cannot reliably predict whether the introduction of new products will be considered anticompetitive, they will have less incentive to engage in costly R&D. Less investment in R&D will result in less innovation, fewer new drugs brought to market, and reduced choice for consumers.

⁵ United States Patent and Trademark Office, Remarks by Director Iancu at the American Intellectual Property Law Association Annual Meeting (Oct. 25, 2018), <https://www.uspto.gov/about-us/news-updates/remarks-director-iancu-american-intellectual-property-law-association-annual>.

Additional Questions for the Record

**Subcommittee on Consumer Protection and Commerce
Hearing on
“Profits Over Consumers: Exposing How Pharmaceutical Companies Game the System”
September 9, 2019**

**Responses of Mr. Jeff Francer
Senior Vice President and General Counsel
Association of Accessible Medicines**

The Honorable Cathy McMorris Rodgers (R-WA)

1. When a brand company discontinues its branded drug, and takes it off the market for reasons unrelated to safety or efficacy, can a generic drug company file a generic drug application for such a discontinued drug and go to market?

When a brand-name drug company discontinues its drug for reasons unrelated to safety or efficacy, a generic drug company typically may seek and obtain approval of a generic version of the discontinued drug, but the brand company’s actions may still create several significant regulatory hurdles for the generic drug company.

First, the generic drug company cannot submit an application for a generic version of a discontinued drug unless it is accompanied by a petition seeking a determination by FDA that the brand drug was not discontinued for safety or effectiveness reasons. A generic drug application cannot be approved unless and until FDA makes a determination that the marketing withdrawal was not for safety or effectiveness reasons. This additional regulatory requirement can result in delays in approval of generic drugs, particularly if the brand-name drug is withdrawn late in the review cycle for the generic version.

Second, when a brand-name drug company withdraws a reference listed drug (RLD), generic drug manufacturers may have difficulty obtaining samples of the brand-name drug on which to conduct bioequivalence and other testing, because the brand-name drug is no longer being sold. And if the generic company cannot demonstrate that its proposed product is bioequivalent to the brand version, the generic drug will not be approved by FDA.

Finally, withdrawal of a brand-name drug from the marketplace often has the intention and effect of destroying the market for potential generic competitors. This is because the main engine of generic competition is automatic substitution of lower-cost generic alternatives. If the brand company withdraws its original drug from the market and begins promoting and selling a new version exclusively, then the market for the withdrawn drug may shrink significantly, likewise diminishing any potential market for generic drug substitution.

The Honorable Michael C. Burgess, M.D. (R-TX)

1. As you mentioned in your testimony, changes in existing pharmaceutical products can result in substantial health benefits. Can you explain the benefits that patients may receive due to these improvements and give some examples?

AAM supports innovation and believes it is a key driver in improving the lives and health of American patients. Accordingly, AAM recognizes that some changes to existing pharmaceutical products can result in substantial health benefits to patients. For example, modifying a drug that must be injected every day to a new dosage form, such as a tablet, that can be taken orally could provide benefits to patients who have difficulty administering, or experience pain from, daily injections. For this reason, AAM has cautioned Congress to tread carefully when regulating “soft switches,” which do not result in the removal of prior versions of the brand drug and thus allow patients and physicians weigh the true benefits of a new product against its costs. AAM believes it is important to encourage innovation, but to do so in a way that does not impair competition and patient access to more affordable generic and biosimilar medicines.