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**A PRESCRIPTION FOR CHANGE:  
CRACKING DOWN ON ANTICOMPETITIVE  
CONDUCT IN PRESCRIPTION DRUG MARKETS**

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**HEARING**  
BEFORE THE  
SUBCOMMITTEE ON COMPETITION POLICY,  
ANTITRUST AND CONSUMER RIGHTS  
OF THE  
COMMITTEE ON THE JUDICIARY  
UNITED STATES SENATE  
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**A PRESCRIPTION FOR CHANGE:  
CRACKING DOWN ON ANTICOMPETITIVE  
CONDUCT IN PRESCRIPTION DRUG MARKETS**

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**TUESDAY, JULY 13, 2021**

UNITED STATES SENATE,  
SUBCOMMITTEE ON COMPETITION POLICY,  
ANTITRUST, AND CONSUMER RIGHTS,  
COMMITTEE ON THE JUDICIARY,  
*Washington, DC.*

The Subcommittee met, pursuant to notice, at 2:30 p.m., in Room 226, Dirksen Senate Office Building, Hon. Amy Klobuchar, Chair of the Subcommittee, presiding.

Present: Senators Klobuchar [presiding], Blumenthal, Ossoff, Lee, Hawley, Cotton, and Blackburn.

Also present: Senators Durbin and Grassley.

**OPENING STATEMENT OF HON. AMY KLOBUCHAR,  
A U.S. SENATOR FROM THE STATE OF MINNESOTA**

Chair KLOBUCHAR. I want to thank my colleague, Senator Lee, and our staff, and his staff who work very well together, as well as Senator Grassley is with us, who has been such a leader when it comes to these competition issues way before it was cool. Thank you for being here, Senator Grassley.

This is the latest in the Competition Policy's Subcommittee series of hearings examining America's monopoly problem. Today, we're going to focus on the lack of competition in our prescription drug markets.

The stakes could not be higher. According to the Centers for Medicare & Medicaid Services, healthcare spending accounted for 17.7 percent of U.S. gross domestic product in 2019. That is more than one-sixth of the American economy. That is projected to rise to 19.7 percent by 2028. Rising prescription drug prices is a key driver in those numbers.

But it isn't just about GDP. It's also about the all too real human costs that we will hear about today. For some, the ability to access prescription drugs is what enables them to work, to care for their families and loved ones, preserve their mental health, or just get through the day without excruciating pain. For others, access to safe and affordable prescription drugs is nothing less than matter of life or death.

Nearly 20 percent—just remember this figure if you forget all of the other ones—nearly 20 percent of older adults report not taking their medicines as prescribed because of cost. That means, and I

have met some of these seniors at home, they're cutting pills in half, they are saving little drops of insulin for the next day.

Even drugs that have been available for decades, like insulin, are out of reach for some. In my State, one of my most memorable families that I've gotten to know is the mom and dad of Alec. He was a restaurant manager, had a pretty good job in the suburbs of the Twin Cities, and when he aged off his parents' healthcare at age 26, he had to start paying for his own insulin. He was trying to cut the doses and do it himself, and he didn't do it right one day, and he died. His mother has made it her life's work to make sure that never happens to anyone again.

Americans should not have to choose between risking their lives and risking financial ruin because of the cost of prescription drugs. I actually got involved in the area of antitrust, not just because I drew the good luck of working with Mike Lee on the Subcommittee, but when I was actually a brand new Senator, and pharmacists from my State and doctors started calling me about an infant heart drug called indomethacin. The price of the drug, the cost of the drug, had suddenly gone up from \$78 per treatment to \$1,614, more than 20 times its original price and 44 times the price in Canada.

What had happened was one company called Ovation—they later sold it to another company—they had cornered the market. They bought the other competitive drug. There is absolutely no doubt. There were two drugs that were able to be used for this condition, and then, once they had done that and reached the monopoly jackpot, they basically raised the prices that much. It took years and years, suit by the FTC that failed because of conservative precedent that was out there when it comes to antitrust or consumer issues.

Other States, red States, blue States joined in the lawsuits, but that just didn't work. And so what happened was it took years and years for another competitor to come in, but all during that time, they reaped the benefit of a monopoly.

So, ideas for solutions. We have the work that Senator Grassley and I have done on pay-for-delay. One court case helped with that, but there is a lot more work that can be done, and I believe that if we put that bill up for a vote on the Senate floor in any which way, we would get that done. As you know, that's when brand names pay off generics to keep their products off the market.

We've got problems of product hopping, in which branded pharmaceutical companies force patients with an established drug with an expiring patent to a new drug with a new patent, often with little or no therapeutic difference, just to avoid competition from generics. That's a bill that our friends Senator Cornyn and Senator Blumenthal have that could get at that.

Sham petitions. Just before a generic is going to come on the market, the brand, it files a petition, says it's not safe, slows it down. That's another bill that Senator Grassley and I have to do something about that.

Other solutions. Senator Lee and I have worked together on a bill to allow the importation of drugs in certain circumstances when there are issues with pricing. Senator Grassley and I have another bill to do that more permanently of reimportation.

We have got the work that we could do on sweeping reform, which is contained in the bill that a number of us has put forward.

Then, finally, making sure that we are funding the agencies who go after these problems. We're proud that we got our bill through, Senator Grassley and I did, on that issue.

We also can empower our seniors to negotiate drug prices. I think seniors can get a pretty good deal through Medicare if negotiation was allowed, something that the President of the United States directly addressed in the State of the Union.

Those are just a few of my ideas. I know there are others, and I want to thank our witnesses for coming today, and with that, I will turn it over to Senator Lee.

**OPENING STATEMENT OF HON. MICHAEL S. LEE,  
A U.S. SENATOR FROM THE STATE OF UTAH**

Senator LEE. Thank you, Chair Klobuchar, and thanks to all of you for being here today. Drug competition in pharmaceutical markets, as well as drug pricing, are frequent and recurring topics of congressional oversight, and with good reason. Access to prescription drugs is an issue that inevitably affects every life at one point or another.

If a lack of competition leads to higher prices, as it tends to do, because one thing we know about competition—when it increases, prices tend to go down, quality tends to go up. The opposite happens when there's diminished competition. So if the lack of competition leads to higher prices, we can live without some things. You can live without the latest smartphone or free shipping for gadgets made in China. But a lot of people can't do without prescription drugs. My wife, Sharon, for example, is one of 7 million Americans who can't live without insulin.

Innovation competition and affordable prices are arguably more important to prescription drug markets than almost any other consumer market we can think of. And it's a consumer market that happens to be particularly important to the sustaining of human life.

This makes the continuing rise in drug prices all the more concerning. When we look at the data from 2007 to 2018, the cost of prescription drugs during that period rose 3 times faster than inflation. That's after we take into account manufacturing discounts.

Last month, AARP released findings that drug price increases outpaced inflation, had cost taxpayers \$38 billion just between 2015 and 2019 alone.

I expect this will only worsen in the wake of the inflationary economic policies that our Government has put in place over the last year and a half, regardless of any Executive order, and regardless of which administration is in power. When our Government expands its role, it tends, inevitably, to inflate, and that has an effect here.

Make no mistake. This is a multifaceted problem, and it's one that requires a multifaceted solution. Antitrust enforcement is not a panacea for drug prices, but it can certainly help. Failure to enforce them can, of course, lead to catastrophic consequences. In fact, our antitrust enforcers have developed an impressive track record thus far in stopping anticompetitive patent litigation settle-

ments and attempts to game the FDA regulatory process to their unfair advantage.

Since the 2013 Actavis decision, pay-for-delay settlements have slowed to barely a trickle. The task is now to remain vigilant until that trickle is no longer even a trickle, but it's gone.

The benefit of antitrust enforcement is that it takes matters on a case-by-case basis rather than attempting to impose a one-size-fits-all approach on the entire market. This allows us to stop—stop harmful conduct without needlessly, unnecessarily burdening pro-competitive and innovative conduct, something that usually proves elusive in comprehensive rulemaking in legislation.

In situations that are more straightforward, like getting access to brand samples in order to develop a generic alternative, it's easier for Congress to step in and remove the need for lengthy investigations and lengthy litigation. This is what we did with the CREATES Act, a bill that I was honored to Co-Sponsor along with Senators Grassley, Leahy, and Klobuchar.

My understanding is this that since it became law back in 2019, at the end of that year, the CREATES Act has already made it much easier for generic competitors to gain access to the samples that they need for FDA-mandated testing. At the time, CBO estimated that the CREATES Act would save taxpayers nearly \$4 billion over 10 years.

Today's hearing may also help shed light on other areas where Congress could step in to reform regulations and policies that create anticompetitive and anticonsumer incentives. I'll be interested to hear the witnesses' thoughts on potential PBM reforms and whether reform to our patent laws might help remove the impetus behind practices like product hopping and patent thickets, saving money for consumers, and freeing up antitrust enforcement resources to address other harms.

I look forward to each of our witnesses testifying today and look forward to our conversation. Thank you.

Chair KLOBUCHAR. Very good. Okay. Excellent. Senator Grassley is going to come back, so we look forward to that, and his name was mentioned enough that he doesn't need to do an opening. But we're very pleased he was here.

I'm going to introduce our witnesses, and thank you, Senator Lee, for mentioning the CREATES Act, which I failed to do, and you did excellent work on that bill.

Our first witness today is Michael Kades. Mr. Kades is the director for markets and competition policy at the Washington Center for Equitable Growth. His research focuses on competition and antitrust enforcement. Prior to joining Equitable Growth, he worked as antitrust counsel for me on this Subcommittee as a detailee from the FTC, so he knows this Committee well.

Before that, he spent nearly 20 years as an attorney at the FTC, including working on a number of healthcare cases. It's good to have him back.

Our second witness is Alden Abbott. Mr. Abbott is currently a senior research fellow at George Mason University, Mercatus Center, where he focuses on antitrust issues. He is the former general counsel of the Federal Trade Commission. Prior to his tenure as FTC general counsel, he worked at the Heritage Foundation, and

BlackBerry, and held several senior positions in the Federal Government.

Look, there are so many of them, I'm not going to say all of them. But it's very—okay, I will, because it's—Deputy Director of the Office of International Affairs, Associate Director of the Bureau of Competition at the FTC, Acting General Counsel, Assistant General Counsel, and Chief Counsel of the National Telecommunications and Information Administration, and Special Assistant to the Assistant Attorney General for Antitrust. That's quite a resume.

Our third witness is Geoffrey Levitt, and Mr. Levitt is co-chair of DLA Piper's life sciences policy and regulatory group. He is testifying today on behalf of the Pharmaceutical Research and Manufacturers of America, a trade group representing many of the country's leading biopharmaceutical companies. He previously served as senior vice president and chief counsel for Pfizer's Upjohn division in China and as chief regulatory counsel for Pfizer and Wyeth Pharmaceuticals.

He also previously served as chair of the Pharmaceutical Research and Manufacturers of America's Law Section Executive Committee.

Next up will be Rachel Moodie. Dr. Moodie is vice president and head of Legal and Intellectual Properties, Biosimilars at Fresenius Kabi, a global—did I say that right? Very good—a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion, and clinical innovation. Previously, she served as a patent attorney for biosimilars at a major pharmaceutical company, and director and patent attorney as well at Merck. She has a Ph.D. in biochemistry and molecular biology.

Our final witness is David Mitchell. Mr. Mitchell is the founder and president of Patients for Affordable Drugs. He is a patient advocate focused on promoting policies to lower the cost of prescription drugs. He's also a patient who relies on prescription drugs and expects to be in continuous treatment for the rest of his life. He has 40 years of experience working on healthcare and public health policy, and has worked to reduce teen smoking, increase use of seat belts, fight drunk driving, and improve child health and safety.

I want to thank the witnesses for being here today. I guess we'll swear in the witnesses. Okay. You want to stand and—thank you. [Witnesses are sworn in.]

Thank you. You can be seated, and I'll now recognize the witnesses for 5 minutes of testimony each, starting with Mr. Kades, then we'll go through in that order, so. Thank you.

**STATEMENT OF MICHAEL KADES, DIRECTOR FOR  
MARKETS AND COMPETITION POLICY, WASHINGTON  
CENTER FOR EQUITABLE GROWTH, WASHINGTON, DC**

Mr. KADES. Thank you, Chairwoman Klobuchar and Ranking Member Lee, for the opportunity to testify about prescription drugs markets and competition, a critical issue. It's also an honor to be back with the Subcommittee, although it's a little more stressful from this side of the dais.

Prescription drugs cost America nearly \$370 billion a year, forcing too many to choose between their health and other necessities,

like rent or food, or to ration among different medicines. Protecting competition in these markets both reduces the financial burden on Americans and improves their healthcare.

Unfortunately, that is not what we are doing. Prescription drug markets are rife with persistent anticompetitive conduct. Current antitrust law as interpreted and applied encourages this activity instead of deterring it. Over the past 4 years, the Federal courts have shown an almost neurotic fear of overenforcement, have increased burdens on plaintiffs, and narrowed the scope of antitrust law.

Courts have raised inappropriate and unnecessary hurdles to antitrust enforcement, which allows anticompetitive activity to escape condemnation. For example, courts are discounting direct evidence of anticompetitive effects, ingenuously accepting business justifications without sufficient evidence, discounting the value of potential competition, and dismissing the likelihood that exclusionary conduct can be successful.

Both economic research and empirical results discredit that approach. As misguided as that approach is, it has opened the door to anticompetitive conduct, particularly in prescription drug markets. By their nature, these markets are susceptible to abusive and anticompetitive conduct. Compared to other industries, harming competition is easy to accomplish and extremely profitable. Preventing or just delaying, generic or biosimilar competition increases the dominant firms' revenues and profits substantially.

So, not surprisingly, within the pharmaceutical industry, some companies have taken advantage of more lenient antitrust rules to adopt increasingly problematic strategies that increase drug costs.

It would take more than 5 minutes to catalog every anticompetitive tactic in these markets. I focus on three in my testimony.

Rebate traps, which are really a penalty provision that allow a dominant firm to punish buyers who seek to purchase a lower cost alternative.

Product hopping, in which a dominant firm tweaks its product to deaden the impact of generic competition. In one case, this amounted to literally putting a tablet inside a capsule and selling it as a new product.

Pay-for-delay patent settlements, in which a branded company pays its generic competitor to stay out of the market. Even in this area, where there has been significant, important enforcement success, that success is both incomplete and tenuous.

It would be wrong, however, to think anticompetitive conduct and market power are uniquely a prescription drug market phenomenon. We are seeing this kind of conduct growing across the economy, in markets as different as digital, agriculture, and labor.

There are two types of broad reforms we can look at. Updating the antitrust laws would go a long way to preventing harmful conduct, while promoting aggressive competition in prescription drug markets and across the economy. The Competition in Antitrust Law Enforcement Reform Act would significantly address most of the problems I discussed in my testimony.

Second, certain problems that are unique to pharmaceutical markets may require special legislation. Senator Lee, you talked about



the CREATES Act, which was a bipartisan bill that followed precisely this approach.

Without reform, attacking competition—I'm sorry. Without reform, attacking anticompetitive conduct in prescription drug markets, and across the economy, will be unnecessarily difficult. Consumers, small business, and workers will suffer. I urge Congress to stem the tide of anticompetitive conduct by restoring the vitality of the antitrust laws, which will substantially improve competition in prescription drug markets.

Thank you, and I look forward to your questions.

[The prepared statement of Mr. Kades appear as a submission for the record.]

Chair KLOBUCHAR. Very good. Thank you very much. Mr. Abbott.

**STATEMENT OF ALDEN ABBOTT, SENIOR  
RESEARCH FELLOW, GEORGE MASON UNIVERSITY,  
MERCATUS CENTER, FAIRFAX, VIRGINIA**

Mr. ABBOTT. Thank you, Chair Klobuchar, Ranking Member Lee, distinguished Members of the Subcommittee. I'm Alden Abbott, senior research fellow at Mercatus Center at George Mason University. My research focuses primarily on antitrust and competition policy. I will focus on three key points.

One: Federal antitrust enforcement has been robust and effective in promoting prescription drug market competition. Not perfect, but effective. New enforcement tools are not needed, but additional resources to support FTC and DOJ enforcement are warranted.

Two: Antitrust enforcement directed at prescription drug markets should remain attentive to potential efficiencies associated with the practices under review. Specialized legislation, generally, is not appropriate in this area. There are exceptions. As already mentioned, the CREATES Act is one, which I testified in favor of a few years ago.

Three: Antitrust enforcement alone will not eliminate all competitive problems in prescription drug markets or in healthcare in general. Indeed, I would argue most of the serious competitive problems will remain because of the nature of a regulatory and legal system in healthcare. Fundamental regulatory reform would be needed.

First, antitrust enforcement. The FTC and DOJ have many decades of experience in studying and bringing appropriate antitrust enforcement actions concerning healthcare markets in general, and the pharma sector in particular. FTC has also carried out public hearings, undertaken sectoral investigations, and issued numerous reports on competition policy in these areas.

An April 2021 Bureau of Competition staff report summarizes the many recent FTC initiatives in pharma. These include actions directed at monopolization and agreements not to compete involving pharma products, mergers involving pharma products, mergers involving distribution, agreements involving monopolization, price and price-related terms, and schemes to obstruct innovative methods of delivering and financing pharma products. In addition, the report describes a variety of FTC friend of the court briefs concerning pharma competition.

DOJ's Antitrust Division has been very busy lately in bringing prosecutions against hardcore cartel conduct by generic drug manufacturers. A March 2021 division update explains seven firms have been prosecuted, five have already agreed to deferred prosecution agreements. Those firms have agreed to pay over \$426 million in criminal penalties for collusion that affected over \$1 billion of generic drug sales. And that investigation continues.

The two recent Government reports tell a success story. The FTC and DOJ would, however, benefit from additional resources to carry out their enforcement duties, given a great economic significance and complexity of pharma market issues.

Second, enforcement should continue to focus on efficiencies. Apart from per se illegal cartel conduct, Federal antitrust enforcers apply the antitrust rule of reason in assessing potentially anticompetitive pharma market practices. They ask whether particular conduct under scrutiny yields consumer welfare-enhancing efficiencies that would offset potential anticompetitive effects. Efficiencies might include, for example, practices that reduce manufacturing or distribution costs to the benefit of consumers. They might also involve enhanced product innovation facilitated by patents and other intellectual property.

In the pharma sector, issues of anticompetitive harm and pro-competitive efficiencies often are associated with patents. Harm may arise from the strategic use of patents to delay or deter entry from potential competitors. At the same time, however, patents may facilitate efficient and innovation-enhancing distribution of new technologies. There is a good reason why the U.S. is a leading country in production of new pharmaceuticals, and that has been our robust patent system.

Patents can be abused, but they can be very important incentive devices as well. I would argue Congress should not likely legislate in this area, except in cases of clear abuses, as in the CREATES Act.

Finally, as I indicated earlier, antitrust is not enough. Broader U.S. healthcare reform itself is important. That's been pointed out by this administration, the prior ones, in open reports. I thank you for your time. I look forward to your questions.

[The prepared statement of Mr. Abbott appears as a submission for the record.]

Chair KLOBUCHAR. Thank you very much, Mr. Abbott. Mr. Levitt.

**STATEMENT OF GEOFFREY LEVITT, OF COUNSEL  
DLA PIPER APPEARING ON BEHALF OF PHARMACEUTICAL  
RESEARCH AND MANUFACTURERS OF AMERICA,  
WASHINGTON, DC**

Mr. LEVITT. Good afternoon, and thank you, Chairwoman Klobuchar, Ranking Member Lee, Chairman Durbin, and Members of the Subcommittee for the invitation to testify.

I've worked for innovative pharmaceutical companies for most of my career, and I appreciate the Subcommittee's focus on ensuring robust competition. While I am currently with a law firm, I spent many years as in-house counsel in the biopharmaceutical industry, as Chairwoman Klobuchar noted, and I bring that perspective to

my testimony today on behalf of the Pharmaceutical Research and Manufacturers of America, or PhRMA.

PhRMA represents the Nation's leading biopharmaceutical research companies, which are dedicated to developing new treatments and cures to enable patients to live longer, healthier lives. PhRMA's activities on behalf of its members are limited by the antitrust laws and PhRMA's antitrust compliance policy. As I am here on behalf of the trade association, I won't be able to comment on individual companies' current or future strategies relating to drug pricing, R&D, marketing, relationships with customers, or how member companies might or might not individually respond in the marketplace to a change in law or regulation.

The highly competitive structure of the U.S. biopharmaceutical market has made it possible to bring new medical advances to patients, while holding medicine's share of health spending nearly constant. This competition has been facilitated by regulatory frameworks that provide abbreviated approval pathways for generic and biosimilar competition, while maintaining incentives for innovative medicines. These frameworks have shifted utilization from brand medicines to generics and biosimilars so successfully that 91 percent of all prescriptions for drugs in the U.S. are filled with generic medicines, saving the healthcare system hundreds of billions of dollars.

Brand medicine prices after discounts and rebates have grown in line with or below inflation for the past 5 years. Last year, these net prices actually declined by 2.9 percent, and this trend is expected to continue. Net prices for brand drugs are projected to remain flat or drop by up to 3 percent annually through 2025. This is due, in large part, to robust competition in the drug pricing market.

However, on the pharmacy benefit manager, or PBM side, negotiating power has become increasingly concentrated, with just three PBMs now controlling more than three-quarters of the market. We know that the rebates and discounts negotiated between drug manufacturers and PBMs are not consistently shared with patients filling their prescriptions.

So, while the overall U.S. biopharma market has seen price growth at or below inflation, the patient experience is often different. Given that nearly half of spending on brand medicines today goes to entities other than the manufacturers, an initial step in any drug pricing discussion, in our view, should be to ensure that these price concessions are shared with patients.

As to innovation, the U.S. is the global leader in this space. Of the nearly 8,000 medicines in development globally, more than half are being developed in the U.S. This is precisely because we reject government price setting and protect intellectual property. This strong intellectual property framework has enabled biopharmaceutical companies over the past several decades to develop new medicines that have saved lives and alleviated the burden of disease in many areas, from cancer to cardiovascular disease to COVID-19.

Undermining IP protections or adopting policies that would chill industry's ability to innovate would unduly restrict—could seriously threaten these dynamics—excuse me. This concern applies

equally to any measure that would unduly restrict companies' ability to obtain patent protection for improvements to existing products that contribute to disease treatment and patient care.

In closing, I want to say that the way biopharmaceutical companies have been frequently mischaracterized by the media and critics bears little resemblance to the industry that I spent decades working in. The reality I experienced was of teams of professionals dedicated to making medicines to cure disease and save lives, with an unwavering focus on ethics and compliance. While we have all observed publicized examples of questionable behavior, we are aware of these examples precisely because we have a system that provides remedies for anticompetitive behavior. Isolated cases that have been the subject of enforcement actions are not evidence of an entire industry run amok, but rather of a healthy, functioning system.

The U.S. biopharmaceutical market is the most innovative in the world precisely because it is highly competitive. We urge caution and respect for the strong IP protections and market-based policies that have been the foundation of American innovation. Thank you, and I look forward to your questions.

[The prepared statement of Mr. Levitt appears as a submission for the record.]

Chair KLOBUCHAR. Thank you very much, Mr. Levitt. Dr. Moodie.

**STATEMENT OF RACHEL MOODIE, VICE PRESIDENT  
AND HEAD OF LEGAL AND INTELLECTUAL PROPERTIES,  
BIOSIMILARS, FRESenius KABI, WASHINGTON, DC**

Dr. MOODIE. Chairwoman Klobuchar, Ranking Member Lee, and Chairman Durbin, thank you for the opportunity to talk today on this important issue.

Fresenius Kabi is a healthcare company that specializes in bringing affordable, off-patent medicines to patients. We employ over 4,000 people in the U.S. and have key domestic manufacturing, research and development, and distribution centers across the country.

During the pandemic, our injectable medicines were routinely used to treat patients in the ICUs, and several of our medicines and devices are currently held in the U.S. Strategic National Stockpile. One of our products is also used in the COVID-19 vaccine.

A balanced and fair patent and rebate system is essential to be able to continue this lifesaving work, as well as providing branded companies with the time that they need to recoup their investments and fund the next generation of innovative drugs before our more affordable products come to market.

However, Fresenius Kabi has experienced a system shift whereby branded pharmaceutical companies are now able to hold on to monopolies for old drugs for much more than 20 years, long after they've aged out of being thought of as being considered innovative. This hurts access for patients to affordable medicines and stresses payment systems that need to be kept solvent to pay for true innovation.

Prolonged monopolies exacerbate rebate practicing and intensify the already misaligned incentives for health plans and pharmacy

benefit managers, the PBMs. By extending the number of years that a rebate and a list price can grow, it exacerbates and grows the patient out-of-pocket costs, and it also puts pressure on the PBMs—the PBM to prefer the more expensive branded products compared to the more affordable alternatives in order to secure the rebate revenue. Of course, these benefits to the PBMs are not passed on to the patients.

So far, the current policy debates around drug prices have failed to address the root cause of the problem, which is an excessive number of patents around drugs, many of which are low quality and do not provide true benefits to patients. Because of the misuse of patent thickets and rebates as marketing tools, and product hopping as another tool to thwart competition, the U.S. branded pharmaceutical industry is not currently operating as a true free market system with downward pressure at an appropriate time.

I'd like to explain how it's possible to grow a patent thicket around a single drug. But to be clear, of course, Fresenius Kabi is in favor of high-quality patents. Our industry cannot exist without it.

Patent thickets comprise mostly of secondary patents, which are those patents that are filed after the core patents on the product are filed. Not all secondary patents are bad. However, the key to forming a patent thicket is you take each secondary patent, let's say, for example, a patent that covers a weekly dosing regimen for a drug, and then you multiply it into child patents, or they're called continuation patents, each having incrementally different words. For example, patent one, if I'm using the same example, might claim dosing every 5 to 7 days. Patent two might claim dosing every 6 to 8 days, and you keep going. This forms a family around a secondary invention.

Let's say you have a drug that has 10 such families, and each family contains, say, 15 continuation patents. That results in a thicket of 150 patents, all derived from just 10 original patent filings. Most of the patents in that thicket are those incremental continuation patents that don't bring new benefits to patients.

I'm not suggesting that all secondary patents are bad. The problem is the sheer volume of patents strategically thicketed around a drug which shields most of the patents from scrutiny.

Biosimilar companies do not have the funds and resources to litigate scores, and certainly not hundreds, of patents. Courts can't even litigate scores of patents effectively in a single lawsuit. So how do we know that many of these patents that are shielded and protected are low quality? The Patent Office offers a procedure called an IPR, an inter partes review or a post-grant review, IPR or PGR, to challenge the validity of a patent.

Statistics from the USPTO show that in 2020, third parties were successful in having their IPRs instituted against 56 percent of all the patents that they challenged, which suggested over half of the patents that were challenged were at least of questionable quality. However, patent thickets can be created at a cost that's easily affordable to branded companies. It costs approximately \$25,000 to obtain and maintain just one patent. Conversely, it costs third parties approximately \$1 million to file a single IPR against a single patent.

Biosimilar applicants cannot economically use IPRs and PGRs to clear a path through hundreds of patents. This is why building a patent thicket is a numbers game, designed to shield patents, side-step the scrutiny of IPRs and PGRs, and create an inappropriate monopoly.

Among the root causes of patent thickets are the examination procedures and incentives at the U.S. Patent Office. This patent thicket trend is particular to the United States. It's true that the U.S. is the innovation capital of the world, and so we must have a strong patent system. But the pendulum of encouraging innovation should not swing so far as it goes into an anticompetitive direction.

As well as exacerbating rebate pricing, inappropriate monopolies also allow branded drugs the time to develop more and more sophisticated life cycle management strategies so that by the time biosimilars come to the market, they're irrelevant. Furthermore, patent thickets in the U.S. are now discouraging development and launch of biosimilars, and while biosimilars of these drugs will eventually reach the U.S., we expect that they will be delayed several years after they come on market in Canada and Europe.

In sum, we urge Congress to address the root cause of the drug pricing problem. Look beyond the policies in the jurisdiction of traditional healthcare entities. Instead, we urge Congress to put an end to the inappropriately long patent monopolies and rebate schemes that reward prescribing the higher-cost branded drugs when the lower-cost drugs are available.

Thank you again for the opportunity to speak on behalf of my company and patients who would benefit from availability of affordable and essential medicines.

[The prepared statement of Dr. Moodie appears as a submission for the record.]

Chair KLOBUCHAR. Thank you very much. Last, but not least, Mr. Mitchell. Then I'm going to concede my time of questioning to our Chair of our Judiciary Committee, who is in charge of getting us out of all kinds of thickets.

[Laughter.]

Chair KLOBUCHAR. I thought that would be a good segue. Mr. Mitchell.

**STATEMENT OF DAVID MITCHELL,  
PRESIDENT AND FOUNDER, PATIENTS  
FOR AFFORDABLE DRUGS, WASHINGTON, DC**

Mr. MITCHELL. Chair Klobuchar, Ranking Member Lee, Chairman Durbin, Members of the Committee, I'm David Mitchell. I'm founder for Patients for Affordable Drugs. More importantly for today, I have an incurable blood cancer, and prescription drugs are keeping me alive. My doctors have me on a four-drug combination right now with a list price of more than \$900,000 per year. Just one of my oral drugs [holds up bottle] that comes in this little bottle is called Pomalyst. It's priced at almost \$21,000 for 21 capsules that I have to buy every 28 days.

Because Medicare beneficiaries like me pay our cost based on list price, I spent more than \$18,000 out of pocket last year just for

Pomalyst. For people with my cancer, multiple myeloma, drugs account for 60 percent of the cost of treatment.

I'm a very lucky man. These drugs are keeping my cancer at bay right now, but eventually, this combination will stop working, and I'll need a new treatment. So, I care deeply about innovation and new drug development, but drugs don't work if people can't afford them. That's why today's hearing is so important. Examining anti-competitive industry practices that both inhibit innovation and drive up prices.

When a drug company makes a truly inventive discovery, it should be rewarded with a patent and receive a fair return. But the drug industry would have you believe that every patent is deserved, and that the volume of patents granted is an indicator of innovative achievements. That could not be further from the truth, as you just heard. Neither new patents nor new drugs necessarily equal real innovation. Worse, in too many cases, manufacturers are abusing America's patent system to prevent competition and block affordable generic and biosimilar drugs from coming to market.

There are a variety of strategies. They've been outlined by everybody up here. Product hopping, patent thicketing, pay-for-delay deals, abuse of the FDA's citizen petition process. More importantly than the problems is that there are solutions. There are bipartisan bills that address these abuses, including legislation led by Members of this Committee, and Chair Klobuchar went through them: Senator Blumenthal's bill with Senator Cornyn, addressing product hopping and patent thickets; Senator Durbin and Cassidy's Remedy Act is another terrific solution for further cracking down on evergreening behaviors; Chairwoman Klobuchar, we hope this year is the year that we see your bills with Senator Grassley, that stop pay-for-delay and citizen petition abuses, be acted into law.

Of course, Biopharma opposes reforms that would constrain its monopolies or curb its unilateral power to dictate prices. It threatens me that any reforms will destroy innovation and access to new drugs. But in fact, it's these anticompetitive practice that actually inhibit innovation. Why? Because if drug companies can block competition, and raise prices on old drugs to drive profits and trigger executive bonuses, they have far less incentive to take risk and invest in R&D to find the innovative new drugs that could command high prices and extend my life.

The headwaters of the drug price problem is high list prices set by manufacturers. There are other anticompetitive practices downstream in the supply chain that should be addressed this year, including those by pharmacy benefit managers. PBMs are black boxes that cut secret, mutually beneficial rebate deals with manufacturers, and none of it is transparent. Drug companies and PBMs enter into rebate arrangements that are specifically designed to thwart lower-cost competition. Rebate walls, rebate traps, and other exclusionary contracting practices should simply be outlawed.

Let's be clear. These deals are not designed to help patients like me by lowering prices or increasing patient choice. No. They are emblematic of our drug pricing system that is built to benefit those who profit from it at the expense of those it is supposed to serve.

We're pleased that the FTC recently decided to tackle these issues. We hope Congress will ensure that the FTC's ability to seek

damages and monetary penalties in consumer protection and competition cases.

Of course, the President's Executive order on competition includes many welcome steps to lower drug prices. But when all is said and done on everything I've just mentioned, we could still wind up paying four times what other wealthy nations pay for the exact same brand drugs. That's why we need comprehensive reforms, including Medicare, to negotiate lower prices. Medicare negotiation is supported by 90 percent of Americans, and it's time to pass it.

In the end, all of the work on drug pricing that's being done up here is about restoring balance to ensure we get the innovation we need at prices we can afford. You hold the power to make the changes the American people are demanding. We're going to try and do our part to make sure their voices are heard. Thank you.

[The prepared statement of Mr. Mitchell appears as a submission for the record.]

Chair KLOBUCHAR. Thank you very much, Mr. Mitchell. Chairman Durbin.

Chair DURBIN. Thank you, Chairman and Senator Lee. This is an important hearing. I think the American people, when given a choice of topics that we might discuss in Congress, would put this at the top of the list. At least, they tell us that when we take polls.

It's interesting to me that we live in a country where so many people can spell the word Xarelto. You just wonder how in the world did that happen? Could it be that the pharmaceutical industry is spending \$6 billion a year? Is it possible advertising? Is it possible that the fact that we see their ads nine times a day on average is educating the Americans on these drugs?

Senator Grassley and I decided to ask the General Accounting Office for some information on this, and they did a study. They found that between 2016 and 2018, advertised drugs on television and other places accounted for 58 percent of Medicare's budget for medications. Coincidence? These ads ballooned Medicare spending to the tune of 320 billion over 3 years. When I asked Blue Cross and Blue Shield in Chicago, "Why are premiums going up?" they said, "Number one reason: the high cost of prescription drugs."

They advertise them on television so consumers will ask for them at the doctor's office. The doctor then has a choice: explain to them why they may not need it, maybe even lose the patient, or just prescribe it. Most times, they just prescribe it, and it ends up being added to the cost of healthcare in America. And it just keeps going up. Unless you're lucky enough to live in Canada, instead, you're going to be stuck with these prices.

Mr. Mitchell, when it comes to this advertising on television, since the United States and New Zealand are the only two countries in the world that allow it, what value is it to the consumer?

Mr. MITCHELL. I think the more information you give to consumers, the better to help them understand the choices they are being called upon to make. I'm not sure that including prices in ads will lower prices, but I do believe that it will help consumers understand better the—what's happening to them.

We also support, frankly, eliminating the tax deduction for consumer advertising by drug companies in order to discourage their



use because they really are used only to sell more drugs at higher prices.

Chair DURBIN. I might just say that the fact that a drug as common as Lantus insulin, approved in 2000, with 45 follow-on patents that helped to block competition for 37 years, during that time, the price of Lantus insulin was hiked 25 times, from \$35 to more than \$300, and that's not an unusual situation. Unfortunately, it's a common situation.

Perhaps if the consumer finally catches on that these drugs are just going wildly high, there might be a second thought about the heavily advertised Humira as to what it might cost on a monthly basis. I'm glad your drugs are saving your life. I'm glad you're here to tell us about it. But there comes a point where you say it's your money or your life when it gets right down to it.

Let me ask you this if I can, Mr. Levitt. In your testimony, you cite the \$83 billion investment in research and development by pharma companies in 2019. You state, quote, "Due to uncertainty around R&D endeavors, investors require higher returns to compensate for higher risk." This pharmaceutical industry responds to every single policy proposal in drug pricing, claiming it will chill innovation, and that a single penny in reduced profits could mean a freeze on lifesaving innovation.

How do you square the colossal amount spent on spending—how do you square the fact that 14 largest drug makers spent more on stock buybacks than on research and development during the past 5 years?

Mr. LEVITT. Thank you, Chairman Durbin. These are individual, obviously, economic decisions by pharmaceutical companies. I would say—let me step back and start out by saying I can assure you that biopharmaceutical companies do not invent lifesaving medicines in order to make them inaccessible to patients. There is a balance between innovation and access, and innovation is critical. R&D spend is very high and has increased significantly over the past several years. It's at a peak now, and the U.S. accounts for the vast majority of that spending.

Companies also put their money into making patients aware of the benefits and potential uses of their products through direct-to-consumer advertising, which is an important means of conveying information to patients about drugs. As you said, prescribers then have the choice of whether to prescribe the drug.

Chair DURBIN. It doesn't work that way. Unfortunately, it just doesn't work that way, and you know it. If you get the consumer remembering the name of the drug, and remembering the person who skipped across the field of flowers, that go into their doctor's and say, "I think I need this," you know that most doctors, instead of getting into a debate, are going to prescribe it. That's why you win on consumer advertising. People are partially educated, and doctors neither have the inclination nor time to debate with those patients.

Mr. LEVITT. Mr. Chairman, I would rather not posit that doctors are making irresponsible prescribing decisions because of their patients coming in to them, but it may be that we have to agree to disagree on that one.

Chair DURBIN. Well, we do disagree on that one. I do want to tell you, there has been a massive investment in innovation in pharmaceuticals. It's been done in Washington with the National Institutes of Health. The numbers are pretty amazing. Funding for the NIH contributed to the published research associated with every single new drug approved by FDA between 2010 and 2019. Three hundred fifty-six new medications.

We're putting billions each year into the NIH. We want to make sure the consumers can afford the products that these pharmaceutical companies generate from that research. Do you think we're getting that kind of return?

Mr. LEVITT. Senator Durbin, I would say that the research ecosystem is a complete whole of which basic research, funded by the Government, by NIH, is an important part. But NIH does not bring drugs into clinical development and marketing approval. That can only be done by pharmaceutical companies. I think if we look at the statements of the NIH itself, they will acknowledge that without the efforts of the pharma industry to develop and bring drugs to market, their basic research would not produce patient-accessible innovation.

Chair DURBIN. If you listen to Dr. Moodie, and she's pretty convincing, the thickets that we've created in patent law cannot serve the purpose of research or innovation or the benefits to the consumers. It's all about monopoly control of some of these drugs so that you can have profits for a longer period of time, isn't that right?

Mr. LEVITT. Mr. Chairman, I guess I would take issue with a couple of comments made by my learned colleague here, Dr. Moodie. First of all, it's not that easy to get a patent in the first place. To get a patent, you have to show that the invention is patentable. It has to have novelty, utility, and other features that entitle it to get a patent.

I would also point out that innovation does not stop upon approval of a product. There are many very important innovations in product development post-approval that benefit patients tremendously. Things like even changing the dosage form of a product from an injectable to an oral, even reducing dosage frequency or allowing for a fixed drug combination instead of having the patient take multi-drugs for HIV or other conditions.

I could go on. There's many, many, many innovations. Improving stability profile—that's something that's been in the news recently. It's obviously a key—

Chair DURBIN. I'm sorry. I'm out of time. I'm sorry. I'll—

Chair KLOBUCHAR. You can—I mean, if you want—Senator Durbin, please—

Chair DURBIN. I just wanted Dr. Moodie—

Chair KLOBUCHAR [continuing]. If you want to allow him to finish, and then Dr. Moodie to respond, and then we'll turn it over to Senator Lee.

Chair DURBIN. That's what I'm looking for. I'd like to ask Dr. Moodie to respond to that.

Chair KLOBUCHAR. Okay. Dr. Moodie.

Dr. MOODIE. Sure. We see the U.S. patent system as being an outlier now compared to other systems around the world. In the

U.S., there are, of course, rules for examining patents that are working well, but it's also easy to circumvent those rules in order to do this numbers gaming, where you can build up incrementally different patents of having claims of incrementally different wording to make an army of continuation patents, all derived from just one original patent filing.

This ends up building a patent thicket that's both protracted and multilayered. Overall, we do believe that the root cause of the problem is the examination procedures and the rules that the USPTO is using, and that by tightening up those rules, it can help provide a more balanced patent system that can provide the benefits to both incentivizing innovation as well as allowing affordable medicines to come onto the market in a more appropriate time.

Chair DURBIN. Madam Chairman, if I could just read one sentence into the record and thank you for your patience.

Chair KLOBUCHAR. Of course.

Chair DURBIN. The top 12 best-selling drugs in America each have an average of 71 patents, and 78 percent of all new patents are for drugs that are already on the market. Thank you.

Chair KLOBUCHAR. Excellent. Not excellent fact. Excellent job, Senator Durbin. Next up, Senator Lee.

Senator LEE. Thank you, Chair Klobuchar. In the last few hours as we've been talking about the CREATES Act, we've seen the filing of what may well be the first complaint. It was a complaint filed in the U.S. District Court for the Eastern District of Pennsylvania, asserting claims under the CREATES Act. I've gone through the complaint. It looks like it's well-written. I can't speak to the merits of it beyond what I've seen, other than to point—this was a complaint filed by Teva Pharmaceuticals against Amicus Therapeutics.

In reading the complaint, it was confusing, mildly, because the fact that one of the real parties in interest, the defendant, is named Amicus, and I think that might throw off the court from time to time.

[Laughter.]

Senator LEE. Mr. Levitt, let's start with you. In 2019, the Office of Inspector General for the Department of Health and Human Services found that the rebate model used by PBMs was at least a significant contributor to high drug prices. What reforms do you think we ought to consider in order to address this? I ask that keeping in mind that some experts believe that PBMs should be required to have a fiduciary obligation to their beneficiaries. Would this help solve the problem?

Mr. LEVITT. Thank you, Senator Lee. We believe that the major need and necessity in this area in terms of reform is greater transparency in pricing and the ability to pass rebates and discounts through to the patients at the point of filling their prescriptions because what's going on here is that we have a growing disparity between list prices, which are then subject to rebates and discounts that are negotiated between a manufacturer and a PBM, and those rebates and discounts then do not reliably find their way to the patient.

We strongly believe in greater transparency, and your point about fiduciary duty on the part of PBMs is interesting. I don't

think we have a position on that yet, but we certainly will look at that very closely.

Senator LEE. Dr. Moodie, do you have any opinion on that?

Dr. MOODIE. When it comes to rebates and patent monopolies, the problem with these inappropriately extended monopolies is that the rebates can then increase for a longer period of time, and so this grows the patient out-of-pocket costs. But—well, I mean, I'm not the expert here on the mechanics of rebates, so I'm happy to hand over to other witnesses on that.

Senator LEE. While we're with you, do you think our patent system encourages or enables some of the anticompetitive conduct by branded pharmaceuticals, and if so, what can we do to change that?

Dr. MOODIE. The way that the patent system's working right now is that it's easy to circumvent certain rules that allow you to repetitively claim a similar invention over and over again. Then this means by building up the numbers of patents by similar applicants, we can't economically clear a path through that many patents.

Then you can create an inappropriate monopoly, because you're shielding your patents from being scrutinized by the checks and balances that were built into the system.

Also, the processes that we use to challenge patents, IPRs and PGRs, have been weakened over the years. And so, what would be very beneficial for third parties, such as ourselves, to be able to really scrutinize the patents and put the checks and balances back into the system would be to strengthen the IPRs tools, as well.

Senator LEE. Yes, I've believed that for some time. One of the things that I've struggled with there is knowing how we do that and trying to figure out where that problem stems from. Do you think the PTO is sort of rubber-stamping weak patent applications? Is that how we're getting there?

Dr. MOODIE. I would say that there are, of course, good secondary patents. When I pointed to those statistics earlier, evidence shows that over half of the patents that are granted are at least of questionable quality. Yes, that is one side of it. We do need to raise the bar with patentability at the USPTO. We also need to tighten up the rules that make it possible to game the system to create lots of patents.

We also need to give third parties better tools to challenge the patents to put back that checks and balances into the system.

Senator LEE. What about within the generic marketplace? I've lost track of the number of drugs that I've followed over the years, where once a drug goes off patent, you'll see some generic competition. You'll see prices go down. Then, in many, many instances, you'll see the price for the same molecule, that's now off-patent skyrocket, sometimes to levels or even above levels where it was selling while it was still on-patent. Do you have any theory as to why that's happening?

Dr. MOODIE. It could be that the generics are dropping out of the market. For various reasons, they just can't make any profit whatsoever. Yes, I mean that's not only a patent issue. That goes beyond that.

Senator LEE. You have some attrition there if they think they can't make money, and then—okay.

Mr. Abbott, we often hear calls for Government-mandated price controls, sometimes as a response to the rising costs of prescription drugs. Do you think that approach would work?

Mr. ABBOTT. I don't think so, Senator. As a general matter, and history shows price controls distort markets, and they create shortages, reduce investment and innovation. The classic example is Federal oil and gas price controls in the 1970s. You had less investment in oil and gas, major shortages.

In the case of pharma, that would mean fewer drug improvements and new drugs, with many patients being denied opportunities for cures or improvements in the cures in treatment of diseases. The U.S. leads the world in pharma innovation and R&D and would surrender it if it adopted price controls. Canada directly regulates drug prices, which has led to widespread drug shortages according to a University of British Columbia study, and those shortages are getting worse.

Also, consider that pharma R&D fell in Canada between 2001 and 2017 significantly, while U.S. pharma R&D more than doubled from \$24 billion to \$56 billion during that period. Importing drugs from Canada with the aim of reducing prices could also import the problems of reduced availability and investment.

Senator LEE. What's cross-subsidization, and what role do you think it might be playing here?

Mr. ABBOTT. The cross-subsidization problem is you have, in many countries, these one-buyer national systems, where drug companies face a monopsonist, like a monopoly buyer, and they are threatened in some situations with lack of protection for intellectual property, or lack of access to markets. That is one of the reasons why prices are a lot lower. In fact, you have anticompetitive buyer activity going on.

Of course, two wrongs don't make a right. The fact that you have price controls there doesn't mean that, well, you're going to solve a problem in the U.S. if you have price controls. If you then have price controls in the U.S., you're just going to get less investment, and the people will be harmed, and the future patients who would have had cures or better health results but won't because there will be a slow rate of introduction of new and improved drugs.

Senator LEE. I see my time is expired. Thank you.

Chair KLOBUCHAR. Thank you very much, Senator Lee. Senator Blumenthal has joined us, so I'll have him go ahead. I have noted, Senator Blumenthal, your work that you and I are doing on rebate traps, as well as the work you are doing with Senator Cornyn on product hopping. Senator Blumenthal.

Senator BLUMENTHAL. Thank you. Thank you, Senator Klobuchar, and I really appreciate all the great work that you're doing and the work that we're doing together, and thank you to you and the Ranking Member for having this hearing. I can't think of a hearing that's more important. Today, I should just note that I'm also a Member of the Armed Services Committee, and we are having a joint hearing with the Intelligence Committee on reports of unidentified aerial whatever you want to call them.

Chair KLOBUCHAR. You still joined us? That's impressive.

[Laughter.]

Senator BLUMENTHAL. Yes. I feel like I have returned to the real world.

[Laughter.]

Senator BLUMENTHAL. It is a real world that bedevil us every time we go home. Literally. I can't think of a better time to have this hearing because we're all back here from visiting our States, where we hear, every one of us, doesn't matter whether we're Republican or Democrat, about a woman, or a family, or a man who is foregoing whatever—clothes, food on the table, or maybe even the medicine itself because of the skyrocketing prices of drugs.

They've increased 40 percent over the last decade and they're continuing to climb, and I want to come right to the point. At least some of this price increase is due to abuse of our patent system. I say with no great pride that the engineers and designers here are many of my own profession, lawyers, who advise how to game that system, and one of the particularly harmful ways to do it is known as product hopping.

All of you know what product hopping is. It's a process by which branded pharmaceutical manufacturers make small, incidental, often irrelevant changes to drug formulas to extend their patent exclusivity and keep competition out. Let me give you an example, which happens to be very timely, as well. Alzheimer's disease is treated by a branded medicine known as Actavis. Knowing that the market exclusivity for this drug was running out, Actavis sought to replace its twice-daily dosage of Alzheimer's treatment with a new extended-release, a once-daily version, without changing the medical benefits, the essential ingredients of the drug.

After the FDA approved the new drug, Actavis was able, strategically to wait for 3 years, 3 whole years, to introduce the new extended-release version, in order to extend its exclusivity in the U.S. market. Once introduced, Actavis used the patent system to hop patients, pushing all of its customers onto the new drug, while pulling the old drug from the market. As a result, it was able to continue charging monopoly prices long after its market exclusivity had run out.

This product hopping practice enables drug companies to stop generics, biosimilars, and other essentially innovations at lower prices, which is kind of the definition of abusing market power.

I want to ask Dr. Moodie, how are biosimilar alternatives hindered by the practice of product hopping?

Dr. MOODIE. Yes, that's very true. Product hopping is a tactic used by branded drug companies to shift market just before biosimilars come to market in order to thwart the competition. This tactic can also be used to increase the price. We feel like advertisements for the new presentations of these product-hops, they often minimize the risks and exaggerate the effectiveness, as well as including unsubstantiated claims of superiority over the biosimilars.

Product hops can be addressed by limiting the promotional material, including the direct-to-consumer advertising that would influence patients and providers to switch to the product hop, unless the product—unless the branded drug company has conducted a clinical trial that proves evidence of clinical superiority.

Another mechanism to address product hopping is to strengthen the Department of Justice and/or Federal Trades Commission's

ability to bring cases against branded drug companies who are engaging in product hopping.

Senator BLUMENTHAL. Thank you. I can tell you also, Senator Cornyn and I have introduced—actually, we’ve reintroduced the Affordable Prescriptions for Patients Act, which would put an end to this anticompetitive practice. It was approved unanimously in the last session of Congress, unanimously by the Judiciary Committee. It never received a vote on the floor, and I’m hoping that we’ll get bipartisan support to do it again.

It would also prohibit some other abusive practices, like patent thicketing, but product hopping, in a way, epitomizes the worst of the present system. I recognize the importance of patents in encouraging innovation. We can all talk about it fairly well, but when it’s abused, it actually impedes innovation and prevents it.

Mr. Mitchell, I’m hoping you, perhaps, can shed light on the human costs of this anticompetitive practice. How are patients affected by product hopping by branded pharmaceutical companies?

Mr. MITCHELL. When a drug is about to come off-patent, as Dr. Moodie just mentioned, and small changes are made that are incremental to try and move people to this new and more expensive drug, usually, they’re stuck in many cases. If it’s a hard switch, it’s a problem. Courts have begun to get that. If it’s a soft switch, sometimes they can be misled into thinking that, without evidence, this is better, a superior drug.

Sometimes the drug—brand drug companies actually disparage their old version of the drug, and so patients are often misled into taking the hopped product, the new product, when the old product would do just fine. Or, say they change the dose from 160 milligrams to 80 milligrams, or 80 milligrams twice a day to 160 milligrams and charge—once a day, and charge a lot more, when they could go on taking the other drug, and it would work just fine.

The fact is, the product hops reduce choice and kind of push people toward more expensive drugs that they don’t necessarily need.

Senator BLUMENTHAL. Thank you. My time has expired. This topic is a big and important one, and I thank all of you for helping us shed light on it. The American people, although they already know, in their pocketbooks and their hearts and, all too often, their bodies, how devastating it can be. Thanks, Senator.

Chair KLOBUCHAR. Thank you very much, Senator Blumenthal. Just to show how big and important this is, we’ve not only had the Chair of the Judiciary Committee at much of this hearing, but also the Ranking Member, who’s been such a leader on these issues, and so Senator Lee and I welcome Senator Grassley.

Senator GRASSLEY. I was going to open with some comments about you and I cooperating on a lot of legislation, but—

Chair KLOBUCHAR. You can go ahead.

[Laughter.]

Senator GRASSLEY [continuing]. I’ll just put those two pages in the record—

Chair KLOBUCHAR. Okay, excellent.

Senator GRASSLEY [continuing]. So I don’t take time for that.

[The information appears as a submission for the record.]

Senator GRASSLEY. I’d like to have the witnesses comment on the issue of pharmacy benefit managers, or PBMs and the possible neg-

ative effects their actions have on prescription drug prices for consumers. PBMs operate with little to no transparency, making it very difficult, if not impossible to understand the price of prescription drugs. Instead, we have a complex web of prices, rebates, and formularies that make it near impossible to understand drug prices.

This problem is made worse by consolidation and concentration within the PBM marketplace. Three companies control 75 percent of the market and are vertically integrated and owned by other players in the healthcare industry. This is a high level of concentration and control over a projected \$358 billion spent on prescription drugs in 2020.

Has there been too much concentration leading to very few companies with too much power, would be one of my questions. The second one would be, should PBMs be required to provide more transparency on how prescription drugs are priced? Anybody can take a crack at it on either side of the issue.

Mr. LEVITT. I'm happy to jump in there, Senator Grassley, if you don't mind.

Senator GRASSLEY. Please.

Mr. LEVITT. We completely agree with you that the current situation with respect to pharmacy benefit managers and the market power and negotiating power that they have, needs to be scrutinized very carefully.

What is often perceived as an increase in prescription drug costs on the part of patients is actually the result of the failure of these PBMs, who, as you said, control three-quarters of the market for prescription drug benefits, the failure of these PBMs to be transparent, or to share or pass through the rebates and discounts that are being negotiated between themselves and manufacturers to the patients at the point of prescription.

This is why, although when you look at net prices, that is the price of pharmaceuticals after rebates and discounts, those prices are stable or declining. But patients are perceiving an increase in costs, and that is because the costs are being shifted onto the patients. We believe that's a problem that really needs to be examined closely.

Senator GRASSLEY. Anybody to add to it, or anybody want to express an opposite position?

Mr. KADES. Senator, I don't know that I want to express an opposite position. I think there clearly has been substantial consolidation in the PBM market, and you would expect that that consolidation leads to market power that—

[Voice heard off microphone.]

Mr. KADES. Sorry about that—that that consolidation, if it leads to market power, you would see that in the PBMs taking a larger and larger share of the rebates. I think that's a really important question, and I think this Committee and those of you who have asked the agencies to focus on it are quite right.

I do want to say that one of the things that can be problematic in this debate is that various actors like to finger-point, and so we should be looking at all actors, but we should also remember that the rebates are a tool used by branded pharmaceutical companies to prevent generic entry, or to limit competition, which is some-



thing your Finance Committee report found—made a finding about on insulin.

Yes, let's look at PBMs, but let's make sure we look at all actors in this marketplace.

Mr. MITCHELL. Senator Grassley, if I may—

Senator GRASSLEY. Yes.

Mr. MITCHELL [continuing]. I think it is wrong that a patient like myself cannot know if the preferred drug on a formulary is there because it's the best drug for me, it's the least expensive drug among equally effective options, or if it's just there because the PBM got a big kickback, a legal kickback that we call a rebate.

We believe that there must be more transparency in the way the PBMs operate. We need to know how much of the rebate is going to lower my premium, lower my out-of-pocket, is going to the profit of the PBM and/or the insurer, and now, they're one and the same for the big three. So, we believe that transparency is key.

The headwaters of the problem of high drug prices is list prices set by drug companies, but these downstream anticompetitive practices by PBMs need to be addressed, and we need to make sure that they're working on behalf of patients.

Senator Lee mentioned maybe they should have a fiduciary responsibility to me. That would be just fine. Thank you.

Senator GRASSLEY. I want to go on to another issue. I'm concerned about the effect of so-called rebate traps, rebate walls on patients' access to quality low-cost medicine. These are practices where drug manufacturers bundle together rebates over multiple products so that if a payer decides to purchase or cover a competitor's alternative cheaper drug, they forfeit the rebates and discount on the entire bundle of a manufacturer's product.

For any of you that want to tackle this, do you believe that companies engage in—bundling rebates over multiple products can be harmful to patients' access to quality, lower-cost drugs? If you believe this kind of action is anticompetitive, what kind of action would you think would help address the issue? Then that will have to be my last question.

Mr. MITCHELL. I'll go again if you don't mind, Senator. I do believe that these things are hurting patients. I think it's very important to recognize, however, that these rebate traps and rebate walls are deals entered into voluntarily, to the benefit of both the drug maker and the PBM, but they are not increasing my choice or lowering my price.

That's why we need you to take a closer look, and to have the ability, through transparency, to examine how these deals are working, and how PBMs are doing their business, but always remembering that there is a mutuality there going on between the drug company and the PBM.

Mr. LEVITT. If I could, Senator. Sorry.

Senator GRASSLEY. Yes.

Mr. LEVITT. To answer your question directly, Senator Grassley, this—if a company uses its market power coercively in such a way as to exert anticompetitive effects and bar competitors from the market, then that is anticompetitive behavior, and it should be scrutinized.

You'll, however, have to realize at the same time, that not all exclusive contracts are necessarily anticompetitive. It really does depend on the terms and conditions, the duration, the market power of the parties. They can be used in such a way as to reduce prices in principle. But again, when they are used in a coercive and anticompetitive way, they're definitely wrong.

Senator GRASSLEY. I think one other person wanted to comment, and then I'll be done. Go ahead.

Mr. KADES. Yes. Senator, that's a great question, and it's absolutely true that dominant companies in this marketplace use rebate traps to forestall entry. That inures mostly, if not entirely, to the benefit of the dominant company. While, in theory, that action should be anticompetitive—illegal under the antitrust laws, we know it's pervasive, it's part of the reason why costs are high in insulin markets, it's why costs are high in the EpiPen market, it's why the drug Remicade, biosimilar competition has not developed.

Part of that reason is because when courts look at this, they're getting it wrong. They're defining markets too broadly. Or, as just recently happened, court looks at a case at summary judgment, before you go to trial, and says, yes, the plaintiff can prove the defendant is a monopolist. They can prove both parties expect a generic entry to take 30 percent of the market. The brand didn't lower price. The brand didn't improve its product, and yet the entry was an absolute failure, and the court says, "Oh, but the rebate increased, so there can't be an antitrust problem."

That's why, when you have laws that are so deferential to dominant firm conduct, then you get this kind of activity that we are all paying for.

Chair KLOBUCHAR. Very good. Thank you. I just thought I would ask each of you the same question, if you could just keep it to 30 seconds. It pertains to the fact that U.S. prescription drug prices are the highest in the world. It's been estimated that our drugs here cost between 4 and 2.5 times more in the United States than they do in other developed countries.

We can argue about what the right number is, but it is clear we are paying far too much, and it's not getting better. According to one study, prescription drug costs in the U.S. rose 76 percent between 2000 and 2017. We are the largest drug market, with so many of the companies located here. And we are grateful for the work that was done to develop the vaccine, but yet, we continue to pay these high prices, so I just want this 30-second answer.

Why are U.S. drug costs so much higher than they are anywhere else in the world, when it's so much of our research money that went into this, and does a lack of competition play a role? Mr. Kades.

Mr. KADES. Thank you, Senator. Yes, competition, absolutely—the lack of competition plays a significant role, but there are other causes which might be addressed by your bill to improve negotiations allowing Medicare to negotiate under Part D or other payment processes that could help control drug prices. The patent system reform would also help. Sorry.

Chair KLOBUCHAR. Thank you. Mr. Abbott.

Mr. ABBOTT. Yes, Senator, prices are high, but there are also institutional factors. For example, a 2018 HHS report indicated that

the expansion of rebates that was actually facilitated, supported by the ACA in some areas, may have actually contributed to the raising of list prices.

But also, recall pharmaceutical companies have to cover the 90 percent plus of efforts that fail to bring forth a new drug. A heart of those efforts are in the United States. We, in effect, are cross-subsidizing other parts of the world as mentioned to Senator Lee.

Chair KLOBUCHAR. Mr. Levitt.

Mr. LEVITT. Senator Klobuchar, other developed countries tend to have very different healthcare systems, with a much greater degree of government involvement and price control than, I think, Americans would be willing to tolerate, and they pay for that degree of government control with less access, less innovation for patients.

Yes, we do spend somewhat more on prescription drugs in this country. We can debate the exact number. Our figures would be lower than yours, but yes, but we also spend more on all aspects of healthcare in this country. I saw a study recently, administrative costs in our healthcare system are 4 times what they are in Canada, so we have to put this in context. Prescription drug costs have remained flat, at around 15 percent of the overall healthcare expenditure in this country, for the past several years.

Chair KLOBUCHAR. All right. I have some responses, but I'm going to keep going down the line. Next, Dr. Moodie.

Dr. MOODIE. We're seeing biosimilars hit foreign markets years before they hit the U.S. That trend is going to continue and get worse because with patent thickets that we're seeing growing up around the newer biological drugs are growing so much faster and bigger than the famous thickets that people are talking about today. The branded drug companies are getting better at this gaming of the numbers game of patent thickets. Just getting biosimilars to the market at a more appropriate time is the best way to bring down those prices, and then you don't need reference pricing, either.

Chair KLOBUCHAR. Okay. Mr. Mitchell.

Mr. MITCHELL. Thank you, Senator. We're paying almost 4 times what other wealthy nations pay for the exact same brand drugs. We—no other country allows brand drug makers to dictate the prices of drugs as we do in this country, and that's why our prices are so high. They negotiate, we don't, and the outcome is prices that range as high as everyone here knows.

Chair KLOBUCHAR. Okay. Thank you. We turn to solutions here. Mr. Kades, in your written testimony, you compared the competition problems in prescription drug markets to the canary in the coal mine for the failure of U.S. competition law. Are you saying these problems in our drug market should have been an early warning sign? Then, I think most importantly, do you think broad-based reforms, as we look at these markets that we've looked at in this Committee, yes, tech and there can be some specific tech laws. What we're going to be doing next month on the agriculture markets and something Senator Grassley's very interested in, as well as what we've seen from online travel on.

Do you think a broad-based support—this is called a softball, leading question—would be most helpful?

Mr. KADES. Absolutely I do, Senator. You talked about the *Ovation* case. All right, and it's a perfect example of where antitrust has gone off the rails. It should be very easy to figure out. If there are only two products that can treat a disease, that—they're in the same market. They have to be, and getting rid of that competition has to be bad. Somehow, the court got that wrong.

Time and again, the Government is spending massive resources, proving essentially what is obvious, and proving—and essentially having to prove water makes things wet.

And so, when we look at the antitrust enforcement in pharmaceutical industries, my good friend, Mr. Abbott says, it's a sign that things are working. But we need to look at what is the conduct that is occurring? And this conduct is so egregious. We've heard about it today. Literally companies bringing products to market where they put a tablet inside a capsule just to prevent generic competition. It's not innovation. The fact that the system allows that tells us the antitrust laws are too weak.

Chair KLOBUCHAR. You would suggest a broad-based support, as well as doing some of these specific things, like pay-for-delay and some of the other things we've been talking about with rebates, patent thickets—the best words that we will all take away from this hearing. Dr. Moodie, thank you. So that's—

Mr. KADES. Yes, I think it is a combined approach.

Chair KLOBUCHAR. I think you also are concerned about the loss of disgorgement and restitution authority at the FTC, is that right?

Mr. KADES. Yes.

Chair KLOBUCHAR. You think that needs to be fixed?

Mr. KADES. Absolutely. Just a very quick example. Back when I was a young attorney and had more hair, the FTC brought a case against a generic company for cornering the market and had claimed \$100 million in disgorgement. That was roughly 80 percent of what the company made by violating the law. As a result of that decision, a strong signal and a strong deterrent, that type of conduct disappeared from the marketplace for the next 40 years.

Taking away that the—the Commission's ability to deprive people of the illegal profits just says, go ahead and violate the antitrust laws because the Federal enforcers, the most they can do is tell you to go forth and sin no more.

Chair KLOBUCHAR. Mr. Levitt, in your testimony, you wrote that for both generics and biosimilars, our laws are intended to, quote, “strike a balance between providing access to medicines and preserving incentives for innovation.” But we are not seeing that balance when it comes, as Dr. Moodie has pointed out. What we are seeing is these deep patent thickets with sometimes more than 100 patents, as she pointed out, filed for a single drug, many of which are filed after the drugs are approved.

Aren't these practices throwing off what you call the delicate balance between patient access and development incentives? I know there have been a lot of questions about the thickets, but I'm getting to that. That will be my last one. I'll ask you, Dr. Moodie for a quick response.

Mr. LEVITT. Thank you, Senator Klobuchar. To begin with, again, as I said earlier, product innovation does not stop upon approval of a product. Particularly with complex products like biologics,

there can be many different kinds of inventions that can take place after approval that can improve the profile of the product in ways that matter to patients: to make it easier to administer, to extend the shelf life or improve the stability, and many, many other characteristics.

Each of these potentially qualifies for a patent, and patents, contrary to what some have said, are not so easy to get. You have to, as I said earlier, show the requisite requirements to get a patent in the first place. Once you get the patent, it is absolutely subject to challenge through either the inter partes review process, or in court, or the PGR process.

In a way, one could take the figure cited by Dr. Moodie that 56 percent of the IPRs succeed as evidence that that process works, that if a patent is weak and it's subject to challenge, then it's going to go down. I can assure you that innovator companies are not in the business of getting weak patents so that they can be struck down. They're getting patents for innovations that improve the product.

We—am I?

Chair KLOBUCHAR. Yes. One more sentence here.

Mr. LEVITT. Okay. I just wanted to say we don't oppose properly targeted legislation on product hopping, and I'm happy to discuss, you know, the specifics of that with the Committee.

Chair KLOBUCHAR. Okay. Dr. Moodie, quickly. We have two Senators here that have been waiting for a while. So—

Dr. MOODIE. Sure. Due to the numbers gaming of the patent system, we can't economically use IPRs and PGRs to clear a path through hundreds of patents. It would be—the system would work better if you would get one patent per secondary or follow-on invention, but now they're creating these families of patents around each invention, to circumvent and shield the patents just through economic means.

Chair KLOBUCHAR. Okay. Very good. Thank you. I don't know who's next, Senator Hawley or Cotton. I'm not going to decide between them. Senator Lee—

Senator LEE. It's your call.

Chair KLOBUCHAR [continuing]. No, you decide, it's your—who is—was Senator Hawley here—are you—what are your rules here?

Senator LEE. Josh was here first, but then left, and Tom came, so—

Chair KLOBUCHAR. Okay, you go for it. Okay. Senator Cotton.

Senator COTTON. Thank you. Thank you all for appearing today. We've heard a lot about patent rights and anticompetitive drug company actions that harm consumers, and I share my concerns on that front.

But I also want to discuss a concern I have about a Biden administration decision that will also jeopardize our ability to deal with any pandemics in the future.

In May, the Biden administration announced its support for a waiver of intellectual property rights at the World Trade Organization. This waiver would mean that American companies that develop lifesaving vaccines and treatments to address the pandemic will lose that intellectual property, and the property will be turned over to the rest of the world, including adversaries like China.

Now waiver may be the technical term for what the Biden administration has decided. A more accurate description would be confiscation. The American companies that spent billions of dollars developing this technology don't exactly have a choice to participate in a waiver of their property rights, of course. We are used to countries like Russia, and China, and Cuba expropriating the property of not only their own citizens, but Americans, as well. But it is unprecedented for an American administration to help our adversaries steal such intellectual property.

I won't put aside the question of whether this is morally right or wrong, because it is clearly wrong to steal the property of an American company and its American shareholders. It is also an incredibly dangerous precedent to set.

However, I want to focus more directly on the practical implications of the Biden administration's decision to steal the property of American companies.

Mr. Levitt, if the Biden administration succeeds in pushing through this expropriation of American companies' property, will this increase the production of vaccines worldwide?

Mr. LEVITT. Thank you, Senator Cotton. The short answer is no. Biopharmaceutical companies share the goal of vaccinating as many people as possible as quickly as possible around the world. But punitive transfers of patents will not help increase production capacity, nor will they accelerate access to COVID-19 vaccines, and, in fact, they also risk putting production in the hands of parties who lack the technical and quality know-how to accomplish this.

The concern that apparently lies behind this move, this unfortunate move of transferring patent rights—patent rights and seizing patent rights is misdirected. If there are any issues about getting product and vaccine out, it's in the supply chain, not in the IP rights that, as you said, have enabled companies to develop these vaccines in an incredibly short amount of time.

Senator COTTON. This supply chain and manufacturing process for the coronavirus vaccines is incredibly complicated, is that correct?

Mr. LEVITT. It absolutely is, Senator.

Senator COTTON. It depends on very customized equipment, as well as highly specialized knowledge, is that correct?

Mr. LEVITT. Vaccine production is among the most complicated manufacturing processes in the world. There are many, many dozens of separate steps, each of which has to be very carefully controlled and under stringent quality requirements. It's absolutely correct.

Senator COTTON. It is not, in fact, the patent rights that these companies have that is the bottleneck for vaccine production around the world, but rather the supply chain and the manufacturing process itself?

Mr. LEVITT. Absolutely correct, in our view. Yes, Senator.

Senator COTTON. If that is the case, who will benefit from this so-called waiver, or what you might better call an expropriation, of American companies' property?

Mr. LEVITT. In our view, it certainly won't be patients. In fact, if anyone, as you said, it's going to be the foreign economic competi-

tors who really don't play by the rules in the first place, and that's very unfortunate.

Senator COTTON. To put names to those competitors, would most of them, or at least many of them be located in China?

Mr. LEVITT. It has been said that that is one of the countries that is in that category, yes, Senator.

Senator COTTON. Mr. Levitt, these technical terms, like a TRIPS waiver, or WTO protections are not exactly things that roll off the tongues of most Arkansans when I visit with them. Can you explain why it matters to them? Why it matters to all Americans that we protect the intellectual property rights of companies to include the patent rights of these vaccine manufacturers?

Mr. LEVITT. Senator, it matters because taking this kind of drastic action to seize intellectual property and violate intellectual property rights is going to endanger future production and innovation by creating confusion and uncertainty among vaccine manufacturers at a time when they are working around the clock to bring needed vaccines to patients.

In short, the damage will be less access to needed medicines, and economic harm, as well, to a vibrant industry that provides high-quality jobs for hundreds of thousands of Americans.

Senator COTTON. All in return for which we don't get any acceleration in the effective production of coronavirus vaccines, is that correct?

Mr. LEVITT. Precisely.

Senator COTTON. Thank you.

Chair KLOBUCHAR. Senator Hawley.

Senator HAWLEY. Thank you, Madam Chair, and thanks to all the witnesses for being here. I want to come back, if I could, to the question of these pharmacy benefit managers and some of the techniques, mechanisms that they use that are causing so much pain to independent pharmacists in particular.

Mr. Kades, if I could just come to you. I know this has been a subject of much discussion throughout today's hearing, but I want to ask you about something I don't think has come up, and that is DIR fees. Could I ask you about the DIR fees that PBMs apply, often retroactively, and ask you to comment on why we wouldn't want to limit the ability of PBMs to apply these fees retroactively?

In other words should—let me state that in the affirmative rather than the sort of double negative there. Shouldn't we limit the ability of PBMs to apply these fees retroactively?

Mr. KADES. In a moment of being humble, I'm going to say that's actually not an issue I'm aware of, and so I don't think I could provide you an answer that would be useful.

Senator HAWLEY. Does anybody else have a view on this down the panel?

Mr. LEVITT. Senator, my apologies, but if you could define the DIR, please. I'm so sorry, I don't recognize that term.

Senator HAWLEY. A DIR—it's a direct or indirect remuneration fee—

[Audio malfunction occurs.]

Senator HAWLEY [continuing]. that is charged, often levied by PBMs as part of the Medicare Part D program. This is something that independent pharmacists are very, very concerned about, cer-

tainly in my State. Many of them look to these DIR fees as a prime driver in their own, frankly, insolvency.

As I talk to pharmacists around the State of Missouri, and we have a long tradition in my State of having a lot of independent pharmacists, this practice—PBMs in general, as you may imagine, they're not fans of, but the practice of DIR fees is something that is particularly, particularly harmful in their view. Their view, and I have to say I tend to agree with them, is that the application of DIR fees retroactively is particularly harmful, it's nontransparent, and it's often devastating to independent pharmacies.

If anybody has a comment on that, I'll gladly take it. Otherwise, I want to ask—

Chair KLOBUCHAR. We can also ask them to—if a few of the witnesses want to put it in writing after they have a chance—okay?

Senator HAWLEY. That would be great. That would be great. We'll give it to you as a QFR. Yes, thank for that, Madam Chair. That's a good suggestion.

Senator HAWLEY. Mr. Levitt, let me just change subject and ask you about your client trade groups' view about what is—

Senator BLACKBURN. Make sure they know I'm on virtually.

Senator HAWLEY [continuing]. What is a reasonable time to profit from a single drug before a generic version can hit the market. Do you have a sense of what that time period, what a reasonable time period should look like?

Mr. LEVITT. Yes, Senator, so I think we can take as a starting point the term of a patent, which, as you know, is 20 years from the date of application. Of course, we also know that a considerable amount of that patent life is consumed in the development and approval process, which is subject to some extension under the Hatch-Waxman law, but certainly not what makes up for the entire time of that process.

At the end of the day, many, many estimates have stated that the effective patent life of a pharmaceutical product on the market averages around 12 to 13 years. That is the figure that pharmaceutical manufacturers take into account in calculating their exclusivity in order to get the return on the pharmaceutical product that will enable them to make a reasonable profit and continue to invest in innovation.

Senator HAWLEY. Does that number take into account the filing of the child patents, or the patents that don't deal with drug structure, such as dosing combination treatments?

Mr. LEVITT. Right. Yes, it does, and I do have to point out one clarification here, which is that these continuation patents, as I understand it, do not extend patent life. They may broaden the scope of an originally granted patent in ways that are presumably justified by the inventions that they cover, but they don't extend the life of a patent, and so I would say that this is factored in to the 12- to 13-year estimate. It's sort of an aggregate global estimate that factors in all of the different inputs into the exclusivity life of a product on the market.

[Audio resumes.]

Senator HAWLEY. That's helpful. Here is where I'm going with this. If we can agree that the life of a patent should be limited, and 12 to 13 years, you've pointed out, but if in principle, as a matter



of policy, we can agree on that, I'm trying to figure out why it is that some of the member companies in the organization you represent have gone to such great lengths to stretch things out in a way that seems almost indefinite. Can you help me with that?

Mr. LEVITT. Senator, I guess I would respectfully take issue with the characterization of stretching out. As I've said before, innovations continue after the approval of a product, and those innovations can come in many, many different areas. I won't take up more of the Committee's time. I've already listed a number of examples, which can be then subject to patenting. If those innovations are truly beneficial to patients, they will get out onto the market and they will have uptake in the market. If they're not, then they won't.

Senator HAWLEY. Let me ask you something about to—to comment on something that former FDA Commissioner Scott Gottlieb said a few years ago, that patent thickets are purely designed to deter the entry of approved biosimilars. His view was that there's no real business need here. It's about profits.

My question would be, if your clients aren't trying to behave in an anticompetitive way, then why aren't all the relevant patent applications for a particular drug filed at once? Up front, so to speak, when the product first comes to market, as opposed to staggered over time in a way, again, that tends to lengthen and lengthen and lengthen the protections?

Mr. LEVITT. Senator, that is because as the manufacturer gains further experience with the product and continues to examine the product for ways that it can be improved upon, that's a process that naturally takes place over time. When you get the initial approval of a product is when it is ready for approval on the basis of safety and efficacy. That doesn't mean the product is perfected at that time, or that it cannot be improved upon in a whole variety of ways that can be beneficial to patient care, to the quality of the product, and to other important attributes.

It's naturally a process that takes place over time, as providers and manufacturers gain more experience with the product and continue to perform scientific research on the characteristics of the product. That doesn't—it just doesn't happen all at once. It's not the way science works.

Senator HAWLEY. I'll leave it at that. My time is nearly expired. I just want to point out that I think that there is agreement that I'm sensing here, at least on this side of the dais, that we've got to do something about the ability of the manipulation of the patent system in order to prevent biosimilars from coming to market in a way that's really harmful to consumers. Thank you, Madam Chair.

Chair KLOBUCHAR. I think you'll see, Senator Hawley, there was a lot of discussion on this side of the aisle, as well, about the patent thicket issues, and the concern, which was one of the reasons we agreed to have Dr. Moodie here as a witness. We thought it was important to hear that perspective. Senator Blackburn, you're next. Thank you.

Senator BLACKBURN. Thank you, Madam Chairman. I really appreciate the hearing on this, and I thank all of you for being here today. I think that it is going to be important that we look at the

entire prescription drug chain when we're talking about possible anticompetitive behavior.

The middlemen, the pharmacy benefit managers, as we have talked about more than once today, control nearly 4 out of 5 prescriptions written in the U.S. That is astounding. This is a vast, a vast arena of influence that they have over issues that end up being life and death issues. Especially concerning to me is the fact that they are controlling the access to so many of these pharmaceuticals. Mr. Mitchell, as you mentioned in your comments, this is something that is really opaque. There is a need for transparency.

In addition to this, these healthcare middlemen have undergone vertical transformation that combine the PBM with insurers, specialty pharmacies, and healthcare providers. Vertical integration can result in increased inefficiencies and consumer benefits. However, such integration can also lead to higher barriers for competition in each individual market.

Onerous audits, clawback provisions, and patient steering are anticompetitive behaviors by the PBMs, and as some of you have referenced today, you know that that is taking place. They have caused small pharmacy business owners to struggle to survive.

In recent years, 40 States, including my home State of Tennessee, have enacted legislation to actually curb some of these PBM practices. States have also taken action against the spread pricing activities of PBMs, which have cost taxpayers hundreds of millions in the Medicaid program.

I do believe it's time for Congress to understand the impact of potentially anticompetitive PBM practices on patients, small pharmacy businesses, and taxpayers. Senator Braun and I have introduced S. 298, the Pharmacy Benefit Manager Accountability Act. I do encourage all of my colleagues on supporting this legislation. Madam Chair, I have a letter for the record, which is a statement from the National Community Pharmacists Association that I'd like to submit.

[The information appears as a submission for the record.]

Chair KLOBUCHAR. It will be entered in.

Senator BLACKBURN. Thank you. Mr. Levitt, if I could come to you, please. I know that Senator Grassley talked a little bit about the Senate Finance report on insulin, and you all had an exchange on that.

Let's look at the incentives in the pharmaceutical supply chain, and let me ask you how you think these incentives are aligned. If they are there to drive costs lower and out-of-pocket costs lower, which by—that is one of the things that I hear from so many individuals. They never see the discount that is there, and there is a lack of appropriate alignment in actually lowering the cost of out-of-pocket expenses. I know Mr. Mitchell had referenced this earlier, also.

If you would, for the record, talk a little bit about that alignment.

Mr. LEVITT. Thank you, Senator. Yes, in our view, that is one of the fundamental problems in the entire drug pricing system today is that the incentives are misaligned, and that savings that may exist upfront in the system between the manufacturers and the

pharmacy benefit managers, in the form of rebates or discounts, there's no incentive to pass those on to consumers.

What we've seen is a growing trend for other entities in the healthcare system, other than manufacturers and consumers, to basically realize those savings for themselves, so that, today, manufacturers, for example, only get a little bit over half of the actual cost of the drugs that they're providing. The rest is going to a variety of stakeholders, including PBMs, Government entities, payers, and others.

But the patients, the problem is, as you pointed out, is that the patients are not seeing those savings at the pharmacy counter. We really believe that that is an issue that needs urgent attention.

Senator BLACKBURN. When we're talking to Tennesseans, that is one of the things that comes up most often. If it is a cardiovascular disease, and they have a certain pharmaceutical or certain cancers, what they have to actually stay alive, what they need every month, and the cost for that and that discount not going to the customers, so I appreciate that.

Mr. Kades, I want to come to you, if I may. Commissioner Chopra from the FTC recently made a statement that I thought was significant. The FTC largely stood by as the PBM industry consolidated to three main giants, and even took steps to undermine State legislation. This would indicate that there is an intentionality to what the PBMs have done, as you now have the three main ones, as I said earlier.

They are there at the juggernaut, if you will, for four out of every five prescriptions that are being made in this country. Can the FTC or should the FTC do more to evaluate the anticompetitive behavior of the PBMs, or should this be given to someone else?

Mr. KADES. Thank you, Senator. The FTC absolutely should be looking at PBMs and considering whether there is anticompetitive conduct and bringing cases where they can. I do think it's important to remember that at the time those—that consolidation occurred, when we look at where merger law is, where the case that Senator Klobuchar talked about, which was a merger monopoly and the Court said, not a problem. We look at other mergers that the Government is losing, it's not at all clear that FTC trying to stop those consolidation, based on what was before them, would have been successful, given how lenient the merger laws have become.

That's not an excuse for them not to try or to look at it now, but I think it's important to understand that part of the problems we're seeing, whether it be PBMs or with branded companies gaming the system is directly related to how we have abandoned antitrust law as a true regulator and promoter of competition.

Senator BLACKBURN. Hindsight is always 20/20, correct? Let me ask each of you this, and I'll ask just for a show of hands. How many of you think that PBMs should be eliminated from the marketplace? There is no one who would eliminate them.

How many of you think that PBMs should be reformed, and that their power should be diminished? Okay, we've got one hand that is there. All right, thank you, Madam Chairman.

Chair KLOBUCHAR. Okay, very good. Thank you. A few things. I misunderstood Senator Hawley when he said on this side of the

dais, we have support for doing something about patent thickets. He meant on this side, like all of us together, as opposed to on the party side. I really appreciate that bipartisan moment, and so that's good.

Then, I thought I'd start out just with something clarifying something that Senator Cotton was asking about. Just a little bit of a different perspective.

Mr. MITCHELL, there is a different look at why President Biden was interested in sharing vaccines with other countries in this pandemic like we have never seen, with very difficult vaccines to develop. Could you talk about how from a public health perspective, not to mention a humanitarian perspective, it's beneficial to America to get other people vaccinated in other countries as soon as possible?

Mr. MITCHELL. I'll say for Patients for Affordable Drugs, we don't have a position on international issues like the TRIPS waiver, but I can speak for myself. A pandemic, by definition, is global, and until we defeat the pandemic globally, we are all going to continue to be at risk from emerging variants like the Delta variant that has popped up and is now killing people disproportionately in this country who haven't been vaccinated, for example.

That didn't come from here, it came from elsewhere. From a public health perspective and trying to look after ourselves in America, but also to be good citizens of the world, making sure people can get vaccines all over the globe is in our best interest, both as people who want to have good health, but also be good citizens.

Chair KLOBUCHAR. Okay. Mr. Kades, are you aware of what happened—I don't know what happened, when President Biden made this announcement, to the stock ratings of the pharmaceutical companies. Did they plummet when this went out there?

Mr. KADES. My understanding, although not an expert in the stock market, that they did not take a substantial hit.

Chair KLOBUCHAR. Okay. All right. Sham FDA petitions. There was a moment of asking questions you didn't know the answer to, but I figured you would have some impression of it.

Mr. Kades, the practice of filing sham petitions risks delaying the approval of generic drugs and biosimilars and imposes unnecessary burdens on limited FDA resources. Senator Grassley and I introduced a bill, the Stop Stalling Act, to give the FTC enhanced authority to crack down on abuses of this process, while allowing petitions submitted in good faith to raise legitimate health and safety concerns. Can you elaborate on the harms to patients and competition caused by the filing of sham FDA petitions?

Mr. KADES. Yes, and it's a tragic story, right? The Government comes up with this idea that when the FDA makes decisions, average citizens and people involved should be able to petition the FTC—I mean, I'm sorry, the FDA and so this improves participation. Nobody in their wildest dreams thought that virtually all the citizens' petitions dealing with generic approvals would be filed by their competitors and the branded companies saying, "Oh, no, this generic product, you know, either you have to put special restrictions on it, or don't approve it, or require more testing."

Even if the petition isn't successful, it can take the time—the FDA has to look at it, has to review it, and even though they're

supposed to decide within 180 days, they have a million things to do.

Simply by using, in ways similar to the CREATES Act, the problem the CREATES Act addressed, using the process of the FDA, a process that was supposed to improve participation, branded companies can delay competition and force all of us to pay more for drug costs without any innovation, without any additional advantage.

I think legislation here to correct that problem would be excellent. I would note that Congress has already tried to fix it once. The branded industry found ways to nullify that, and so I think Congress should take another crack at it.

Chair KLOBUCHAR. Okay. Mr. Abbott, you talked about in your written testimony, is that the need for greater resources for enforcers, these are your words, “is particularly acute with regard to pharmaceutical enforcement given the great economic significance and complexity of pharmaceutical market issues.” We don’t agree on everything in this hearing, but, given that you see this acute need, would you recommend that we get some additional resources for enforcement of the laws to the Agencies?

Mr. ABBOTT. Thank you for that question, Senator. Yes.

Chair KLOBUCHAR. Very good. Thank you, and you know, we have this bill that Senator Grassley and I did, that actually has passed the Senate now, to change the merger fee statute that would add over \$100 million to the two Agencies, and we haven’t gotten a lot of objections to it because including the Trump administration did support this when we tried to get it done at the end of the year, so. All right. Thank you.

Mr. MITCHELL, our Medicare program is limited by law in its ability to negotiate drug prices. Removing the noninterference clause—you, I think, mentioned this—so we can allow 43 million patients on Medicare Part D to lower the cost of their medication would be a critical way. I think it would help everyone, not just the seniors who benefit from this.

Do you think that removing the noninterference clause is a good idea, and what additional reforms do you think would be required for Medicare to get better price terms for the enormous quantity of drugs that it purchases?

Mr. MITCHELL. Yes, we believe the noninterference clause should never have been inserted in 2003, and that it needs to be removed. It needs to be removed not only for Part D drugs, but for Part B drugs, as well. You know, the specialty drugs, many of which are Part B drugs, account for 0.4 percent of all prescriptions, but 46 percent of all spending on drugs in this country.

We would love to see the noninterference clause eliminated, negotiations extended to D and B, and the prices negotiated by Medicare extended to the private sector to help employers who provide healthcare for 156 million Americans.

Chair KLOBUCHAR. Very good. Thank you. Just a few last questions here. It has been a long hearing. Mr. Kades, as we look to merger, I mean, there’s a lot of predictions, and we’re seeing them now. We’re seeing this merger bonanza, not just in pharma, across the way. What can the FTC do to better police pharmaceutical mergers under current law? Another softball. Would reforming the

laws, as suggested in my bill, would that enable the Agencies to do more to police anticompetitive mergers—changing the burden for big mergers, other ideas that we have out there?

Mr. KADES. Yes. Merger enforcement is going to be critical for the Agencies. I think it's fair to say that they need to be more risk-seeking, but under the current standards, the law is too lenient.

I absolutely agree that it's time for Congress to reset that balance. Because what we see now is that the average litigated merger case, it's not a complicated case, but it still goes to trial. The Government has to go—even when it wins, has to prove that a merger monopoly is problematic.

I think ideas of adopting new presumptions makes sense, and we have 20 years of economic research that actually identifies better situations where mergers are likely to be harmful. That should be incorporated into the law.

I think changing the standard to make it clear that potential competition matters, and rejiggering the balance between competition and consolidation, and finally, obviously, just giving the Agencies more resources.

Chair KLOBUCHAR. Okay. Last thing, because it's good to end with something Senator Lee and I have been working on together. Way back, Senator Collins and I worked on, when there were drug shortages, and there still are, obviously, from time to time, using that as a reason to bring in drugs from other countries when they didn't have kids' cancer drugs and things like that, which was actually happening.

This is looking at it a different way, of allowing the Secretary of Health and Human Services to respond when sellers of older off-patent drugs are in a position to drastically raise prices due to a lack of competition. We would put together the Short on Competition Act, along with Senator Durbin and Grassley, to address the problem by allowing temporary importation of the same product from other countries that have strong drug safety standards. Then, of course, Senator Grassley and I have a more permanent bill.

Would allowing the safe importation of drugs inject some competition into our system because maybe, you know, I think our argument here is if you do have the competition, or you have the lower prices, then you wouldn't have to go to this. But if you don't, why not allow some competition from safe countries?

Mr. KADES. Particularly from safe countries, I think that's an excellent idea and would improve competition. What we find particularly in older—

Chair KLOBUCHAR. Do you think maybe even if it was just out there as a threat that that might keep some prices down sometimes? You know, the *Ovation* case? Other things?

Mr. KADES. It very well could. But one of the problems on older drugs is to get approval, a company—they tend to be smaller markets, and a company has to go through 18 months, spend money for that, and so when the price went sky high with Daraprim, there were all sorts of products on the market in Europe that had been on the market for 20 years. Let's find a way to inject that competition back into the United States, and maybe you're right, the price increase wouldn't have happened, or it wouldn't have lasted as long.

Chair KLOBUCHAR. Okay. Senator Lee.

Senator LEE. Mr. Kades, there's a bill called the TEAM Act that I introduced along with Senator Grassley, and one of its provisions would require courts to find that conduct is anticompetitive where there is direct evidence of clear intent to harm competition. In your view, would this make it easier for antitrust enforcers to stop anticompetitive conduct in the pharmaceutical industry?

Mr. KADES. Yes, I think it would help improve antitrust enforcement. The number of times when I was litigating, where I felt like it was a triangle litigation, was the FTC versus what the company said in its documents versus what they were saying on the stand, you know, you would think fact finders would say the stuff you put in your documents that said, we were doing this to harm competition matters, but you know, they see the person on the stand and they're like, "Okay, well, I guess I don't believe that, so." You know, I do think it would help.

I would say that you know, one thing to think about is once you make that law, companies will be more careful about what they put in their documents, but that's just a minor comment. I—

Senator LEE. Right. Yes, and that's our hope and our intent, and certainly our expectation is that that would help, as would the fact that it roughly doubles the total amount that we would spend on the enforcement of our antitrust laws.

In your written testimony, you allude to the way that courts have come to treat economic evidence in antitrust cases. One of the provisions of the TEAM Act would limit the ability of courts to give credit to defendants for justifications that are speculative, out of market, or that don't benefit consumers. Would this help some of those same problems based in protecting competition in healthcare markets?

Mr. KADE. Absolutely. It's sort of the same dynamic as your last question. Once you get to litigation, magically, companies have all sorts of justifications that aren't in the record.

Senator LEE. Right.

Mr. KADE. And so tightening up those requirements would be very helpful.

Senator LEE. Thank you. Mr. Abbott, as I alluded in my opening remarks, I have reason to be concerned about the cost and availability of insulin. I was excited to see recently that Walmart has broken into the insulin market and has launched two new low-cost products. What can you tell me about why it's taken so long for this kind of disruption to occur, and why haven't we seen this kind of innovation from a traditional pharmaceutical company?

Mr. ABBOTT. I'm not an expert, Senator, on the traditional pharmaceutical companies, but I will notice that it's interesting that discount retailers, and Walmart, obviously, is a prime example, have been very important figures in healthcare. In fact, there was some recent study that Medicare Part D, that some costs for generic, some Medicare Part D bargaining was actually higher than the prices negotiated by Walmart, so this suggests, again, that perhaps there should have been more companies doing this.

The private sector is very good at bargaining, and if you lift regulatory barriers to the ability of companies to enter into these markets, that's all to the good.

I think one of the big problems here is all the discussion with the PBMs and of other big actors is you have so many large, entrenched actors, and regulatory structure, and I don't have an exact answer here, but it may be that regulatory structure made a lot of large companies reluctant to enter. But that's my thought.

Senator LEE. Yes. Dr. Moodie, what I was talking to Mr. Abbott about relates, in many ways, to restrictions on entry. Anytime you have a viable market, in order to have actual competition, you sort of need to have the ability of new entrants to enter a marketplace. So, I'm always worried about restrictions on entry that make it more difficult for people to enter into a marketplace.

Many times, we see drug manufacturers imposing really high prices just, well, because they can. I mean, that is sometimes what will happen if someone has the ability to do that without facing competition. In a normal market, this would prompt entry into the marketplace by a would-be competitor, and thus spawn competition. Competition would, in turn, bring about corrections in price. It certainly wouldn't reward someone for continuing to escalate the price of their own product. It would end up punishing them.

But in the drug space, entry can take many years, and can cost millions or tens of millions, or hundreds of millions, or billions of dollars of investment to break into it. What do you think we could do to make it easier so that patients benefit from competitive markets? Is there anything we can do to limit the effect of restrictions on entry?

Dr. MOODIE. Sure. I mean, there has been a lot of talk about price controls. We don't think that's the solution. The solution is more competition. Of course, it does take you know, up to 10 years to develop a biosimilar. It takes a long time. By the time those biosimilars are ready to launch, we're then seeing the thickets that I described earlier, which contain large families of patents around the same inventions.

What we should also do is preserve pro-competitive settlements. It's important that we don't assume that all patent settlements are anticompetitive, because pro-competitive settlements, which are those settlements that do not include pay-for-delay, those settlements are one of the few tools that we have to address a patent thicket as a whole because, as I mentioned before, it's not economically possible to litigate scores and hundreds of patents.

Those pro-competitive settlements act as a compromise that strike a right balance. Because we can't litigate so many patents, if we were to not have any settlements, you would often see the biosimilars coming to market much later at the end of the expiry of the last patents in the thicket, including the lower quality ones, which are shielded from scrutiny.

And so, a pro-competitive settlement brings the launch date earlier as a kind of a compromise of, yes, the overall settlements. It strikes that right balance of bringing the products to market earlier. We just have to be careful that any legislative proposals of course have to target those anticompetitive settlements, but carve out the pro-competitive settlements, as well.

Senator LEE. Yes, that's a fair point. I mean, if we were to discourage or even prohibit settlements generally in this area, one can imagine ways in which that could harm consumers. It would harm



basically everyone except perhaps lawyers, who could benefit from the ability to generate revenues to fund indefinite generations of their posterity in their private college tuition expenses.

But other than lawyers, it probably would benefit no one and hurt everyone. Thank you.

Chair KLOBUCHAR. Thank you very much, Senator Lee. Thank you to our witnesses. It has been a long hearing, and I think a good one. I was talking to some reporters yesterday about this, and I think that they said, "But we've heard these hearings before, and is anything actually going to happen?" I came out of this more hopeful than I was before. I think you have a number of Senators very interested in your patent thicket issue, Dr. Moodie.

I think that there has been long-term interest in funding the Agencies, even from our conservative witness here, in making sure that we have ample enforcement authority and we have, I should say, ample resources to do the work, and I think there also are some things that we can do specific to the pharmaceutical issues, as we talked about product hopping and the pay-for-delay and the sham petitions, all of which are of bipartisan interest.

But then, I also think that there are some bigger things that we need to do if we really want to get this done. Some in the pharma area with negotiation of prices, Mr. Mitchell, but then also, as Mr. Kades has so well pointed out, beyond pharma, to look at our anti-trust bills as laws, as we have done so often in this country's history, where we see a problem and we adjust, and we make some changes to them so that they can be actually used in an effective way.

I think we know that somehow the pendulum has swung too far one way, and that's part of why we've been having these tech issues, and other things because we just don't have the tools to match the sophistication of our economy. When that has happened in the past, actually people who sat in these chairs—well, maybe not right in this room. It probably didn't exist 100 years ago. I know it didn't. But they adjusted. They made changes to the laws, and I truly believe that's what we need to do again.

I want to thank the witnesses, and we're going to leave the record open for a week.

Do you want to add anything, Senator Lee? You're in your own thicket over there? Oh, good.

[Laughter.]

Senator LEE. Thank you.

[Laughter.]

Chair KLOBUCHAR. Okay. All right. The hearing is adjourned. Thank you everyone.

[Whereupon, at 4:58 p.m., the hearing was adjourned.]

[Attitonal material submitted for the record follows.]



## A P P E N D I X

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## TESTIMONY

## ADDRESSING ANTICOMPETITIVE CONDUCT IN PHARMACEUTICAL MARKETS: ANTITRUST ENFORCEMENT IS ROBUST AND EFFECTIVE, BUT ADDITIONAL MARKET-ORIENTED LEGAL REFORM WOULD BE HELPFUL

**Alden F. Abbott**

*Senior Research Fellow, Mercatus Center at George Mason University*

US Senate Committee on the Judiciary, Subcommittee on Competition Policy, Antitrust, and Consumer Rights  
A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Drug Markets

July 13, 2021

Chair Klobuchar, Ranking Member Lee, and distinguished members of the Subcommittee on Competition Policy, Antitrust, and Consumer Rights:

My name is Alden Abbott, and I am a senior research fellow at the Mercatus Center at George Mason University. My research focuses primarily on antitrust and competition policy. I formerly served as general counsel of the Federal Trade Commission (FTC) and as a senior manager in the FTC's Bureau of Competition. I have also served in the Antitrust Division and Office of Legal Counsel at the US Department of Justice (DOJ). I welcome the opportunity to give testimony that highlights key considerations in addressing anticompetitive conduct and consolidation in prescription drug markets.

In this testimony, I will focus on three key points:

1. Federal antitrust enforcement has been robust and effective in promoting prescription drug market competition. New antitrust enforcement tools are not needed, but additional resources to support FTC and DOJ enforcement are warranted.
2. Antitrust enforcement directed at prescription drug markets should remain attentive to potential efficiencies associated with the practices under review, including the importance of protecting the legitimate exercise of intellectual property rights. Specialized legislation generally is not appropriate in this area.
3. Antitrust enforcement alone will not eliminate all competitive problems in prescription drug markets or in healthcare in general. Absent fundamental regulatory reform of the healthcare system, significant competitive distortions that hamper competition will remain.

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*The ideas presented in this document do not represent official positions of the Mercatus Center of George Mason University.*

**FEDERAL ANTITRUST ENFORCEMENT HAS BEEN ROBUST AND EFFECTIVE IN PROMOTING PRESCRIPTION DRUG MARKET COMPETITION, BUT ADDITIONAL RESOURCES TO SUPPORT FTC AND DOJ ANTITRUST ENFORCEMENT ARE WARRANTED**

The FTC and DOJ have many decades of experience studying and bringing appropriate antitrust enforcement actions concerning healthcare markets in general and the pharmaceutical sector in particular. Furthermore, the FTC has also carried out public hearings, undertaken sectoral investigations, and issued numerous reports on competition policy in these areas.

The broad scope of the FTC's current enforcement efforts in the pharmaceutical sector is described in some detail in an April 2021 FTC staff report produced by the FTC Bureau of Competition Health Care Division.<sup>1</sup> This report summarizes the many recent FTC initiatives in this area. These include enforcement actions directed at monopolization and agreements not to compete involving pharmaceutical products; mergers involving pharmaceutical products; mergers involving distribution; and agreements involving monopolization, price and price-related terms, and schemes to obstruct innovative methods of delivering and financing pharmaceutical products. In addition, this report describes a variety of FTC industry guidance statements and FTC "friend of the court" briefs (filed in private antitrust suits) dealing with pharmaceutical products and distribution issues (including such "hot topics" as reverse payments, product hopping, restricted distribution, the Noerr-Pennington Doctrine, regulatory issues, and market definition issues).

The DOJ's Antitrust Division has been particularly busy lately prosecuting hard-core cartel conduct by generic drug manufacturers. A March 2021 Antitrust Division update describes the impressive results of the division's ongoing investigation in this area:

In recent years, the Division has uncovered price-fixing, bid-rigging, and customer-allocation schemes in one of the most important markets for the health and wallets of American consumers: the generic drug industry. Indeed, nearly 90% of all prescriptions in the United States are filled with generic drugs.

To date, the investigation has resulted in charges against seven generic pharmaceutical companies and four senior executives for conspiring to fix prices, rig bids, and allocate customers for essential generic drugs relied on by millions of American consumers, including the elderly and vulnerable, to treat a range of diseases and conditions. Of the four executives charged, three have pleaded guilty. Of the seven companies, five have admitted to the charged conduct and entered into deferred prosecution agreements (DPAs) to resolve the charges, under which they collectively agreed to pay over \$426 million in criminal penalties for collusion that affected over \$1 billion of generic drug sales. Most recently, in July 2020, Taro Pharmaceuticals U.S.A., Inc. was charged for participating in two conspiracies to fix prices, rig bids, and allocate customers that impacted over \$500 million in sales of generic drugs used to prevent and control seizures and treat bipolar disorder, pain and arthritis, and various skin conditions. The company entered into a DPA to resolve the charges under which it agreed to pay a \$205.7 million criminal penalty—the highest ever for a domestic cartel.<sup>2</sup>

These two recent examples of the government dealing with pharmaceutical competition tell a success story. Based on my prior government experience and my review of current developments, I conclude that the FTC and DOJ have done an outstanding job of enforcing the antitrust laws in the

1. Federal Trade Commission, *Overview of FTC Actions in Pharmaceutical Products and Distribution*, April 2021.

2. "Generic Investigation Targets Anticompetitive Schemes," US Department of Justice, updated March 24, 2021, <https://www.justice.gov/atr/division-operations/division-update-spring-2021/generic-drugs-investigation-targets-anticompetitive-schemes>.

pharmaceutical sector.<sup>3</sup> Moreover, I believe that the existing antitrust laws provide federal enforcers ample legal tools to continue to carry out their enforcement mission in superlative fashion in this area.<sup>4</sup> As I indicated in recent testimony before the House Subcommittee on Antitrust, Commercial, and Administrative Law,<sup>5</sup> however, the FTC and DOJ would benefit from additional resources to carry out their antitrust enforcement duties. The need for more resources is particularly acute with regard to pharmaceutical enforcement, given the great economic significance and complexity of pharmaceutical market issues.

**ANTITRUST ENFORCEMENT DIRECTED AT PRESCRIPTION DRUG MARKETS SHOULD REMAIN ATTENTIVE TO POTENTIAL EFFICIENCIES AND TO PROTECTING THE LEGITIMATE EXERCISE OF INTELLECTUAL PROPERTY RIGHTS; SPECIALIZED LEGISLATION IS NOT APPROPRIATE IN THIS AREA**

Apart from per se illegal cartel conduct, federal antitrust enforcers apply the antitrust rule of reason when assessing potentially anticompetitive pharmaceutical market practices. Doing so involves weighing whether particular conduct under scrutiny yields consumer-welfare-enhancing efficiencies that would offset its potential anticompetitive effects. These may include, among other possible socially desirable effects, efficiencies in pharmaceutical product distribution practices; efficiencies affecting the settlement of pharmaceutical litigation; and innovation-related efficiencies associated with patenting practices in pharmaceuticals. It is unwise to generalize about the presence or likelihood of such efficiencies in the abstract. Antitrust enforcement involves the assessment of detailed case-specific facts, including facts bearing on the verifiability and magnitude of possible efficiencies. Although efficiencies should not be assumed, neither should they be summarily discounted. Careful evaluation and weighing of all effects, procompetitive and anticompetitive, are required, if the rule of reason is to be applied in an optimal, cost-beneficial fashion.

In the pharmaceutical sector, issues of anticompetitive harm and procompetitive efficiencies often are associated with patents. Harm may arise from the strategic use of patents to delay or deter entry from potential competitors. At the same time, patents may facilitate the efficient and innovation-enhancing distribution of new technologies and may act as beacons to attract investments in R&D that help generate dynamic efficiencies through the creation of new products and services.<sup>6</sup> In assessing particular

3. For example, anticompetitive "reverse payment" litigation settlements (whereby a brand name pharmaceutical company pays a generic pharmaceutical producer to delay entering the market) appear to have been disincentivized owing to vigorous FTC enforcement. According to a December 2020 FTC staff report analyzing recent pharmaceutical patent settlement agreements, very few agreements involved reverse payments that are likely to be anticompetitive. Commenting on this report, then-FTC Chair Joseph Simons states that "the report shows, following the [Supreme Court's] Actavis decision [submitting reverse payments to antitrust scrutiny] and subsequent case law applying it, a continued decline in use of the types of reverse-payment agreements that are most likely to harm consumers." Federal Trade Commission, "FTC Staff Issues FY-2017 Report on Branded Drug Firms' Patent Settlements with Generic Competitors," press release, December 3, 2020, <https://www.ftc.gov/news-events/press-releases/2020/12/ftc-staff-issues-fy-2017-report-branded-drug-firms-patent>.

4. More generally, as I stated in April 2021 testimony before the House Subcommittee on Antitrust, Commercial, and Administrative Law, "I do not believe that major statutory changes in the antitrust field would be helpful. . . . Although a few marginal adjustments to the antitrust statutes appear appropriate, such as elimination of the nonprofit exception to FTC jurisdiction, the mainstream consensus consumer-welfare approach should be retained. . . . In my opinion, the FTC staff possesses the legal tools (with the exception of the nonprofit limitation, discussed earlier) to fully investigate and take action against anticompetitive behavior in [the health care] sector." Alden F. Abbott, "Lack of Resources and Lack of Authority over Nonprofit Organizations Are the Biggest Hindrances to Antitrust Enforcement in Health Care" (Testimony before the US House Committee on the Judiciary, Subcommittee on Antitrust, Commercial, and Administrative Law, Mercatus Center at George Mason University, Arlington, VA, April 29, 2021), 3–4.

5. Abbott, "Lack of Resources and Lack of Authority," 1–2.

6. F. Scott Kieff, *Views of the Honorable F. Scott Kieff, Commissioner, United States International Trade Commission, on the United States Federal Trade Commission's and the United States Department of Justice Antitrust Division's Joint Guidelines for the Licensing of Intellectual Property* (Washington, DC: International Trade Commission, September 23, 2016).

pharmaceutical market practices, antitrust enforcers should seriously consider the possible efficiency-related ramifications, not just the potential competitive harm, arising out of the use of patents.

Congress should exercise restraint and precision when legislating with respect to particular institutional features of pharmaceutical markets (for example, the role of pharmaceutical benefit managers or other specialized entities).<sup>7</sup> Without compelling evidence that a particular feature has no potential redeeming efficiency benefits under any conditions, it is best, as a general matter, to rely on case-by-case antitrust enforcement evaluations of the role of such features in particular settings. That approach avoids the risk that a blanket legislative classification would eliminate many practices that frequently yield efficiencies and enhanced consumer welfare in the pharmaceutical sector.

#### ANTITRUST ENFORCEMENT ALONE WILL NOT ELIMINATE ALL COMPETITIVE PROBLEMS IN PHARMACEUTICAL MARKETS; ABSENT SUBSTANTIAL REGULATORY REFORM, SIGNIFICANT DISTORTIONS OF COMPETITION WILL REMAIN

Although effective antitrust enforcement is of course important, it cannot be expected to eliminate all competitive problems in pharmaceutical markets. As FTC Commissioner Christine Wilson has stated, speaking more generally of the healthcare system,

The health care system is so fundamentally broken that antitrust cannot fix all that ails it. I believe many of these problems come down to consumers' ability and incentive to choose among different products and services. Because insurers pick up much of the tab, one set of consumers—patients—have very little incentive to compare the prices of various health care providers. Even if they were inclined to comparison shop, it's not clear they could, given the opacity of most prices. And the ability to comparison shop based on quality—in other words, patient outcomes—is even more limited, given the dearth of data available to patients.<sup>8</sup>

Like the broader US healthcare system itself, pharmaceutical markets are rife with distortions related to current regulation. To take just one example, professor Joanna Shepherd has explained “that the current system of government price controls and distortive rebates creates perverse incentives for drugmakers to continue increasing drug list prices.”<sup>9</sup>

Non-antitrust-related pharmaceutical market reform—and, more generally, healthcare reform overall—would be a most worthwhile endeavor. It should be acknowledged that the federal antitrust agencies have over the years done an outstanding job in calling for statutory and legislative reforms to improve healthcare competition under both Republican and Democratic administrations.<sup>10</sup> Enhancing competition in healthcare markets (including, of course, pharmaceutical markets), whether through enforcement or legislative and regulatory reform, has been and should remain a nonpartisan endeavor.

7. Nevertheless, targeted statutory amendments, narrowly tailored to address specific competitive healthcare sector problems, may be appropriate in certain circumstances. A good example is the newly minted CREATES (Creating and Restoring Equal Access to Equivalent Samples) Act, which deals with regulatory abuses that had allowed branded pharmaceutical companies to forestall competition from both generic drug and biosimilar producers. The CREATES Act, which was enacted in December 2019, establishes a private right of action that allows developers of generic drug and biological products to sue brand companies that refuse to sell them product samples needed to support their applications for regulatory approval. “Access to Product Samples: The CREATES Act,” US Food and Drug Administration, current as of March 13, 2020, <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/access-product-samples-creates-act>.

8. Christine S. Wilson, “The FTC’s Ongoing Efforts to Promote Competition and Choice in Our Health Care System” (remarks, *The Price of Good Health – 2020 and Beyond*, Council for Affordable Health Coverage, Washington, DC, January 16, 2020), 12.

9. Joanna Shepherd, “Drug Prices and Distortions in the Pharmaceutical Market,” *Truth on the Market*, January 11, 2019.

10. Maureen Ohlhausen, “Beyond Law Enforcement: The FTC’s Role in Promoting Health Care Competition and Innovation,” *Health Affairs Blog*, January 26, 2015; “Healthcare Competition Advocacy,” US Department of Justice, accessed April 26, 2021, <https://www.justice.gov/atr/health-care-competition-advocacy>.

**CONCLUSION**

Federal antitrust enforcement has been robust and effective in promoting prescription drug market competition and thereby enhancing consumer welfare. New antitrust enforcement tools are not needed, nor is specialized pharmaceutical legislation, but additional resources to support FTC and DOJ enforcement are warranted. Antitrust enforcement in this area should fully take into account efficiencies, including innovation-related efficiencies associated with patents. Antitrust enforcement in itself, however, is not a panacea. Without significant regulatory reform, significant distortions of competition will remain in pharmaceutical markets.



**PATIENTS FOR AFFORDABLE DRUGS™**

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

*before the*

**Subcommittee on Competition Policy, Antitrust, and Consumer Rights  
of the  
U.S. Senate Committee on the Judiciary**

*for a hearing on*

**“A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription  
Drug Markets”**

**July 13, 2021**

Chairwoman Klobuchar, Ranking Member Lee, Members of the Subcommittee, thank you for having me today for this important hearing examining how we can stop anticompetitive conduct in prescription drug markets that is hurting American patients, consumers and taxpayers.

***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 just over four years since we launched, we have collected over 27,000 stories of patients struggling to pay high drug prices. And we have built a community of more than 340,000 patients and allies who support policies to lower drug prices.

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

My doctors currently have me on a four-drug combination of infused and oral cancer drugs. These four drugs carry a combined list price of more than \$900,000 per year. Just one of my oral drugs, called Pomalyst, is priced at almost \$21,000 for 21 capsules, which I must buy every 28

days. And because Medicare beneficiaries like me pay our costs in Part D based on list price, I spent more than \$18,000 out of pocket last year — just for Pomalyst. To help manage the cost of my infused drugs, I spend another \$3,000 per year to purchase a Part B supplement. And of course, I have the base costs of Medicare to pay as well. For people with my cancer — multiple myeloma — drugs account for 60 percent of the cost of treatment.<sup>1</sup> Sixty percent.

I am a very lucky man — these drugs are currently keeping my cancer at bay, and I tolerate them well. But the reason I am on four drugs is because each began to stop working, so the doctors first increased the dose, then increased the frequency, and then added another drug. Eventually I will fail on this combination, too. When that happens, I will be what doctors call “triple refractory” to all of the three major classes of drugs used to treat my disease. The cancer will begin to increase in my blood and I will need a new treatment. Fortunately, there are options out there.

But one of the new drugs approved this year that I might be a candidate for carries a list price of \$419,500. That’s just for the drug — it doesn’t cover the hundreds of thousands of dollars required to administer the drug and manage my health in the wake of the treatment.

The point is: I need these innovative drugs. I care deeply about innovation and new drug development. My life depends on it. Without innovation, I will die sooner than I hope to. That is just an unfortunate fact.

But my 10-year journey as a cancer patient has taught me one irrefutable fact: Drugs don’t work if people can’t afford them.

## *Section II. The Price of Drugs and Need for Change*

Drugs are too expensive in the United States, and there is no justification for the high prices. When drug makers hike prices each year, they don’t do so because the drug becomes more valuable. Drug companies raise prices because they can. We let them.

The result is that Americans pay nearly four times what people in other wealthy nations pay for the exact same brand-name drugs.<sup>2</sup>

<sup>1</sup> Tran, D., Kamalakar, R., Manthena, S., & Karve, S. (2019, November 13). Economic Burden of Multiple Myeloma: Results from a Large Employer-Sponsored Real-World Administrative Claims Database, 2012 to 2018. *Blood*, 134, 3414. <https://doi.org/10.1182/blood-2019-131264>

<sup>2</sup> House Committee on Ways and Means. (2019). A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices. [https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices\\_0.pdf](https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf)

Consequently, nearly 40 percent of people report having difficulty affording their medications.<sup>3</sup> When their prescription drug prices are too high, Americans face challenges affording other expenses, such as food and housing. One survey found that over 20 percent of people took on debt or declared bankruptcy because of their medications.<sup>3</sup>

The issue of drug prices disproportionately harms communities of color. One in two Latinos in the United States takes a prescription medication, and 20 percent are uninsured.<sup>4</sup> Black Americans are more likely to live with chronic pain, diabetes, and high blood pressure than white Americans and are nearly two times more likely to be uninsured.<sup>5</sup>

The pandemic only made it worse, as millions of Americans lost jobs, income, and insurance coverage. As expensive as my drugs are, even with Medicare, I never lose sight of the fact that 30 million Americans without insurance are exposed to the full list price.<sup>6</sup>

People struggle to pay the prices with and without insurance.

Americans are desperate for relief. A Politico-Harvard poll from early this year found that nearly 90 percent of voters across both parties thought it was “extremely important” that Congress and the president take action on drug pricing. That includes 91 percent of Democrats and over 80 percent of Republicans.<sup>7</sup> And voters are worried you won’t do enough to help them — over 60 percent fear Congress won’t go far enough to reform our broken drug pricing system.<sup>8</sup>

You can change all this. You can restore balance to ensure we get the innovation we need at prices we can afford. And you can do it now.

### ***Section III. Innovation and Drug Prices: The False Choice***

<sup>3</sup> Nguyen, A. (2021, March 22). *Survey: Americans Struggle to Afford Medications as COVID-19 Hits Savings and Insurance Coverage*. GoodRx. <https://www.goodrx.com/blog/survey-covid-19-effects-on-medication-affordability/>

<sup>4</sup> UnidosUS Action Fund. (2021). *A Vicious Cycle of Health Inequity: How High Prescription Prices Hurt Latino Health and Prosperity*.

<https://www.lowerdrugpricesnow.org/wp-content/uploads/UNIDOS-RX-REPORT-Vicious-Cycle.pdf>

<sup>5</sup> Patients For Affordable Drugs Now. (2020, December 14). *High Prescription Drug Prices Perpetuate Systemic Racism. We Can Change It*. <https://patientsforaffordabledrugsnow.org/2020/12/14/drug-pricing-systemic-racism/>

<sup>6</sup> Garfield, R. & Tolbert, J. (2020, September 17). *What We Do and Don't Know About Recent Trends in Health Insurance Coverage in the US*. Kaiser Family Foundation. <https://www.kff.org/policy-watch/what-we-do-and-dont-know-about-recent-trends-in-health-insurance-coverage-in-the-us/>

<sup>7</sup> POLITICO & Harvard T.H. Chan School of Public Health. (2021, January). *The American Public's Priorities for the New President and Congress*. <https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2021/01/Politico-HSPH-Jan-2021-PollReport.pdf>

<sup>8</sup> Hart Research Associates. (2021, April 20). *Memo for Protect Our Care*. <https://www.protectourcare.org/wp-content/uploads/2021/04/Garin-Memo-Protect-Our-Care-April-2021.pdf>

Of course, the biopharmaceutical industry opposes any reforms that would curb its unilateral power to dictate prices for brand drugs. So it rolls out its well-worn claim that any limits on its ability to set high prices will destroy innovation and access to new drugs.

No one cares more about innovation than patients. But if you pull back the curtain on this fear-mongering, the argument doesn't hold up.

Experts from both sides of the aisle agree it's possible to curb the pharmaceutical industry's pricing power without threatening valuable innovation.<sup>9-10</sup> There are five reasons why:

- 1) Biopharma corporations enjoy profit margins that are almost three times the average of the S&P 500.<sup>11</sup> Brand-name pharmaceutical companies could lose \$1 trillion in sales over 10 years and remain the most profitable industry in the United States.<sup>12</sup> There is more than enough headroom to lower drug prices and leave drug companies with plenty of profit to attract investment and fund research and development. And if drug pricing legislation curbs profits, the industry can maintain or even increase R&D investment by shifting the billions spent on stock buybacks, marketing, advertising, and lobbying.
- 2) It doesn't cost nearly as much as the industry says it does to develop a new drug. Pharma claims it costs \$2.87 billion to bring a new drug to market. But that's based on industry-funded research and undisclosed source data.<sup>13-14</sup> Independent studies have found the cost to develop a drug is likely less than \$1 billion.<sup>15-16</sup>

<sup>9</sup> Frank, R. G. (2019, November 13). Drug companies exaggerate — controlling drug prices won't threaten innovation. *The Hill*.

<https://thehill.com/opinion/healthcare/470266-drug-companies-exaggerate-controlling-drug-prices-wont-threaten-innovation>

<sup>10</sup> Waikar, S. (2020, September 2). *Pharma Companies Argue That Lower Drug Prices Would Mean Fewer Breakthrough Drugs. Is That True?*. Kellogg School of Management at Northwestern University.

<https://insight.kellogg.northwestern.edu/article/pharma-companies-argue-lower-drug-prices-fewer-breakthrough-drugs>

<sup>11</sup> Yardeni Research. (2021, January 19). *S&P 500 Sectors & Industries Profit Margins (quarterly)*.

<https://www.yardeni.com/pub/sp500margin.pdf>

<sup>12</sup> West Health. (2019, November 14). *New Analysis Finds Large Drugmakers Could Lose \$1 Trillion in Sales and Still Be the Most Profitable Industry*.

<https://www.westhealth.org/press-release/new-analysis-finds-large-drug-makers-could-lose-1-trillion-in-sales-and-still-be-the-most-profitable-industry/>

<sup>13</sup> DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics*, 47, 20-33. <https://doi.org/10.1016/j.jhealeco.2016.01.012>

<sup>14</sup> Tufts Center for the Study of Drug Development. (n.d.). *Financial Disclosure*.

<https://csdd.tufts.edu/financial-disclosure>

<sup>15</sup> Wouters, O. J., McKee, M., & Lutyen, J. (2020). Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. *JAMA*, 323(9), 844-853. <https://doi.org/10.1001/jama.2020.1166>

<sup>16</sup> Prasad, V., & Mailankody, S. (2017). Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval. *JAMA Internal Medicine*, 177(11), 1569-1575.

<https://doi.org/10.1001/jamainternmed.2017.3601>

- 3) A tremendous amount of research and development is coming from taxpayers. The National Institutes of Health (NIH) is the single largest biomedical research agency in the world. NIH-funded research is associated with all 356 new drugs that were approved by the FDA from 2010 to 2019.<sup>17</sup> NIH Director Francis Collins has said: “Finding new treatments thus requires NIH to play a lead role — by investing in the early stage of therapeutic development to ‘de-risk’ such projects.”<sup>18</sup> Drug companies argue high drug prices are required to reimburse the industry for the financial and scientific risk it takes on during research and development. In reality, the U.S. government takes on most of those early risks, further undermining the industry’s argument for high prices.

Our experience with COVID-19 vaccines illuminates this point with crystal clarity.

Several years back when the big drug companies were unwilling to invest their own money in technology that led to some of the most effective vaccines today, the U.S. government did.<sup>19-20</sup> The biopharmaceutical industry publication BioCentury explains<sup>21</sup>:

“The Defense Research Advanced Projects Agency (DARPA) has taken risks where others wouldn’t. Its pursuit of high-risk, high-reward technologies, combined with its mission-driven approach to managing projects is promising to pay off in the fight against COVID-19. DARPA was behind the creation of DNA and RNA vaccines, funding early R&D by Moderna Inc. and Inovio Pharmaceuticals Inc. at a time when the technologies were considered speculative by many scientists and investors.”

In fact, a study issued recently said: “The unprecedented development of COVID-19 vaccines less than a year after discovery of this virus was enabled by more than \$17

<sup>17</sup> Ledley, F., Cleary, E., & Jackson, M. (2020, September 2). *US Tax Dollars Funded Every New Pharmaceutical in the Last Decade*. Institute for New Economic Thinking.

<https://www.ineteconomics.org/perspectives/blog/us-tax-dollars-funded-every-new-pharmaceutical-in-the-last-decade>

<sup>18</sup> Collins, F. S. (2017, May 17). *Testimony on the Transformative Power of Biomedical Research*. National Institutes of Health.

<https://www.nih.gov/about-nih/who-we-are/nih-director/testimony-transformative-power-biomedical-research>

<sup>19</sup> Edwards, D. J. (2020, April 14). *New products alone are not enough. Pharma can do more to halt COVID-19*. Access to Medicine Foundation.

[https://accessmedicinefoundation.org/media/uploads/downloads/5e95d85128fb9\\_ATMF\\_Viewpoint\\_Role\\_for\\_pharma\\_in\\_C-19\\_200414%20\(1\).pdf](https://accessmedicinefoundation.org/media/uploads/downloads/5e95d85128fb9_ATMF_Viewpoint_Role_for_pharma_in_C-19_200414%20(1).pdf)

<sup>20</sup> Johnson, C. Y. (2020, December 6). A gamble pays off in ‘spectacular success’: How the leading coronavirus vaccines made it to the finish line. *The Washington Post*.

<https://www.washingtonpost.com/health/2020/12/06/covid-vaccine-messenger-rna/>

<sup>21</sup> Usdin, S. (2020, March 25). DARPA’s gambles might have created the best hopes for stopping COVID-19. *BioCentury*.

<https://www.biocentury.com/article/304691/darpa-jump-started-technologies-behind-some-of-the-leading-covid-19-vaccine-and-antibody-hopes>

billion of research on vaccine technologies funded by NIH *prior to the pandemic*.<sup>22</sup>  
[emphasis added]

According to Kaiser Health News: “Basic research conducted ... at the National Institutes of Health, Defense Department, and federally funded academic laboratories has been the essential ingredient in the rapid development of vaccines in response to COVID-19.”<sup>23</sup>

Of course, the government invested an additional \$20 billion through Operation Warp Speed and other programs.<sup>24</sup> As a result of all that taxpayer investment, The New York Times concluded: “A new method of developing vaccines was already waiting to be tested ... The government was willing to spend whatever it took, eliminating financial risks and ... allowing mass production to begin even before trials were done.”<sup>25</sup>

One noted industry expert, Jack Scannell, summed it up this way: “Before we pat the drug industry on the back too much, one has to recognize it got involved in this partly because the whole thing has been de-risked by government.”<sup>26</sup>

- 4) Pharma’s claims that patients will suffer an alarming loss of new drugs if anything is done to curb its unilateral pricing power isn’t supported by the facts. The Congressional Budget Office found that we could cut pharma revenue by up to \$1 trillion dollars over a 10-year period and lose only eight of 300 expected new drugs.<sup>27</sup> And many of those eight drugs would not be real losses at all because only 10 to 15 percent of new drugs that come to market actually represent true therapeutic advances.<sup>28</sup> The loss of a few drugs each year will have minimal impact on the health of Americans.
- 5) Big Pharma threatens that patients will lose access to newly developed drugs. It points out that more drugs are available — and are available faster — in the United States than in other wealthy countries. It frequently references a white paper from the White House

<sup>22</sup> Bentley University. (2021, April 22). *COVID-19 vaccine development built on >\$17 billion in NIH funding for vaccine technologies*. [https://www.eurekalert.org/pub\\_releases/2021-04/bu-cvd042121.php](https://www.eurekalert.org/pub_releases/2021-04/bu-cvd042121.php)

<sup>23</sup> Allen, A. (2020, November 18). Government-Funded Scientists Laid the Groundwork for Billion-Dollar Vaccines. *Kaiser Health News*.

<https://khn.org/news/vaccine-pioneers-basic-research-scientists-laid-groundwork-for-billion-dollar-pharma-products/>

<sup>24</sup> Congressional Research Service. (2021, March 1). *Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials*. <https://crsreports.congress.gov/product/pdf/IN/IN11560>

<sup>25</sup> LaFraniere, S., Thomas, K., Weiland, N., Gelles, D., Stolberg, S. G., & Grady, D. (2020, November 30). Politics, Science and the Remarkable Race for a Coronavirus Vaccine. *The New York Times*. <https://www.nytimes.com/2020/11/21/us/politics/coronavirus-vaccine.html>

<sup>26</sup> Neville, S., & Kuchler, H. (2020, November 27). Covid vaccines offer Big Pharma a chance of rehabilitation. *Financial Times*. <https://www.ft.com/content/75029036-13f3-4ca2-8954-5a7207c0c3db>

<sup>27</sup> Congressional Budget Office. (2019, October 11). *Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare*. <https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf>

<sup>28</sup> Light, D. W., & Lexchin, J. R. (2012). Pharmaceutical research and development: what do we get for all that money?. *BMJ*, 345. <https://doi.org/10.1136/bmj.e4348>

Council of Economic Advisers (CEA) to explain why: “Drug manufacturers usually pursue market access in the United States before other markets due to the higher prices in the United States.”<sup>29</sup> The CEA could also have mentioned the other big reason drug companies file for approval first in the United States: It is the largest market in the world.<sup>30-31</sup>

Given that U.S. prices for brand-name drugs are almost four times what many other wealthy nations pay, we can lower prices by a meaningful amount and still offer the highest prices by far in the largest market in the world, preserving the incentive to file first for approval in the United States.<sup>2, 32</sup>

There are other important policies in the U.S. drug pricing system that lead to more drugs being available here compared to other countries, none of which would be altered by lowering prices:

- Medicare must cover all drugs in six protected classes, which even PhRMA acknowledges ensures access to these drugs.<sup>33-34</sup>
- Medicare must cover at least two drugs in each class of drugs.<sup>35</sup>
- Medicaid must cover every drug offered by a manufacturer in the United States if the manufacturer agrees to give Medicaid a best-price guarantee.<sup>36</sup>

Pharma’s threats to innovation and access don’t hold up. It is clear that we can restore balance to have fair prices and profits and still get the innovation we need.

<sup>29</sup> The Council of Economic Advisers. (2018). *Reforming Biopharmaceutical Pricing at Home and Abroad*. <https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>

<sup>30</sup> IQVIA. (2020, March 5). *Global Medicine Spending and Usage Trends*.

<https://www.iqvia.com/en/insights/the-iqvia-institute/reports/global-medicine-spending-and-usage-trends>

<sup>31</sup> Association of Community Cancer Centers v. Alex M. Azar II. Civil Action No. CCB-20-3531 (2020).

<https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Complaint-on-MFN-Rule-Filed-2020-12-04.pdf>

<sup>32</sup> Mulcahy, A. W., Whaley, C., Tebeka, M. G., Schwam, D., Edenfield, N., & Becerra-Ornelas, A. U. (2021).

*International Prescription Drug Price Comparisons*. RAND Corporation.

[https://www.rand.org/pubs/research\\_reports/RR2956.html](https://www.rand.org/pubs/research_reports/RR2956.html)

<sup>33</sup> Centers for Medicare & Medicaid Services. (2019, May 16). *Medicare Advantage and Part D Drug Pricing Final Rule (CMS-4180-F)*.

<https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f>

<sup>34</sup> Powaleny, A. (2015, December 10). *Medicare Part D’s six protected classes*. PhRMA.

<https://catalyst.phrma.org/medicare-part-d-six-protected-classes>

<sup>35</sup> *What Medicare Part D drug plans cover*. (n.d.). CMS.gov. Retrieved May 3, 2021 from

<https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover>

<sup>36</sup> Kaiser Family Foundation. (2019, May 1). *Medicaid’s Prescription Drug Benefit: Key Facts*.

<https://www.kff.org/medicaid/fact-sheet/medicaids-prescription-drug-benefit-key-facts/>



Equally important, we must remember that people can't afford existing drugs they need right now. More than 1.1 million Medicare patients could die over the next decade because they cannot afford to pay for their prescriptions.<sup>37</sup>

***Section IV. What We Can Do About It: Patent Reform To Stimulate Innovation and Lower Prices Through Competition***

When a drug company makes a truly innovative discovery, it should be rewarded with a patent and receive a fair return for the risk and investment. Our patent system is designed to facilitate these rewards for innovation so that drug companies are incentivized to pursue true clinical breakthroughs and inventions that bring meaningful benefits to patients.

But the drug industry would have you believe that every patent is deserved and that the sheer volume of patents granted is an appropriate indicator of innovative achievements. That couldn't be further from the truth.

Neither new patents nor new drugs equal new innovation. Worse, in too many cases 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.<sup>38</sup>

Of the roughly 100 best-selling drugs, nearly 80% obtained an additional patent to extend their monopoly period.<sup>39</sup>

In fact, gaming of the patent system to extend monopolies beyond the time intended under law inhibits true innovation patients like me need. If drug companies can block competition and raise prices at will on old drugs to drive profits and executive bonuses, they have far less incentive to take risk and invest in R&D to find innovative new drugs that could command high prices and save lives.

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<sup>37</sup> West Health. (2020, November 19). *New Study Predicts More Than 1.1 Million Deaths Among Medicare Recipients Due to the Inability to Afford Their Medications*.  
<https://www.westhealth.org/press-release/study-predicts-1-million-deaths-due-to-high-cost-prescription-drugs/>

<sup>38</sup><https://www.bloomberg.com/news/articles/2017-11-01/most-new-drug-patents-are-for-old-remedies-research-shows>

<sup>39</sup>Feldman, R. (2018). May your drug price be evergreen. *Journal of Law and the Biosciences*.  
<https://academic.oup.com/jlb/article/5/3/590/5232981?login=true>



A report issued just last week by the House Oversight Committee highlighted how this works for a drug I took for more than five years — Revlimid<sup>40</sup>:

“Celgene paid its top executives millions of dollars in salaries and bonuses as they repeatedly increased the price of the cancer drug Revlimid. Between 2006 and 2018, Celgene paid its top executives over \$450 million in compensation. Internal company data show that Celgene’s executives would not have met several annual bonus targets if not for their decision to increase the U.S. price for Revlimid.”

There are a variety of strategies used by drug corporations to extend monopolies, including product hopping, patent thickening, pay-for-delay deals, and abuse of the FDA’s citizen petition process.

These tactics lead to longer exclusivity than our laws intend. 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.<sup>41</sup>

Let’s start with product hopping. This tactic occurs when a brand-name company switches a patient population from an older product facing competition to a different formulation that has a later expiring patent and therefore, is not facing competition. The “new” drug typically offers little or no new clinical benefit, it can be as simple as changing a product from a tablet to a capsule.

This switching is enabled by two anticompetitive behaviors. In “hard” switches, the brand-name company removes the older product from the market, forcing patients onto the new version. With “soft” switches, the company engages in aggressive marketing to prescribers and patients, urging them to switch to the newer formulation.<sup>42</sup> By switching their market to a new drug, brand-name companies effectively eliminate the market for new generics that rely on automatic substitution state laws to gain traction in the patient populations.

As patients, 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

<sup>40</sup> House Committee on Oversight and Reform. (2021, July). Drug Pricing Investigation: Industry Spending on Buybacks, Dividends, and Executive Compensation. <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf>

<sup>41</sup> FN-Wang B., Liu J., & Kesselheim A.S. (2015). Variations in time of market exclusivity among top-selling prescription drugs in the United States. *JAMA Internal Medicine* 2015;175(4):635-637.

<sup>42</sup> Jones, G. H., Carrier, M. A., Silver, R. T., & Kantarjian, H. (2016). *Strategies that delay or prevent the timely availability of affordable generic drugs in the United States*. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915805/>

reformulated drug were to reduce this type of side effect, it might meet the standard of an innovative change meriting a patent extension.

Unfortunately, this is often not the case for patients. Two drugs that have 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 writes:

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

Patent thickening is a tactic similarly designed to undermine market dynamics at the expense of patients. This strategy occurs when drug companies file dozens of non-innovative patents in order to create an impenetrable patent thicket around a drug product; these patents create a protective "thicket" around a product since a prospective generic or biosimilar competitive must litigate through each of the patents in order to gain market entry.

Imbruvica, a best-selling cancer drug manufactured by AbbVie, provides a perfect case study. The Initiative for Medicines, Access, and Knowledge (I-MAK) found that AbbVie has filed 165 patent applications on the product and *more than half* of these were filed after market approval. Almost sixty percent of the patents cover indications or various formulations of the drug, not active ingredients. The 88 patents granted to date mean that Imbruvica will not face competition until 2036 or later — giving the drug over two decades of monopoly pricing power.<sup>43</sup>

The encouraging news is that there are multiple bills in Congress designed to close loopholes in our patent system that are harming patients. All have bipartisan support.

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<sup>43</sup> Initiative for Medicines, Access, and Knowledge. (2020.) *Overpatented, Overpriced: Imbruvica's Patent Wall*. <https://www.i-mak.org/wp-content/uploads/2020/08/I-MAK-Imbruvica-Patent-Wall-2020-07-42F.pdf>

- *Affordable Prescriptions for Patients Act of 2021* (S. 1435)<sup>44</sup>: This bill, led by Senators Cornyn (R-TX) and Blumenthal (D-CT), establishes a definition for product hopping and establishes it as an anticompetitive behavior under the Federal Trade Commission Act. To address patent thickets, the bill narrows permitted patent assertions by biologic companies to 20, effectively limiting the number of patents that have to be challenged by biosimilar competitors.
- *The REMEDY Act*—which has not yet been reintroduced this Congress—is led by Senators Durbin (D-IL) and Cassidy (R-LA). The bill streamlines the generic approval process by allowing brand-name drug makers to assert only one patent during patent infringement proceedings. This patent must be chosen at the time of approval of the brand-name product, thus preventing the company from choosing among frivolous patents which are usually not obtained until after market approval. This legislation curb abusive patent thickets and allow generic manufacturers to bring more affordable drugs to market sooner.

There are two final anticompetitive behaviors that I urge this Congress to address.

First, through “pay-for-delay” or “reverse patent settlement” deals, brand-name companies gives a generic or biosimilar company something of value to delay that company’s introduction of a lower-price competitor. These collusive agreements impede competition and keep prices high for patients.

To address this tactic, we support the bipartisan *Preserve Access to Affordable Generics and Biosimilars Act* (S. 1428), led by Senators Grassley and Klobuchar.<sup>45</sup> This bill presumes that patent infringement settlements where something of value is transferred from a brand-name to a generic company is anticompetitive and permits the Federal Trade Commission (FTC) to enter into proceedings against parties to such an agreement.

Second, the citizen petition process at the FDA was designed so that patients could raise safety concerns about drug approvals. But research has revealed that the process has been co-opted by corporations looking to block competition. Brand-name drug makers were behind 92% of all citizen petitions filed between 2011 and 2015. But they were not raising legitimate safety concerns, which is why the FDA threw out nine of every 10 of the industry’s “sham” petitions.<sup>46</sup>

<sup>44</sup> Affordable Prescriptions for Patients Act of 2021. S. 1435.  
<https://www.congress.gov/bills/117/congress/senate-bill/1435?q=%7B%22search%22%3A%5B%22cornyn%22%5D%7D&s=3&r=11>

<sup>45</sup> Preserve Access to Affordable Generics and Biosimilars Act. S 1428.  
<https://www.congress.gov/bills/117/congress/senate-bill/1428/cosponsors?q=%7B%22search%22%3A%5B%22Preserve+Access+to+Affordable+Generics+and+Biosimilars+Act%22%5D%7D&r=1&s=4>

<sup>46</sup> <https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1956&context=aulr>

We support the following citizen petition reform bills in this congress:

- The *Stop STALLING Act* (S. 1425), a bipartisan bill led by the Chair of this Subcommittee, Senator Klobuchar (D-MN), and by Judiciary Ranking Member Grassley (R-IA), deems sham petitions as anticompetitive under the FTC Act, giving the Commission authority to penalize companies engaged in this behavior.<sup>47</sup>
- Under the *Ensuring Timely Access to Generics Act* (S. 562), led by Senators Shaheen (D-NH) and Cassidy (R-LA), FDA can deny a citizen petition that (1) was submitted primarily to delay a generic approval, or (2) does not raise valid scientific or regulatory issues. Currently, the FDA may deny a petition only if it meets both #1 *and* #2.<sup>48</sup>

To achieve true innovation at prices we can afford over the long haul, we must reform our patent and exclusivity system.

#### ***Section V: Stop Anticompetitive Practices Downstream In The Supply Chain***

While the headwaters of our drug pricing problems are the list prices set by drug corporations, there are other reforms needed downstream in the supply chain. Pharmacy benefit managers (PBMs) are black boxes that cut secret mutually beneficial rebate deals with manufacturers, and none of it is transparent.

It is simply wrong that patients like me don't know if the preferred drug on a PBM formulary is there because it is the best drug, because it is the least expensive drug among equally effective options, or because the PBM got a big, legal kickback from the manufacturer. Without transparency, it is impossible to know how much of a rebate is going to the PBM, to the insurer, to lower my premiums, or to reduce my out-of-pocket costs at the pharmacy counter. With more than \$300 billion in drugs moving through PBMs, that is a bad way to run a railroad.<sup>49</sup> It's time for transparency to ensure PBMs are operating in the best interests of those they are supposed to serve — patients and consumers.

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<sup>47</sup> Stop STALLING Act. S 1425.

<https://www.congress.gov/bills/117th-congress/senate-bill/1425/cosponsors?q=%7B%22search%22%3A%5B%22stop+stalling%22%5D%7D&r=1&s=10>

<sup>48</sup> Ensuring Timely Access to Generics Act. S 562.

<https://www.congress.gov/bills/117th-congress/senate-bill/562?q=%7B%22search%22%3A%5B%22s.562%22%5D%7D&r=1&s=3>

<sup>49</sup> Pew Charitable Trusts. (2019, March 8). *The Prescription Drug Landscape, Explored*.

<https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored>

A research letter published just last week in the Journal of the American Medical Association demonstrated this point.<sup>50</sup> The authors revealed that Medicare Part D could have saved \$2.6 billion on 184 generic drugs in 2018 if it had paid what Costco did. The authors report:

"While price competition is strong for these drugs, the program leaves room for intermediaries to capture much of this value. Our findings show that in systems like Costco's, where incentives are set up to deliver value to the consumer, that is what happens."

In other words, PBMs are not maximizing value to patients like me — they are maximizing profit for themselves at the expense of patients and payers. They can do this because they have a stranglehold on their industry — the three major PBMs have 76% of the market share.<sup>51</sup> In addition to this horizontal consolidation, PBMs are increasingly merging vertically with insurance companies themselves. These recent trends give PBMs the ability to have an outsized impact on the choices and prices patients face. We welcome the focus of this Committee and the Biden administration on the potential harm to consumers brought about by potential antitrust violations within the PBM industry.

I also urge Congress to enact transparency requirements and determine how rebates are actually working — how much is going to reduce premiums and out-of-pocket for patients and consumers and how much is going to increase profits for the PBMs or insurer plan manager.

Drug companies and PBMs also enter into rebate arrangements that are designed to thwart lower cost competition. These are commonly called “rebate walls,” defined as:

“Exclusionary contracting practices that a drug manufacturer deploys to limit the ability of rivals from gaining preferred access to the formulary, or any access at all. Branded manufacturers leverage their position as market leaders by offering financial incentives to pharmacy benefit managers and health insurers in the form of ‘all or nothing’ conditional volume-based rebates, in exchange for virtually exclusive positioning on the formulary. ...If the payer does not accept the rebate agreement for a particular indication, it may lose all rebates for its product on all covered indications.”<sup>52</sup>

<sup>50</sup> Trish E., Gascue L., Ribero R., Van Nuys K., & Joyce G. Comparison of Spending on Common Generic Drugs by Medicare vs Costco Members. *JAMA Internal Medicine*. Published online: [https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2781810?guestAccessKey=89d9de51-fc11-4451-97aa-90b352b7867b&utm\\_source=For\\_The\\_Media&utm\\_medium=referral&utm\\_campaign=fim\\_links&utm\\_content=tf1&utm\\_term=070621](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2781810?guestAccessKey=89d9de51-fc11-4451-97aa-90b352b7867b&utm_source=For_The_Media&utm_medium=referral&utm_campaign=fim_links&utm_content=tf1&utm_term=070621)

<sup>51</sup> The Advisory Board. (2019). *Pharmacy benefit managers, explained*. <https://www.advisory.com/en/daily-briefing/2019/11/13/pbms>

<sup>52</sup> Cohen, J. (2021, March 1). Rebate Walls Stifle Prescription Drug Competition. *Forbes*. <https://www.forbes.com/sites/joshuacohen/2021/03/01/rebate-walls-stifle-prescription-drug-competition/?sh=1ccc940366ac>

Let's be clear: These deals are designed to benefit both the manufacturer seeking to block competition and the PBM that gets a bigger rebate. These deals are not designed to help patients like me by lowering prices or increasing patient choice. They are emblematic of our drug pricing system meant to benefit those who profit from it at the expense of those it is supposed to serve.

We are pleased that the FTC made a decision recently to tackle these issues as well, authorizing staff to issue civil investigative demands and subpoenas to drug corporations and PBMs.<sup>53,54</sup> We also hope Congress will ensure the ability of the FTC to seek damages and monetary penalties for consumer protection and competition cases.

Of course, the Biden Administration's new push to promote competition in the U.S. economy is also welcome as it aims to foster and lower prescription drug prices. We hope to offer suggestions and support to HHS as it crafts its comprehensive plan in the next 45 days.

#### *Section VI: Allow Medicare To Negotiate*

Even if Congress and the Administration were to enact all these reforms to curb anticompetitive practices and stimulate competition, we would still have one huge problem with drug prices in the United States: drug corporations would still have the ability to dictate prices unilaterally with no check on how high they can go. In the end, Americans could still be paying almost four times what other wealthy nations pay for the exact same brand name drugs.

That's why comprehensive reform of drug pricing in America must include allowing Medicare to negotiate directly with drug corporations for lower prices.

Two immediate situations drive home the need for Medicare negotiations and lower prices that extend to the private sector:

- **COVID-19 Vaccines.** These vaccines, which are critical to ending the scourge of COVID-19, were developed with government funding and purchased for every American at between \$10 and \$19.50 per dose with taxpayer dollars.

Now they are poised to jump in price — a lot, if you listen to the stated intentions of

<sup>53</sup> Kelly, C. (2021, June 2). Anticompetitive Drug Rebates May Need FTC Rulemaking for Timely Reform, Commissioners Say. *Pink Sheet*. <https://pink.pharmaintelligence.informa.com/PS144415/Anticompetitive-Drug-Rebates-May-Need-FTC-Rulemaking-For-Timely-Reform-Commissioners-Say>

<sup>54</sup> Sandburg, B. (2021, July 6). U.S. FTC Removing 'Handcuffs' to Pursue Pharma Companies, PBMs for Antitrust Violations. *Pink Sheet*. <https://pink.pharmaintelligence.informa.com/PS144579/US-FTC-Removing-Handcuffs-To-Pursue-Pharma-Companies-PBMs-For-Antitrust-Violations>

vaccine producers. Executives at Pfizer, Moderna and Johnson & Johnson, three of the companies whose coronavirus vaccines have been approved for emergency use in the United States, have said they will maintain their current pricing models during the pandemic but expect to raise prices after it ends. Frank D'Amelio, Pfizer's chief financial officer, recently said that in a post-pandemic environment, "Obviously, we're going to get more on price," noting that vaccine prices are normally \$150 to \$175 per dose.<sup>55,56</sup>

Many experts now predict that Covid-19 booster shots will become a regular part of our lives for years.<sup>57</sup> An increase in the price of coronavirus vaccines would have considerable impact on American health care spending. If Pfizer raised the price of its coronavirus vaccine from \$19.50 per dose to \$175, a yearly shot for every American adult would cost \$44.7 billion and could increase annual U.S. drug spending by 9 percent.<sup>58,59</sup>

- **Biogen's new Alzheimer's drug-Aduhelm.** The price announced by Biogen introduces enormous financial burdens for Medicare, taxpayers, employers, and patients. Roughly three million Americans live with mild Alzheimer's disease, the newly limited label indication for Aduhelm.<sup>60</sup> Biogen has said it expects that 80 percent of patients receiving Aduhelm will be covered by Medicare.<sup>61,62</sup> Aduhelm will cause significant spending burdens to Medicare because it carries a high price *and* could be taken by millions of Medicare beneficiaries. Even if only one million patients take Aduhelm, this would increase Part B drug spending by \$56 billion. To put this number in perspective, Aduhelm by itself could soon double Medicare Part B's annual drug spending, which is currently \$37 billion per year.<sup>63</sup>

<sup>55</sup> Fang, L. (2021, March 18). Drugmakers Promise Investors They'll Soon Hike COVID-19 Vaccine Prices. *The Intercept*. <https://theintercept.com/2021/03/18/covid-vaccine-price-pfizer-moderna/>

<sup>56</sup> [https://s21.q4cdn.com/317678438/files/doc\\_financials/2020/q4/PFE-USO\\_Transcript\\_2021-02-02.pdf](https://s21.q4cdn.com/317678438/files/doc_financials/2020/q4/PFE-USO_Transcript_2021-02-02.pdf)

<sup>57</sup> Axios. (2021, March 15). *Covid-19 boosters set to become routine: "Immunity doesn't last forever."* [https://www.axios.com/covid-boosters-routine-0a5e0f06-b2e8-4e0c-ac0d-085507e3d404.html?utm\\_source=newsletter&utm\\_medium=email&utm\\_campaign=newsletter\\_axiosvitals&stream=top](https://www.axios.com/covid-boosters-routine-0a5e0f06-b2e8-4e0c-ac0d-085507e3d404.html?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top)

<sup>58</sup> [https://www.census.gov/data/tables/time-series/demo/popest/2010s-national-detail.html#par\\_textimage\\_1537638156](https://www.census.gov/data/tables/time-series/demo/popest/2010s-national-detail.html#par_textimage_1537638156)

<sup>59</sup> IQVIA. (2020, August 4). *Medicine Spending and Affordability in the U.S.: Understanding Patients' Costs for Medicine*. <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us>

<sup>60</sup> National Institute on Aging. (2021, March 18). *Half of Alzheimer's disease cases may be mild*.

<https://www.nia.nih.gov/news/half-alzheimers-disease-cases-may-be-mild>

<sup>61</sup> Alzheimer's Association. (2021). *2021 Alzheimer's Disease Facts and Figures*. <https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf>

<sup>62</sup> Tozzi, J. (2021, June 8). Biogen's Costly, Unproven Drug Feared as Health Budget Buster. *Bloomberg*. <https://www.bloomberg.com/news/articles/2021-06-08/biogen-s-costly-unproven-drug-feared-as-health-budget-buster>

<sup>63</sup> Owens, C. (2021, June 9). New Alzheimer's drug could blow up health spending. *Axios*. <https://www.axios.com/alzheimers-drug-health-costs-medicare-aadf854c-e45a-4c6b-b284-e2cb324f08ab.html>



Patients who seek to take Aduhelm will face steep out-of-pocket costs for the drug and related medical services. In Part B, beneficiaries are subject to a 20 percent coinsurance, which will translate to about \$11,500 in coinsurance per year.<sup>64</sup> The median annual income for a Medicare beneficiary is about \$29,650, so paying for this drug could consume nearly 40 percent of a patient's annual income.<sup>65</sup> If a patient buys a Medigap policy to cover Part B out-of-pocket costs, that can cost \$3,000 per year. These costs are untenable for many of those living with the disease. The nature of the drug — a monthly infusion for the rest of a patient's life — means that patients *and* taxpayers will foot the bill over a span of many years.

Aduhelm is not proven to work and even the Alzheimer's Association, a leading advocate for Aduhelm's FDA approval, has said that the drug's list price is "simply unacceptable" and will "pose an insurmountable barrier to access."<sup>66,67</sup>

This is why we need Medicare negotiations. We cannot simply continue to allow drug corporations to set prices as high as they think they can get away with.

The Medicare negotiation bill in the House — H.R. 3 — and reportedly the bill being developed in the Senate Finance Committee won't only allow Medicare to negotiate, it also includes other common-sense solutions to fix our drug pricing system that have enjoyed bipartisan support. It would penalize companies that hike the prices of Part B and D drugs faster than the rate of inflation. It would limit annual out-of-pocket costs for Medicare beneficiaries so patients like me wouldn't have to spend upwards of \$18,000 a year for a single prescription. But we cannot lower out-of-pocket costs without lowering prices, or patients, consumers, and taxpayers will wind up absorbing the high list price through higher premiums, higher taxes, or less money in their paychecks.

<sup>64</sup> Herman, B. (2021, June 8). Aduhelm's price to squeeze Medicare and patients. *Axios*.

<https://www.axios.com/aduhelm-biogen-drug-price-medicare-44628ff-6564-453f-9e01-2b04e80ff8f2.html>

<sup>65</sup> Koma, W., Neuman, T., Jacobson, G., & Smith, K. (2020, April 24). Medicare Beneficiaries' Financial Security Before the Coronavirus Pandemic. *Kaiser Family Foundation*.

<https://www.kff.org/medicare/issue-brief/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic/>

<sup>66</sup> Bulik, B.S. (2021, May 14). Celeb-backed Alzheimer's Association campaign aims to build grassroots support for Biogen's aducanumab ahead of FDA decision. *Fierce Pharma*.

<https://www.fiercepharma.com/marketing/alzheimer-s-association-campaign-more-time-supports-biogen-s-aducanumab-awaiting-fda>

<sup>67</sup> Higgins-Dunn, N. (2021, June 14). Biogen's \$56K price on Aduhelm 'simply unacceptable,' Alzheimer's Association says after vouching for FDA approval. *Fierce Pharma*.

<https://www.fiercepharma.com/pharma/biogen-s-56k-price-tag-for-aduhelm-simply-unacceptable-and-needs-fixed-alzheimer-s>



The legislation in the House is estimated to save the federal government over \$450 billion dollars.<sup>68</sup> We don't know yet the savings that might be generated by a new bill being written in the Senate Finance Committee. Whatever the number, we can put those savings to work in a variety of important ways.

Big Pharma claims using these savings to address other critical needs is tantamount to using the industry as a "piggy bank".<sup>69</sup> But in reality, it is pharma that has treated patients and taxpayers as piggy banks for years — raising prices at will to hit profit targets and trigger executive bonuses.<sup>70</sup>

Pharma is absolutely right about one thing: America does have other priorities. We don't have unlimited resources and we can only spend a dollar once, and every dollar we send to pharma in unjustified profits — or "rents," as economists like to call them — is a precious dollar we don't have to tackle other urgent needs. It's a dollar we don't have to reduce health care disparities, provide coverage to the uninsured, or increase funding for research on new drugs based on public health needs instead of private profit seeking.

That's why it is so important that H.R. 3 directs a portion of the savings to the NIH to fund the very innovation pharma claims will come to a halt if we rein in prices. We hope that legislation under consideration in the Senate will do the same.

It's no surprise that Medicare negotiation is so popular, with 90 percent of Americans saying they support the policy.<sup>71</sup> That includes overwhelming majorities from both political parties.

Increasingly, employers support government intervention to limit the prices of drugs. In a recent survey of employers with more than 5,000 employees, almost 4 in 10 said they somewhat or strongly agreed that the government should negotiate lower drug prices; only three percent disagreed.<sup>71</sup>

Medicare negotiation is a solution with massive bipartisan support among the American people. It is time for Congress to finally pass it into law.

## ***Section VII: Conclusion***

<sup>68</sup> Congressional Budget Office. (2019, December 10). Budgetary Effects of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act. [https://www.cbo.gov/system/files/2019-12/hr3\\_complete.pdf](https://www.cbo.gov/system/files/2019-12/hr3_complete.pdf)

<sup>69</sup> Florko, N. (2021, April 13). PhRMA chief talks strategy — and he's surprisingly optimistic about drug pricing reform. *STAT*. <https://www.statnews.com/2021/04/13/phrma-chief-talks-strategy/>

<sup>70</sup> McAuliff, M. (2020, September 30). Sky-High Drug Prices Driven by Pharma Profits, House Dems Charge. *Kaiser Health News*. <https://khn.org/news/sky-high-drug-prices-driven-by-pharma-profits-house-dems-charge/>

<sup>71</sup> Claxton, G., Levitt, L., Gremminger, S., Kramer, B., & Rae, M. (2021, April 29). How Corporate Executives View Rising Health Care Cost and the Role of Government. Kaiser Family Foundation. <https://www.kff.org/report-section/how-corporate-executives-view-rising-health-care-cost-and-the-role-of-government-findings/>

Let's be clear: Big Pharma is not fighting for the interest of patients — it's fighting to maintain its unilateral power to dictate prices of brand-name drugs. Recently, the head of the trade association PhRMA affirmed that fact in a moment of candor. He said his industry is “particularly adept at ... rolling the tanks, if you will, to push back against policy proposals *adverse to the industry's interests*.”<sup>43</sup>

Of course, Big Pharma wants to disguise that truth. Instead, it blames others and distracts attention from its central role in making drugs unaffordable.

And it tries to scare us by saying that if we don't bend to its will, we won't get the drugs we need for the future. It poses questions like: How much would you pay to save a life?

And that's easy. When it's you or someone you love, the answer is anything. You'll empty your bank account, mortgage your home, cash out your 401k.

But that's the wrong question. We should be asking: *How do we restore balance to ensure we get the innovation we need at prices we can afford?*

One of our patients is Marcus LaCour from Ohio.<sup>72</sup> He's a husband, a father, and a minister. He is also a person with type 1 diabetes. Since he was diagnosed in high school, struggling to afford insulin has been a pattern in his life. He's been forced to rely on samples from his doctor, ration his insulin, or simply go without. In some of his hardest times, he rationed his insulin while his wife skipped meals to help pay for it. This should not happen in America.

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

All of you hold the power to fix this broken system. It's time to enact comprehensive reforms to make our system work for the people it is supposed to serve and lower prescription drug prices.

Thank you.

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<sup>72</sup> Patients For Affordable Drugs. (2021, April 5). *I've been forced to ration my insulin or simply go without*. <https://patientsforaffordabledrugs.org/2021/04/05/marcus-lacour-innovation/>

A Canary in the Coal Mine for the Failure of U.S. Competition Law:  
Competition Problems in Prescription Drug Market<sup>1</sup>

Michael Kades

Director, Markets and Competition Policy, Washington Center for Equitable Growth  
Subcommittee on Competition Policy, Antitrust, and Consumer Rights:  
Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Drug  
Markets  
July 13, 2021

Thank you, Chairwoman Klobuchar and Ranking Member Lee, for the opportunity to testify about the critical issues of competition and prescription drug markets. Antitrust is, to quote Sen. Klobuchar, “cool again.” The president’s executive order signed last Friday and his accompanying remarks are testament that we are in an antitrust moment as dramatic as any since 1914, when Congress passed the Clayton Act and created the Federal Trade Commission.

All too often in the press or on social media, competition and monopoly are synonymous with digital platforms. Without doubt, those markets raise important competition issues and deserve the attention that they are receiving. Market power and its abuse, however, extends across the U.S. economy.<sup>1</sup> This subcommittee should be commended for its investigation into market problems throughout the economy. The substantial antitrust reform proposals offered by both Chairwoman Klobuchar and Ranking Member Lee, respectively, reflect a judgment that the antitrust laws, as currently interpreted and enforced, are failing to protect competition.

The subcommittee is correct to examine competition in prescription drug markets. Prescription drugs cost nearly \$370 billion a year, forcing too many Americans to choose between their health and other necessities. Further, the impact is often borne by those least able to bear it: lower-income Americans and those from historically disadvantaged groups.

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<sup>1</sup> See, generally, Nancy L. Rose, “Opening Statement of Professor Nancy L. Rose,” Testimony before the Senate Judiciary Committee Subcommittee on Antitrust, Consumer Protection, and Consumer Rights, “Competition Policy for the Twenty First Century: The Case for Antitrust Reform,” March 11, 2021, available at <https://www.judiciary.senate.gov/meetings/competition-policy-for-the-twenty-first-century-the-case-for-antitrust-reform>; J. B. Baker and others, “Joint Response to the House Judiciary Committee on the State of Antitrust Law and Implications for Protecting Competition in Digital Markets,” April 30, 2020, available at <https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=rja&uact=8&ved=2ahUKEwiPhpf1itzxAhXUEIkFHZdRAZcQFjABegQIBBAD&url=https%3A%2F%2Fequitablegrowth.org%2Fwp-content%2Fuploads%2F2020%2F04%2FJoint-Response-to-the-House-Judiciary-Committee-on-the-State-of-Antitrust-Law-and-Implications-for-Protecting-Competition-in-Digital-Markets.pdf&usq=AOvVaw0TA1Os9olu1tf91QiHBMH>; Jonathan B. Baker, *The Antitrust Paradigm: Restoring a Competitive Economy* (Cambridge, MA: Harvard University Press, 2019); Fiona Scott Morton, “Reforming U.S. antitrust enforcement and competition policy” (Washington: Washington Center for Equitable Growth, 2020). On labor market power, see Suresh Naidu, Eric Posner, and E. Glen Weyl, “Antitrust Remedies for Labor Market Power,” *Harvard Law Review* 132 (2) (2018).

It is an important industry, and one that is rife with anticompetitive conduct. Although not the sole cause of high prescription drug costs, abusive practices that distort competition contribute to the problem. Too many companies exclude competition through a variety of anticompetitive tactics, including rebate traps, product hopping, sham litigation, citizen petition abuse, and pay-for-delay patent settlements.

Anticompetitive activity is prevalent for two related reasons. First, the economic dynamics of prescription drug markets make anticompetitive conduct both uniquely effective and profitable. Second, the courts have increasingly stripped the antitrust laws of their potency. As a result, too often, anticompetitive conduct escapes condemnation. Rather than deterring anticompetitive conduct, the antitrust laws, as currently interpreted by the courts, almost invite it.

It would be wrong, however, to think anticompetitive conduct and market power are uniquely a prescription drug market phenomenon. Rather, prescriptions drug markets, where these problems have existed for decades, were the canary in the coal mine. We are seeing similar problems across the economy, including in agricultural markets, digital markets, and labor markets. Although the competitive dynamics and potential anticompetitive conduct differs across industries, one common thread exists. The antitrust laws, as enforced and interpreted, do not sufficiently deter anticompetitive conduct. As the letter to the House Judiciary Committee that I signed with 11 other economists and lawyers explains: “current antitrust doctrines are too limited to protect competition adequately, making it needlessly difficult to stop anticompetitive conduct in digital markets.”<sup>2</sup> The same judgment applies to prescription drug markets and many others.

As Equitable Growth’s antitrust transition report explains, “Without new legislation, the agencies can still address these issues, but the task will be more challenging and take far longer.”<sup>3</sup> The courts have made it clear that they believe the antitrust laws have, at most, a limited role in protecting competition because the market can fix itself. And, therefore, do no harm is the prevailing approach. Unless Congress takes a different view by passing legislation, dominant firms will have little concern about the antitrust laws limiting their conduct.

For prescription drug markets, there are two broad types of reform. Congress can restore the vitality of antitrust laws generally, which will, when combined with vigorous enforcement, deter much of the anticompetitive conduct occurring in prescription drug markets and in other industries. Current economic research strongly supports such reforms. The Competition and Antitrust Law Enforcement Reform Act would address most of these problems.

Second, certain problems that are unique to pharmaceutical markets may require specific legislation, as the CREATES Act effectively eliminated two specific anticompetitive strategies

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<sup>2</sup> Baker and others, “Joint Response to the House Judiciary Committee on the State of Antitrust Law and Implications for Protecting Competition in Digital Markets.”

<sup>3</sup> Bill Baer and others, “Restoring competition in the United States: A vision for antitrust enforcement for the next administration and Congress” (Washington: Washington Center for Equitable Growth, 2020), available at [https://equitablegrowth.org/research-paper/restoring-competition-in-the-united-states/?longform=true#promoting\\_competition\\_as\\_a\\_federal\\_government\\_priority](https://equitablegrowth.org/research-paper/restoring-competition-in-the-united-states/?longform=true#promoting_competition_as_a_federal_government_priority).

that delayed lower-cost, generic competition.<sup>4</sup> Existing legislation—such as the Preserve Access to Affordable Generics and Biosimilars Act, which addresses pay-for-delay patent settlements; the Stop STALLING Act, which addresses abuse of the Food and Drug Administration’s citizen petition process, and the Affordable Prescriptions for Patients through Promoting Competition Act, which would address product hopping and patent thickets—are examples of this approach.

Stopping anticompetitive conduct has the additional advantage that it is unlikely to deter innovation. As Competition itself drives innovation. In contrast, anticompetitive conduct often spurs rent-seeking activity. In pharmaceutical markets, weak antitrust enforcement may encourage companies to engage in minor product development as a tool to exclude competition.<sup>5</sup> Although policy makers should consider the trade-off that can occur between lower costs and promoting innovation, effective antitrust laws should avoid that choice and lead to lower costs and increased innovation.

The remainder of statement discusses why prescription drug costs matter, the nature of competition in these markets, the prevalence of anticompetitive conduct, the failure of antitrust to deter such conduct, and proposals for address these problems.

#### **A. Why prescription drug costs matter**

In 2019, the United States spent almost \$370 billion on prescription drugs, accounting for roughly \$1 out of every \$10 spent on healthcare.<sup>6</sup> Prescription drug costs are not just a pocketbook issue.<sup>7</sup> When prescription drugs are unaffordable, it affects the patient, not just her pocketbook. Twenty-nine percent of people report not taking their medicines as prescribed at some point in the past year because of the cost, which rises to 35 percent of people with household incomes of less than \$40,000. Across the country, people are making choices about which medicines they can afford or are choosing between life-saving drugs and necessities such as food or rent.<sup>8</sup>

The burden of prescription drug costs disproportionately affects lower-income Americans and historically disadvantaged groups. Prior to the pandemic, 25 percent of White Americans

<sup>4</sup> Michael Kades, “The CREATES Act Shows legislation can stop anticompetitive pharmaceutical industry practices” (Washington: Washington Center for Equitable Growth, 2021), available at <https://equitablegrowth.org/the-creates-act-shows-legislation-can-stop-anticompetitive-pharmaceutical-industry-practices/>.

<sup>5</sup> For an example, see the discussion on product hopping, *infra*.

<sup>6</sup> See Center for Medicare and Medicaid Services, “National Health Expenditure by type of service and source of funds. CY 1960-2019” (n.d.), available at <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nationalhealthaccounts/historical.html>.

<sup>7</sup> Ashley Kirzinger and others, “KFF Health Tracking Poll – February 2019: Prescription Drugs” (San Francisco: Kaiser Family Foundation, 2019), available at <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>.

<sup>8</sup> Patients for Affordable Drugs and its founder, David Mitchell, have put a human face on this issue by collecting and publishing the stories of individuals bearing the burden of high-cost prescription drugs See “Featured Stories, available at <https://p4ad-main.friends.landslide.digital/our-stories/> (last accessed July 12, 2021).

said they do not take prescriptions due to costs, compared to 30 percent of Black Americans.<sup>9</sup> In a 2019 AARP survey, 48 percent of Hispanic/Latinx respondents said they did not fill prescriptions provided by their doctor, the main reason being cost. Twenty-seven percent of Latinx respondents said that they cut back on necessities such as food, fuel, and electricity to be able to afford a prescription drug.<sup>10</sup>

## **B. The nature of competition in pharmaceutical markets creates incentives to delay and prevent competition**

Prescription drugs fall into two broad categories. The more traditional and common ones are called small molecule drugs (ibuprofen, antibiotics, etc.). A newer but growing category is biologics, which are protein-based and derived from living matter or manufactured in living cells using recombinant DNA biotechnologies (Humira).<sup>11</sup> Critically, price competition, whether for small molecule drugs or biologics, comes from a limited set of potential competitors. And the incentives to prevent that competition are large.

### **1. Generic competition for small molecule drugs**

The impact of the Hatch-Waxman Act on competition for small molecule drugs cannot be overstated. Prior to its passage, few generics were available. Today, generic competition has a dramatic impact. A generic product, on average, captures 90 percent of the market within a year of entering the market,<sup>12</sup> and the branded company's profits plummet.

Simply delaying generic competition can be very profitable. Generic competition leads to substantial price decreases. Eventually those prices fall to roughly 15 percent of the branded price.<sup>13</sup> While generic companies earn profits, the big winners are consumers, who end up receiving the same therapeutic benefit at a far lower cost. Conversely delaying or preventing that competition is profitable for the branded company.

### **2. Biosimilar competition for biologics**

Biologics drugs such as Humira represent an increasingly large portion of prescription drug costs. Currently, the biologic market is more than \$210 billion.<sup>14</sup> They offer great promise

<sup>9</sup> Tomi Fadeyi-Jones and others, "High Prescription Drug Prices Perpetuate Systemic Racism. We Can Change It" (Washington: Patients for Affordable Drugs Now, 2020), available at <https://patientsforaffordabledrugsnow.org/2020/12/14/drug-pricing-systemic-racism/>.

<sup>10</sup> AARP, "2019 Prescription Drug Survey – Hispanic/Latino Likely Voters" (2019), available at [https://www.aarp.org/content/dam/aarp/research/surveys\\_statistics/health/2019/hispanic-latino-voters-prescription-drug-survey-fact-sheet.doi.10.26419-2Fres.00295.004.pdf](https://www.aarp.org/content/dam/aarp/research/surveys_statistics/health/2019/hispanic-latino-voters-prescription-drug-survey-fact-sheet.doi.10.26419-2Fres.00295.004.pdf).

<sup>11</sup> Federal Trade Commission, "Emerging Health Care Issues: Follow-on Biologic Competition" (2009), available at [www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf](http://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf).

<sup>12</sup> U.S. Department of Health and Human Services, "Some Observations Related to the Generic Drug Market" (2015), available at [https://aspe.hhs.gov/system/files/pdf/139331/ib\\_GenericMarket.pdf](https://aspe.hhs.gov/system/files/pdf/139331/ib_GenericMarket.pdf).

<sup>13</sup> Ibid.

<sup>14</sup> IQVIA Institute, "Biosimilars in the United States" (2020), available at <https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024>.



in combating debilitating and rare diseases.<sup>15</sup> But they tend to be very expensive, costing patients tens, or even hundreds, of thousands of dollars per year.

In biologic markets, price competition to a branded product comes from a biosimilar product. Like generic small molecule products, biosimilars have no clinically meaningful difference from the corresponding biologic drug.<sup>16</sup> Biosimilar drugs, however, are more expensive to develop than generic small molecule products, and they require more testing. Experts expect that biosimilar production would be priced at less of a discount and achieve a lower level of market penetration than generic small molecule drugs.<sup>17</sup> With many biologics having high prices and large revenues—in 2020, Humira sales exceeded \$16 billion<sup>18</sup> and Keytruda (an oncology treatment) exceeded \$14 billion<sup>19</sup>—biosimilar competition can save hundreds of millions of dollars per year per drug even if the biosimilar product is priced at a modest discount (25 percent) and gains only a modest share (30 percent).

That competitive dynamic for biosimilars is more complicated than for small molecule generic drugs because there are many decision-makers and overlapping legal and regulatory structures. Successful competition means the product has obtained approval from the Food and Drug Administration, the product has a preferred status on the insurer's formulary, and a doctor, who has little or no financial incentive, has prescribed it. If competition breaks down at any point in that chain, prescription drug costs increase.

### **C. Anticompetitive conduct in prescription drug markets is both prevalent and persistent**

Anticompetitive conduct in prescription drug markets is both prevalent and persistent. Even in areas where antitrust enforcement has had moderate success, such as with pay-for-delay settlements, it has taken more than a decade, the success is fragile, and it requires substantial resources. In other areas, antitrust enforcement has been less successful at stopping anticompetitive conduct at all.

The list of anticompetitive conduct is large; here, I discuss three types of common practices.

#### *1. Rebate traps*

A rebate trap can effectively deter competition or limit its impact in pharmaceutical markets, particular biologic ones. Pharmaceutical companies give pharmacy benefit managers

<sup>15</sup> BIO, "What is Biotechnology" (n.d.), available at <https://www.bio.org/what-biotechnology>.

<sup>16</sup> U.S. Food and Drug Administration, "What is a Biosimilar?" (n.d.), available at <https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM585738.pdf>.

<sup>17</sup> Federal Trade Commission, "Emerging Health Care Issues: Follow-on Biologic Drug Competition."

<sup>18</sup> Kevin Dunleavy, "Special Reports: Humira" (New York: Fierce Pharma, 2021), available at <https://www.fiercepharma.com/special-report/top-20-drugs-by-2020-sales-humira>

<sup>19</sup> Merck and Co. Inc., "Financial Highlights Package Fourth Quarter 2020" (2021), p.9, available at [https://mms.businesswire.com/media/20210204005437/en/857100/1/Final~Financial\\_Highlights\\_Package\\_01272021.pdf?download=1](https://mms.businesswire.com/media/20210204005437/en/857100/1/Final~Financial_Highlights_Package_01272021.pdf?download=1).

(companies that manage drug benefits for insurers) rebates for a preferred status on the formulary. It might seem like a larger rebate means lower prices. Sometimes it does, but not always. Facing biosimilar competition, the incumbent company can raise its list price, increase its rebate, and make it dependent on market share (say, 95 percent). If the share of the incumbent biologic falls below that, the PBM receives no rebate and must reimburse the incumbent based on the list price for all units. Alternatively, the incumbent can offer a bundled discount across a range of products, which the new entrant cannot match.

The strategy can harm competition in at least three ways. First, there can be a large installed base. For example, 80 percent of patients are unwilling to switch to a new product because they are on a long-term regime. In principle, a new product should be able to compete for the other 20 percent of the market. Even if the new product is less expensive, however, the PBM may be worse off because it loses the rebate for the 80 percent of the market that will not shift. More generally, particularly with biosimilar products, it may take time for doctors and patients to become comfortable with a new product. Finally, the incumbent could be sharing its monopoly rents with the PBM. The economic theory is well-accepted.<sup>20</sup>

Questionable rebates are common in prescription drug markets. According to a Senate staff report, rebating “appears to be contributing to both increasing insulin WAC prices and limited uptake of lower-priced products.”<sup>21</sup> Mylan Pharmaceuticals used rebating to combat lower-prices competition to its Epipen product, which treats severe allergic reactions. Rebates may also explain why significantly less-expensive biosimilar versions of Remicade had difficulty gaining traction in the market.<sup>22</sup>

Notably, courts have struggled with this rebate trap. In the Epipen antitrust case, for example, the District Court granted the defendant’s summary judgment motion and dismissed the antitrust case. It did so, even though it agreed that the plaintiff could prove the following at trial: Epipen had a monopoly. Mylan Pharmaceuticals, the manufacturer of Epipen, and Sanofi, the manufacturer of the competing product, both expected Sanofi’s product to gain 30 percent or more of the market within 3 years. Instead, Mylan, through a rebate trap, prevented Sanofi’s success while increasing both Epipen’s net price and profits.<sup>23</sup> If proven, those facts are the very definition of exclusionary conduct.

<sup>20</sup> See Fiona Scott Morton and Zachary Abrahamson, “A Unifying Analytical Framework for Loyalty Rebates,” *Antitrust Law Journal* 81 (3) (2017): 777–836; Gianluca Faella, “The Antitrust Assessment of Loyalty Discounts and Rebates,” *Journal of Competition Law and Economics* 4 (2) (2008): 375–410, available at <https://ssrn.com/abstract=1146721>.

<sup>21</sup> U.S. Senate Finance Committee, “Insulin: Examining the factors driving the rising cost of a century old drug” (n.d.), p.66, available at [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf). WAC is the wholesale acquisition cost.

<sup>22</sup> Ronny Gal and Sanford Bernstein, “Biosimilars (June update): Market growth moderating as pricing offsets unit growth and innovators compete” (U.S. Biopharmaceuticals, 2021), ex. 3.

<sup>23</sup> See, generally, Brief for the American Antitrust Institute, *Sanofi-Aventis v. Mylan*, No. 21-3005, 10th Cir., June 4, 2021, available at <https://www.antitrustinstitute.org/wp-content/uploads/2021/06/TSAC-AAI-No.-21-3005.pdf>.



## 2. *Product hopping*

Product hopping is another anticompetitive tactic used to prevent or delay competition. A branded company makes a small change to its product shortly before a generic competitor enters. For example, the new product might be a different form of the medication (switching from tablet to capsule), different dose, or a once-a-day version of the product. It then takes a range of actions to move the franchise from the old product to the new, tweaked product. At the most aggressive, it can withdraw the original product from the market. Less draconian tactics can be just as effective. The company could increase the price of the original product well above the price of the new product. It could tell doctors the original product is not safe or has worse side effects.

Why would a company disparage and disadvantage its own product? The answer lies in the dynamics of pharmaceutical competition. A pharmacist can fill a prescription for a branded product with a bioequivalent generic. That is why a branded product loses share so quickly to its generic alternative. But the generic of the original product is not bioequivalent to the new version. Therefore, there is no substitution, and the branded company maintains its sales. According to one study, product hopping on just five products increased prescription drug costs by \$4.7 billion a year.<sup>24</sup>

In an industry that prides itself on taking risks to develop life-saving drugs, product hopping is the opposite. The modifications are minor and involve little risk of value, but they provide little value to the patients. One need look no further than Asacol, a product used to treat ulcerative colitis, a chronic disease of the colon. As part of a product hop, Allergan, the manufacturer, put an Asacol tablet inside of a capsule and obtained approval for a new product, Delzicol. That is not innovation; it is just anticompetitive gaming of the system.

## 3. *Pay-for-delay patent settlements*

Even when antitrust enforcement has had success, it is incomplete. A pay-for-delay patent settlement occurs when a branded company pays the generic or biosimilar company to delay launching its competitive product. The settlement eliminates the potential for competition. Both the branded and generic company profit at the expense of consumers.

The antitrust battle over these settlements has raged for roughly two decades. In a series of decisions that began in 2003, various courts concluded that this practice was acceptable.<sup>25</sup> In these courts' view, the fact that the branded company's patent might exclude the generic meant that the branded company could pay the generic not to compete for any period of time until the patent expired.

<sup>24</sup> Alex Brill, "The Cost of Brand Drug Product Hopping" (Washington: Matrix Global Advisors, 2020), available at <https://www.affordableprescriptiondrugs.org/app/uploads/2020/09/CostofProductHoppingSept2020-1.pdf>.

<sup>25</sup> *Federal Trade Commission v. Watson Pharms., Inc.*, 877 F.3d 1298 (11th Cir. 2012); *Ark. Carpenters Health and Welfare Fund v. Bayer AG*, 544 F.3d 1323 (Fed. Cir. 2008) *In re Tamoxifen*, 466 F.3d 187 (2nd Cir. 2005); *Valley Drug Co. v. Geneva Pharms.*, 344 F. 3d 1294 (11th Cir. 2003).

These rulings had a devastating impact on generic competition. The number of potential pay-for-delay deals with significant payments increased from zero in fiscal year 2004 to a high of 33 in fiscal year 2012.<sup>26</sup> The deals increased prescription drug costs by \$63 billion.<sup>27</sup>

In 2013, in the *Androgel* case (*FTC v. Actavis*), the Supreme Court rejected the lenient view that patent holders could simply pay potential infringers to stay off the market. According to the Supreme Court, an agreement in which the branded and generic companies eliminate potential competition and share the resulting monopoly profits likely violates the antitrust laws, absent some justification.<sup>28</sup> The Supreme Court's decision has limited pay-for-delay deals. In fiscal year 2017, the most recent year of reported data, the number of potential pay-for-delay deals with significant payments fell to three.<sup>29</sup>

That success has been incomplete, and it overlooks the cost of enforcement. The Supreme Court approach requires a case-by-case analysis of a practice that virtually always is anticompetitive. That allows companies to find new ways to hide compensation or offer a plethora of alternative justifications for their conduct. Based on the past mistakes and some open hostility to the Supreme Court's decision, courts could accept one of these defenses and create a costly loophole.

Further, the approach is resource intensive. Indeed, the FTC resolved the *Androgel* case itself almost 6 years after the Supreme Court decision allowing the case to go forward and more than a decade after the case was filed. The FTC continues to litigate multiple cases against the same parties over the same product.<sup>30</sup>

#### **D. Failure of antitrust law**

Anticompetitive conduct in prescription drug markets has been occurring for decades and has flourished despite the Federal Trade Commission having devoted substantial resources to trying to stop the conduct. It regularly litigates to judgment to stop egregious anticompetitive conduct with only limited success. The obstacles to successful enforcement are likely to increase because the Supreme Court has taken away the FTC's ability to seek monetary remedies.

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<sup>26</sup> Federal Trade Commission, "Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003" (2020), available at <https://www.ftc.gov/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-10>.

<sup>27</sup> Michael Kades, "Competitive Edge: Underestimating the cost of underenforcing U.S. antitrust laws" (Washington: Washington Center for Equitable Growth, 2019), available at <https://equitablegrowth.org/competitive-edge-underestimating-the-cost-of-underenforcing-u-s-antitrust-laws/>.

<sup>28</sup> *Federal Trade Commission v. Actavis*, 570 US 136, 158 (2013).

<sup>29</sup> Federal Trade Commission, "Emerging Health Care Issues: Follow-on Biologic Competition."

<sup>30</sup> Federal Trade Commission, "FTC Again Charges Endo and Impax with Illegally Preventing Competition in U.S. Market for Oxycodone ER," Press release, January 25, 2021, available at <https://www.ftc.gov/news-events/press-releases/2021/01/ftc-again-charges-endo-impax-illegally-preventing-competition-us>.

We are in this situation because “antitrust enforcement faces a serious deterrence problem, if not a crisis.”<sup>31</sup> Judicial decisions have contributed to this problem. They “have thrown up inappropriate hurdles that limit the practical scope of the antitrust laws’ application to anticompetitive exclusionary conduct, including monopolization, and to anticompetitive mergers.”<sup>32</sup> These developments make it less, not more, likely that antitrust law will condemn harmful conduct.

### 1. *Hostility to direct evidence of market power*

In most antitrust cases, the plaintiff must prove that the defendant had market or monopoly power. A plaintiff can infer it by proving the relevant market and establishing that the defendant has a high market share. The alternative is to prove the actual anticompetitive effect of the conduct—such as higher prices, lower quality, and lower output.<sup>33</sup> As the Supreme Court explains, “proof of actual detrimental effects, such as a reduction of output can obviate the need for an inquiry into market power, which is but a surrogate for detrimental effects.”<sup>34</sup>

Courts, however, increasingly shy away from direct effects evidence, making plaintiffs go through the often pedantic process of defining markets, particularly in pharmaceutical cases. Invariably, the impact of delaying or limiting competition is obvious. Delaying a generic or biosimilar competitor prevents prices from falling. That should end the market power inquiry. Courts, however, reject the obvious direct evidence for the less reliable market definition evidence.

In *Mylan Pharms. Inc. v. Warner Chilcott*, the court ignored the substantial impact generic competition would have on pricing. Instead, it relied on its own assessment of the qualitative similarities between the product at issue and other branded products. It defined the relevant market to include many products and found that the defendant’s market share was too small to establish market power.<sup>35</sup> Even when the court reaches the right result using the wrong methodology, it unnecessarily complicates the case and increases the cost of litigation.<sup>36</sup>

### 2. *Leniency toward dominant firms*

In various ways, courts over the past four decades have limited the role of antitrust law in regulating conduct by dominant firms. A series of policy judgments have driven this development. Courts too often believe that monopolies spur innovation and discount the value of potential competition. Judicial doctrine reflects these policy choices. Courts are highly skeptical of refusals to deal and predatory pricing, even though modern economics establishes that such

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<sup>31</sup> Baer and others, “Restoring competition in the United States: A vision for antitrust enforcement for the next administration and Congress.”

<sup>32</sup> *Ibid.*

<sup>33</sup> *Federal Trade Commission v. Indiana Federation of Dentists*, 476 U.S. 447 (S.Ct. 1986).

<sup>34</sup> *Ibid.*, pp. 460–61.

<sup>35</sup> *Mylan Pharms., Inc. v. Warner Chilcott*, 838 F.3d 421 (3rd Cir. 2016).

<sup>36</sup> *Federal Trade Commission v. Abbvie, Inc.*, 976 F.3d 327 (2020).

conduct can be successful in limiting competition and profitable.<sup>37</sup> Exacerbating this tendency, courts often focus on the wrong facts.

These developments help explain why antitrust enforcement has struggled to stop anticompetitive conduct in prescription drug cases. In loyalty rebate cases, courts focus on issues such as whether the rebates increased and whether the practice eliminated competition completely, not whether the rebates allow the defendant to maintain its monopoly power by limiting competition. In product hopping cases, too often courts accept any proffered justification to dismiss the case, ignoring the obvious anticompetitive incentive and impact.<sup>38</sup> In the pay-for-delay context, the fact that the eliminated competition was potential or uncertain led many courts to discount the harm.

One doctrine, refusals to deal, or when a firm refuses to deal with its competitor, deserves special mention. According to some courts, a refusal to deal can violate the antitrust laws only if the defendant has terminated an existing relationship. Under that standard, it is at least questionable whether the government would have been successful in breaking-up AT&T's phone monopoly in the 1980s.<sup>39</sup> This development should shock anyone who supports free markets and competition.

It also helps explain the rise of an anticompetitive strategy in prescription drugs. Some branded companies would prevent their potential generic competitors from obtaining samples of the branded product. Without those branded samples, the generic company could not conduct the tests necessary for approval. Members of the Senate Judiciary Committee identified the problem and introduced legislation, the CREATES Act, to solve the problem, which it did.<sup>40</sup> If the courts had not whittled away the restrictions on monopolists' refusing to deal with competitors, however, the practice may have never arisen.

### 3. *Weaker deterrence*

Federal government antitrust enforcers have limited options to address the harm caused by anticompetitive activity, which is particularly problematic in prescription drug markets. The rewards are large. Delaying competition by a single year can generate hundreds of millions (and potentially billions) of dollars in additional revenue. If the government's only remedy is an order forbidding the defendant from repeating the conduct, violating the law has little downside.

A recent Supreme Court decision exacerbated this dynamic. The Court determined that the Federal Trade Commission lacks the authority to seek monetary remedies for violations of the law. The FTC can not seek to compensate victims or deprive companies of the profits they earned by violating the law.<sup>41</sup> This development will simply encourage pharmaceutical

<sup>37</sup> For a discussion of these issues, see Baker and others, "Joint Response to the House Judiciary Committee on the State of Antitrust Law and Implications for Protecting Competition in Digital Markets."

<sup>38</sup> *Mylan Pharms., Inc. v. Warner Chilcott*, 838 F.3d 421 (3rd Cir. 2016).

<sup>39</sup> Howard Shelanski, "The Case for Rebalancing Antitrust and Regulation," *Michigan Law Review* 109 (5) (2011).

<sup>40</sup> Kades, "The CREATES Act shows legislation can stop anticompetitive pharmaceutical industry practices."

<sup>41</sup> *AMG Capital Management v. Federal Trade Commission*, 144 S. Ct. 1341 (2021).

companies to adopt profitable, anticompetitive tactics that will further increase prescription drug costs.

### **E. Proposals to restore effective antitrust enforcement**

The courts have made antitrust enforcement too difficult, although not impossible, and prescription drug markets are a prime example. The question for this committee and Congress is whether to accept the approach the courts have taken. Congress can correct these errors, restore the vitality of the antitrust laws, and deter anticompetitive conduct, which would inject competition into prescription drug markets. Two types of reforms exist: general antitrust proposals and laws tailored specifically to prescription drug markets.

#### *1. General antitrust reforms*

There are broad principles Congress should enshrine to improve antitrust enforcement. First, direct evidence of anticompetitive effect should be sufficient for an antitrust case. Second, Congress can correct courts' willingness to defer to dominant firms' conduct by changing legal standards to stress that the risk of eliminating potential competition can violate the antitrust law. Congress should establish legal rules that, in appropriate cases and based on sound economics, require defendants to prove their conduct does not harm competition, and new legislation should nullify existing precedents that inappropriately limit antitrust law, such as precedents on refusal to deal and predation. Finally, Congress should restore the FTC's authority to seek monetary remedies and give the government the ability to obtain civil fines for antitrust violations.<sup>42</sup>

Existing legislative proposals would address these issues. The Competition and Antitrust Law Enforcement Reform Act takes precisely this approach and would dramatically improve competition in prescription drug markets in particular, and throughout the economy generally.<sup>43</sup> Although more limited, the Tougher Enforcement Against Monopolists Act would increase penalties, limit courts' ability to rely on speculative justifications, and would require courts to find a violation where there is direct evidence of intent to harm competition.<sup>44</sup>

#### *2. Pharmaceutical-specific reforms*

As the CREATES Act establishes, targeted solutions can be effective. A number legislative proposals are pending. Although the current Supreme Court rule on pay-for-delay settlements protects competition better than the lower courts had, it still has required the FTC to

<sup>42</sup> In this statement, I am focusing on reforms that would improve competition in the prescriptions drug markets. There are other reforms discussed in Baker and in Baer that would address problems in other areas such as monopsony. For a more detailed discussion, see Baker and others, "Joint Response to the House Judiciary Committee on the State of Antitrust Law and Implications for Protecting Competition in Digital Markets." See also Baer and others, "Restoring competition in the United States: A vision for antitrust enforcement for the next administration and Congress."

<sup>43</sup> *Competition and Antitrust Law Enforcement Reform Act of 2021*, S. 225, 117th Cong. 1st sess. (2021), available at [https://www.klobuchar.senate.gov/public/\\_cache/files/e/1/e171ac94-edaf-42bc-95ba-85c985a89200/375AF2AE4F2AF97FB96DBC6A2A839F9.sil21191.pdf](https://www.klobuchar.senate.gov/public/_cache/files/e/1/e171ac94-edaf-42bc-95ba-85c985a89200/375AF2AE4F2AF97FB96DBC6A2A839F9.sil21191.pdf).

<sup>44</sup> *Tougher Enforcement Against Monopolists Act*, S. 2039, 117th Cong. 1st sess. (2021), available at [https://www.lee.senate.gov/public/\\_cache/files/23028e91-a982-43d0-9324-f6849c7522fc/hen21863.pdf](https://www.lee.senate.gov/public/_cache/files/23028e91-a982-43d0-9324-f6849c7522fc/hen21863.pdf).

spend substantial resources to prevent clearly anticompetitive conduct. Congress should pass legislation that creates a strong presumption against pay-for-delay deals such as the Preserve Access to Affordable Generics Act. Not only would such legislation stop the practice, but it would also free up resources so that the FTC could investigate and challenge other anticompetitive activity in the pharmaceutical industry. Other specific legislation could address patent thickets, where a company accumulates substantial patents for the purposes of blocking entry, citizen petition abuse, and product hopping.

### **Conclusion**

Anticompetitive conduct in pharmaceutical markets is a serious problem that increases costs and undermines healthcare, particularly for the most vulnerable in society. The competition problems in these markets flow, in substantial part, from four decades of judicial decisions that have enfeebled the antitrust laws. Prescription drug markets were one of the first areas to feel the effects of this development, but more industries are exhibiting similar problems. Congress needs to stem the tide of anticompetitive conduct by restoring the vitality of the antitrust laws.

Thank you for the opportunity to testify about this important question, and I am happy to answer any questions.



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July 13, 2021

Testimony by

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Before a hearing of the Committee on the Judiciary  
Subcommittee on Competition Policy, Antitrust, and Consumer Rights

*A Prescription for Change: Cracking Down on Anticompetitive Conduct  
in Prescription Drug Markets*

#### Introduction

Chairwoman Klobuchar, Ranking Member Lee and esteemed members of the committee, my name is Rachel Moodie and I am the vice president for Biosimilars Patents and Legal for Fresenius Kabi, a health care company that specializes in injectable medicines, biosimilars and medical technologies. Thank you for the opportunity to address the subcommittee today about this important issue.

Fresenius Kabi employs more than 4,000 people in the United States with key domestic manufacturing, research and development, and distribution centers in Illinois, Nevada, North and South Carolina, New York, Pennsylvania, and Wisconsin.

Fresenius Kabi specializes in bringing affordable, off-patent medicines to patients with critical and chronic conditions. During the pandemic, our injectable medicines were used routinely to treat patients in ICUs and several of our medicines and devices are currently held in the U.S. strategic national stockpile. A product of ours is also used in the injection process for COVID-19 vaccines. A fair and balanced patent and rebate system is critical to being able to continue this lifesaving work and reforms are needed to realize the many benefits of a new class of drugs known as biosimilars. We have already introduced biosimilars in Europe and Canada, turning the promise of effective and affordable biologic therapies into reality for many patients. And we are working to bring high-quality biosimilars to the United States as well.

#### Misusing Patents to Maintain Monopolies

A balanced patent system provides branded drug companies with time to recoup their investments and to fund the next generation of innovative drugs before biosimilars come to market. However, Fresenius Kabi has experienced a system shift whereby branded drug companies have misused patents and rebate schemes to maintain monopolies over drugs for 20 years or more, long after such drugs are considered innovative. This hurts patient access

**Fresenius Kabi**  
**Page 2**

to more affordable treatments and stresses payment systems that must be kept solvent to allow for true innovation.

**Higher Costs for Patients**

Prolonged monopolies exacerbate rebating practices and intensify already mis-aligned incentives to health plans and pharmacy benefit managers (PBMs) by extending the number of plan years a rebate and list price can grow before lower cost competition enters the market. This sustains and grows higher out-of-pocket costs for patients and increases the pressure for PBMs to prefer the higher cost branded product in order to maintain their rebate income rather than preferring the lower cost generic and biosimilar (these savings given to PBMs are not applied to patient out-of-pocket costs).

Thus far, the current policy debate around drug pricing has failed to address the root cause - numerous, but low-quality patents that do not provide true benefits to patients. We appreciate the committee's interest in tackling the root cause of the problem and addressing its negative impact on innovation and cost to consumers.

**The Root Cause: Patent Thickets**

Because of the misuse of so-called "patent thickets" and rebates as marketing tools, and the use of product hopping as an additional tool used to prevent competition, the U.S. branded pharmaceutical industry is not currently operating in a true free market system with downward pressure at the appropriate time. We urge Congress to take action now to preserve competition and reinstate market forces in the U.S. pharmaceuticals and biologics market.

I'd like to explain how it is possible to build a patent thicket to create an inappropriate monopoly. To be clear, Fresenius Kabi is in favor of the granting of truly innovative, high-quality patents.

Patent thickets comprise mostly secondary patents, which are those patents that are filed after the core drug patents are filed. Not all secondary patents are bad. However, the key to forming a patent thicket is to take each secondary patent (e.g., a weekly dosing regimen) and to multiply it by filing divisional/continuation patents (taking the same example: patent 1 claims dosing every 6-8 days; patent 2 claims dosing every 5-7 days, etc.). This results in a patent family containing multiple divisional/continuation patents having incrementally different claims. A hypothetical thicket may contain 10 patent families and each family may contain around 15 divisional/continuation patents, resulting in a thicket of 150 patents, all derived from just 10 original patent filings. However, the majority of these patents are those incremental divisional/continuation patents that do not typically provide new clinical benefits to patients.

I am not suggesting that **all** secondary patents are of low quality – the problem is that the sheer volume of patents, strategically, thicketed around a drug, shields most of the patents from scrutiny. Biosimilar companies do not have the funds or other resources to litigate scores of patents. Furthermore, courts cannot effectively litigate scores of patents in a single



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lawsuit. Challenging even a single patent at trial can cost tens of millions of dollars in litigation fees. A patentee only needs to succeed on a single claim of one patent to potentially delay generic and biosimilar medicines by many years.

How do we know some patents are of low quality? The patent system allows third parties, like Fresenius Kabi, to challenge the validity of a patent by filing an inter partes review or post grant review (IPR or PGR). Statistics from the U.S. Patent and Trademark Office (USPTO) show that in 2020 third-parties were successful in having their IPRs instituted against 56% of all patents that were challenged.<sup>1</sup> This suggests that more than half of the patents granted are of at least questionable quality.

Patent thickets can be created at a cost that is easily affordable to a branded pharmaceutical company (approximately \$25,000 to obtain and maintain a patent). Conversely it can cost as much as \$1 million to challenge a single patent via an IPR or PGR).<sup>2</sup> A biosimilar applicant cannot economically use IPRs or PGRs to clear a thicket that contains hundreds of patents. This is why building a patent thicket is a numbers game designed to shield patents, sidestep the scrutiny of IPRs and PGRs, and create an inappropriate monopoly.

Among the root causes of patent thickets are the examination procedures and incentives at the U.S. patent office that make it possible to grow large thickets around a single biological drug. The patent thicket trend around expensive biologic drugs appears to be specific to the United States. While we see scores of patents litigated against a single biosimilar in the U.S., we see low single digit numbers of patents litigated in Canada and Europe for corresponding molecules.

It is true that the U.S. is the innovation capital of the world, which is why a strong patent system is important, but we must be careful that the pendulum for encouraging innovation does not swing too far in an anti-competitive direction. A robust patent system must strike the right balance between encouraging development of new drugs and enabling access to affordable treatments for patients.

**Take Action to Reinstate Market Forces**

We request Congress to address the “numbers game” by tightening up the USPTO rules and regulations that currently permit an excess of continuation/divisional patents to be filed from a single patent filing. To address the USPTO rules that enable the granting of an army of divisional/continuation patents that have only incrementally different claim wording. We also request that a cap be instated to limit the number of patents that can be asserted against a biosimilar product.

Delayed competition, through inappropriate monopolies, allows rebates and list prices of branded drugs to grow unchecked and forces eventual biosimilar entrants to fight for market share in an environment where rebates perversely incentivize the prescribing of more expensive drugs. Inappropriate monopolies also allow branded drugs to develop sophisticated life cycle strategies thereby making the biosimilar irrelevant once it actually launches. Furthermore, patent thickets in the U.S. are discouraging development and launch of biosimilars of certain blockbuster biological drugs because of the dynamics I have

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described here today. While biosimilars of these drugs will eventually reach the U.S., it will be years after they are available in foreign markets.

In sum, we urge Congress to address the root cause of the drug pricing problem and look beyond policies in the jurisdiction of traditional health care entities. Instead, we urge Congress to put an end to inappropriately long patent monopolies and rebate schemes that reward prescribing high-priced drugs when lower-cost alternatives are available.

Thank you again for the opportunity to speak on behalf of my company, and on behalf of patients and physicians who benefit from access to affordable and essential medicines.

Respectfully submitted,

**Rachel Moodie, PhD**

Vice President, Biosimilars Patents and Legal  
Fresenius Kabi

TESTIMONY OF GEOFFREY LEVITT  
OF COUNSEL, CO-CHAIR, LIFE SCIENCES POLICY AND REGULATORY, DLA PIPER  
REPRESENTING PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA  
BEFORE THE SENATE JUDICIARY COMMITTEE

July 13, 2021

Chairwoman Klobuchar, Ranking Member Lee, and Members of the Committee, thank you for inviting me to participate in today's hearing. The robust competition that exists in today's biopharmaceutical marketplace is critical to both innovation and affordability, and I appreciate the opportunity to explore this topic with you in depth.

I am here today on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. The biopharmaceutical sector is one of the most research-intensive industries in the U.S. Since 2000, PhRMA member companies have invested more than \$900 billion in the search for new treatments and cures. In 2019 alone, PhRMA member companies invested \$83 billion in research and development (R&D), the highest level of investment on record.<sup>1</sup>

The incredible progress that the biopharmaceutical industry has made in the fight against COVID-19 is a reflection of the decades of private-sector investments in infectious disease, deep scientific and technical expertise, and strong intellectual property protections that have supported an unprecedented level of R&D investment as well as new levels of collaboration and coordination to get as many shots in arms around the globe as possible.

PhRMA appreciates the Committee's interest in opportunities to enhance competition in the health care marketplace. It is more critical now than ever that we advance thoughtful policies that continue to incentivize critically needed innovation while supporting a competitive marketplace. We support market-based solutions that will spur continued brand-to-brand, generic, and biosimilar competition while incentivizing medical advances critical to saving and improving patient lives. My comments provide context on the role of medicines in improving health outcomes for patients; the statutory frameworks that increase access to generic and biosimilar medicines while preserving incentives for innovation; antitrust remedies; the competitive marketplace for prescription medicines; the role and importance of IP rights to support innovation and foster competition through public disclosure of inventions; and several areas of market distortions in the health care marketplace.

At the outset, it's important to recognize how well competition has worked in the biopharmaceutical marketplace. Competition has shifted utilization from brand medicines to generics so successfully that 91 percent of all prescriptions for drugs are in the U.S. are currently filled with generic medicines. Robust brand to brand competition as well as competition from generics and biosimilars and other factors has resulted in prescription medicines accounting for just 14 percent of total health care spending over the past decade, even while many new, breakthrough treatments entered the market to help patients who previously had no therapeutic options.<sup>2</sup> In fact, net per capita spending on prescription medicines has remained effectively flat, increasing just 0.5 percent on average per year over the past 10 years.<sup>3</sup> On average, brand medicine net prices have increased in line with or below

the rate of inflation for the past five years; and last year, net prices for brand medicines *declined* by 2.9 percent on average.<sup>4</sup>

#### **Prescription Medicines are Transforming the Trajectory of Disease**

Prescription medicines play a central role in transforming the trajectory of many debilitating diseases, resulting in decreased death rates, improved health outcomes, and better quality of life for patients.

- *Cardiovascular disease:* Tremendous strides have been made against cardiovascular disease over the past 40 years, due in large part to advances in treatment. Since 1980 alone, the death rate from heart disease has declined by more than 50 percent.<sup>5</sup> And between 1980 and 2000, approximately two-thirds of the decline in coronary heart disease mortality, the most common type of heart disease, is attributable to medical therapies.<sup>6</sup>
- *HIV/AIDS:* Once considered acutely fatal, HIV/AIDS is now a chronic and manageable disease. This dramatic change followed the introduction of highly effective antiretroviral therapy in the mid-1990s, which transformed treatment and led to a 91 percent decline in death rates in the United States.<sup>7</sup> Between 2010 and 2017 alone, the death rate from HIV has declined by nearly half. Much of this decline CDC attributes to improvements in early diagnosis and helping people get on and stay on lifesaving treatment.<sup>8</sup>
- *Hepatitis C:* More recently, we've seen a remarkable transformation in treatment of another viral disease: hepatitis C. Just ten years ago, the only available treatment cured just half of patients and caused debilitating side effects. Today, a broad range of treatments with increasing efficacy and minimal side effects and cure rates approaching nearly 100 percent are available for patients with all forms of the disease, including many challenging to treat subpopulations.<sup>9,10</sup> The introduction of curative medicines also reduces health care costs previously associated with treated hepatitis C. In Medicaid, these medicines have been estimated to produce a total of \$12 billion in savings net of treatment costs by 2022.<sup>11</sup>
- *Cancer:* New medicines are also driving gains in the life expectancy of cancer patients. Since peaking in the early 1990s, cancer death rates in the United States have declined 31 percent.<sup>12</sup> Researchers attribute 73 percent of these gains to new treatments, including new medicines.<sup>13</sup> Targeted therapies and emerging immunotherapies are transforming the treatment paradigm for patients with many forms of cancer and have the potential to reduce the use of traditional forms of cancer treatment—including chemotherapy, surgery, and radiation.<sup>14</sup> As a result of remarkable advances, between 2000 and 2016 alone, new cancer drug approvals in the U.S. have been associated with 1.3 million avoided cancer deaths across 15 of the most common tumor types.<sup>15</sup>

Researchers are pursuing cutting-edge research and novel scientific strategies to continue to drive therapeutic advances for patients. There are currently more than 8,000 medicines in clinical development globally with the potential to impact U.S. patients.<sup>16</sup> And across the medicines in the pipeline, 74 percent have the potential to be first-in-class treatments.<sup>17</sup> Medicines in development include:

- *Cell and Gene Therapies:* Cell and gene therapy represent overlapping fields of biomedical research with similar therapeutic goals, which target DNA or RNA inside or outside of the body. Both approaches seek to modify genetic material to improve functioning or fight disease. Cell therapy involves taking cells from the patient or a donor and genetically altering and reinserting into the patient to treat the underlying cause of the disease. Gene therapy treatment involves making an addition to, silencing, or altering a gene. These treatments represent the translation of basic scientific understanding into innovative new treatment options for patients. There are nearly 400 cell and gene therapies in development focused on a variety of diseases and genetic conditions, ranging from blood disorders, eye disorders, cancer, and infectious diseases, among others.<sup>18</sup>

- *Cancer*: In addition to the cell and gene therapy approaches that are just beginning to transform the lives of patients, several novel approaches – including, antibody-drug conjugates, immune checkpoint modulators, personalized medicines, RNA therapeutics, metabolic immunotherapies, and vaccines – are showing tremendous promise across the pipeline against a broad range of cancers. Today, there are more than 1,300 medicines and vaccines currently in development for cancer.<sup>19</sup>
- *Diseases Affecting Children*: New treatment options for infants, children and adolescents can be complex and often require different clinical approaches than adult treatment pathways. There are currently nearly 600 pediatric medicines currently in development to meet the unique needs of children. Potential medicines include treatments for pediatric patients with range of conditions like genetic diseases, many forms of cancer, infectious diseases, and skin disorders.<sup>20</sup>

Today's biopharmaceutical pipeline has tremendous promise and represents a new frontier of research with the potential to continue to transform the lives of patients. In this new era of medicine, science that was once considered unimaginable is now on the verge of producing a complete paradigm shift in the treatment of the most complex and challenging diseases of our time. As the health care market continues to evolve towards value-driven payment and greater patient engagement in health care decision-making, we need to ensure it is sustainable and balances patient access to innovative medicines without sacrificing investment in further treatments and cures.

#### **Overview of the Statutory Frameworks that Increase Competition while Preserving Incentives for Innovation**

As noted by former Director of the U.S. Patent and Trademark Office (PTO) Andrei Iancu, “the progress we have made in the past 200 years is absolutely unparalleled in human history and most of that has been backed by patents.”<sup>21</sup> That progress is due to recognition by the Framers of our Constitution of the importance of robust IP protections, empowering Congress in Article 1 Section 8 of the Constitution “To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.” Under Section 101 of the Patent Act, 35 U.S.C. § 101, Congress provided that broad categories of inventions are eligible for patent protection: new and useful processes, machines, manufactures, or compositions of matter, as well as “any new and useful improvement.”

In the biopharmaceutical sector, Congress recognized the need to provide approval pathways that foster competition through the market entry of generic and biosimilar medicines while also maintaining incentives for innovation. Two key statutory frameworks simultaneously reward innovation while establishing streamlined approval pathways for generic or biosimilar products. Both patents and the exclusivities provided under the statutory schemes, the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, and the Biologics Price Competition and Innovation Act (BPCIA), have been successful in both fostering innovation and creating robust generic and growing biosimilar markets.

Toward that end, the Hatch-Waxman Act strikes a careful balance between innovation and access. Hatch-Waxman was enacted in response to a landscape in which innovator companies were losing substantial effective patent life during clinical development and the FDA review and regulatory approval process, while at the same time generic companies lacked a reliable abbreviated pathway for approval of generic copies of drugs approved after the 1962 amendments to the Federal Food, Drug, and Cosmetic Act once IP protections expired. The Hatch-Waxman Act created a framework that allowed generic companies to develop products during the period of innovator patent protection without liability for patent infringement,<sup>22</sup> overturning a Federal Circuit decision to the contrary,<sup>23</sup> and seek FDA approval to market products immediately upon patent expiration, or even prior to patent expiration if they successfully challenge patents through the litigation framework created by the Hatch-Waxman Act. Given the nature of the framework created, patent litigation is a natural part of the generic pathway, as are settlements of such litigation. The patent challenge procedure under the Hatch-Waxman Act has proven to be a robust means for generic applicants to seek to market generic versions prior to expiration of listed patents. As a result, the effective patent life for small molecule medicines is about 12 years, meaning brand medicines typically face generic

competition at between 12 and 13 years after brand launch even though the basic patent term is 20 years.<sup>24</sup> Over the 37 years since enactment of the Hatch-Waxman Act, patent challenges from generic manufacturers (in the form of paragraph IV certifications) have been filed more frequently and earlier in the brand-name drug life cycle, with many patent challenges coming at the earliest time possible under the statute—in the case of a new chemical entity, as early as 4 years after FDA approval.<sup>25</sup>

These frameworks have fostered competition in the biopharmaceutical marketplace. For example:

- Prescription drug costs have remained a small and stable share of health care spending year after year because our market-based system leverages competition to control costs throughout the lifespan of a prescription medicine.<sup>26</sup>
- Over the past 10 years, net per capita spending on medicines has remained effectively flat, increasing just 0.5 percent, on average, per year.<sup>27</sup>
- While patents might prevent a competitor from bringing an exact duplicate of a medicine to market during the term of the patent, they do not act as an absolute bar against bringing similar, but non-infringing, products to market. For example, in less than a year after market entry of the first breakthrough treatment for hepatitis C, from a class of treatments known as direct-acting antivirals (DAAs), multiple competitors entered the market, resulting in lower prices and improved cure rates for patients. The competition was so fierce that the average net daily cost for the range of medicines available in the DAA class today is nearly 80 percent lower than the launch price of the first breakthrough DAA.<sup>28</sup> In the case of the cholesterol-lowering drugs, PCSK9 Inhibitors, large purchasers have used their market power to negotiate significant rebates and discounts. Today, net prices are 78 percent lower than the list prices of the first to market PCSK9 inhibitor to enter the market.<sup>29</sup>
- The competitive market is structured to take maximum advantage of savings from brand competition. Competition among brand medicines often begins well before approval, as companies race to be first to market. Multiple companies simultaneously compete to research, develop, and secure FDA approval of first-in-class treatments. In fact, 88 percent of first-in-class medicines launched between 2005 and 2011 already had a competitor in Phase II clinical development at the time of their launch. For drugs approved between 2005 and 2011, the average time an approved medicine was alone in its class was 2.3 years.<sup>30</sup>
- Following generic entry, the U.S. market continues to drive long-term affordability by taking maximum advantage of the savings provided by generic drugs. Today, more than 90 percent of all prescriptions for drugs in the U.S. are filled with generics—due largely to the concentration of purchasing power by payers and the aggressive use of utilization management tools to rapidly shift utilization towards generics.<sup>31</sup> Competitive pressure resulting from the expiration of IP protection is expected to fuel this dynamic in the years ahead, with competition from generics and biosimilars expected to reduce U.S. brand sales by \$128 billion through 2025.<sup>32</sup>

The BPCIA, enacted in 2010, was intended to strike a balance between providing access to biosimilar medicines and preserving incentives for innovation in the biologics space. Through the BPCIA, Congress created an abbreviated approval pathway for biosimilar and interchangeable biological products. Biosimilar applicants also may develop products during the period of innovator patent protection without liability for patent infringement. At the same time, Congress provided incentives for innovation by providing for a data protection period governing when biosimilar applications could be submitted (as early as four years after approval) and approved (as early as 12 years after approval of the reference or innovator product). Congress also created a different procedure for litigating in court validity and applicability of patents covering the biosimilar product. Although the dynamics of the Hatch-

Waxman Act and BPCIA litigation procedures differ, they both allow for, and naturally lead to, premarket patent litigation.

While the BPCIA is a little more than a decade old, and biosimilar development is significantly more complex and expensive than generic drug development, the benefits of the BPCIA for innovation and competition are already coming to fruition. The FDA approved the first biosimilar product for marketing in the U.S. in March 2015 and, as of July 2021, 29 biosimilars have been approved in the U.S, with 20 already available on the market. Recognizing that the European Union (EU) has had a biosimilars pathway in place for a longer time period, the U.S. biosimilar approval rate is comparable to the EU at the same point in time.

Several factors have been cited as potentially impacting the timing of biosimilar market entry and success of biosimilars, including costs, complexities related to manufacturing and scale up of manufacturing, and lack of awareness and education among potential prescribers and payers of biosimilars.

FDA is implementing an action plan aimed at accelerating the market entry and uptake of these extremely complex products, which are in many ways more difficult to develop and produce than small molecule pharmaceuticals. PhRMA supports the FDA's efforts to implement a science-based regulatory approach in a timely manner that will ensure patient safety while facilitating a robust biosimilars market. We concur with the FDA that physician education and experience with biosimilars will be critical to fostering biosimilar uptake, as it was for generic drugs. We support FDA's continued efforts to develop "effective communications to improve understanding of biosimilars among patients, clinicians, and payors."<sup>33</sup> These efforts have raised awareness of the FDA's role in the biosimilar approval process, increasing the public's understanding of both biologics and biosimilars, and helping stakeholders understand the data and information that inform biosimilarity determinations. Congress has also recently taken action to help increase understanding. In April 2021, the Advancing Education on Biosimilars Act was signed into law,<sup>34</sup> encouraging FDA to maintain and operate an educational website and advance awareness among health care providers, patients and caregivers about biosimilar and interchangeable biosimilar biological products.

We agree that confidence among stakeholders is essential to developing a robust marketplace for biosimilar products. As America's health care system continues to evolve, biosimilars will play an increasingly critical role in bringing new options to patients and decreasing prescription drug spending. Annualized savings from biosimilars reached \$6.5 billion in the second quarter of 2020, and savings are modeled to exceed \$100 billion in aggregate over the next five years.<sup>35</sup>

IP fosters both innovation and competition, and these dual purposes can be enhanced with carefully crafted statutory schemes. The Hatch-Waxman Act and the BPCIA are two such schemes, with the Hatch-Waxman Act creating today's robust generic marketplace and the BPCIA well on its way to expanding competition from biosimilars in the biologics marketplace.

#### **Existing Antitrust Laws and Authority Effectively Support Competition**

Current antitrust laws, as well as the authority to enforce those laws, have played a critical role in addressing allegations of anticompetitive conduct on a case-by-case basis. The three core U.S. antitrust laws, the Sherman Act, the Federal Trade Commission (FTC) Act, and the Clayton Act prohibit business practices and mergers that unreasonably deprive consumers of the benefits of competition, resulting in higher prices for products and services. These antitrust laws do not regulate pricing itself but focus instead on anticompetitive behavior that excludes competition in a manner harmful to consumers. The Sherman Act, which addresses agreements that unreasonably restrain trade (Section 1) and unilateral conduct like unlawful monopolization (Section 2), carries severe civil and criminal penalties and is enforced by the Department of Justice as well as private litigants. The FTC Act generally prohibits "unfair methods of competition" and "deceptive acts or practices" and captures conduct not covered by the

Sherman Act, though it is well-recognized that violations of the Sherman Act also violate the FTC Act. However, only the FTC can enforce Section 5 of the FTC Act, which specifically prohibits unfair methods of competition.

Thus, price increases or reductions in output that result from anticompetitive behavior—collusive conduct, such as price fixing and bid rigging, as well as abuses of market power, such as anticompetitive tying and exclusive dealing—are already within the scope of existing competition law. Likewise, there are existing legal frameworks to address allegations of sham litigation, fraud on the FDA, and fraud on the patent office.

Policy approaches that seek to address perceived abuses of the patent system should distinguish customary business behavior and rigorous competition from any clearly identifiable conduct that interferes with the competitive process, whether via agreement or unilateral conduct. It would be inappropriate to put FTC in the role of substituting its business judgment for that of companies and second-guessing companies on a retrospective basis, which could have a substantial chilling effect on innovation or even punish procompetitive behavior. The current antitrust laws as well as the authority to enforce those laws are generally sufficient to address allegations of anticompetitive conduct on a case-by-case basis.

#### **The Competitive Market for Prescription Medicines Balances Innovation, Patient Access, and Cost Containment**

Medicines have revolutionized the treatment of many serious health conditions, saving lives, improving quality of life, and reducing the need for hospitalization. Prescription medicines have also been shown to be powerful tools to reduce overall health care costs for many conditions. In fact, a recent *Health Affairs* article concluded that one-half of the spending slowdown among Medicare beneficiaries between 1999 and 2012 was attributable to slower growth in spending for cardiovascular diseases; and of this savings, one-half was attributable to use of medications to treat cardiovascular risk factors.<sup>36</sup>

Looking forward, continued advances and better use of medicines will be indispensable in addressing some of our society's biggest health and economic challenges. Research shows better use of medicines, such as improved adherence to needed treatments, would save an estimated \$213 billion per year in avoided health care spending.<sup>37</sup> As medicines' role in effective health care has grown sharply, and many new medicines have been brought to patients, retail and physician-administered prescription medicines combined have remained at just 14 percent of total U.S. health care spending.<sup>38</sup> New medicines developed by biopharmaceutical innovator companies accounted for less than one-half of all spending on prescription medicines—or about 7 percent of total health care spending in 2018.<sup>39</sup>

The ability to bring important medical advances to patients while holding medicines' share of health spending nearly constant is made possible by the highly competitive structure of the U.S. market. Fierce market competition among brand, generic, and biosimilar medicines shifts utilization from brand medicines to generics and biosimilars and results in sizable rebates, discounts, and other price concessions. As a result, net prices for brand medicines are, on average, 44 percent lower than the list price.<sup>40</sup> In 2018, net prices for brand-name medicines declined by 2.9% after discounts and rebates were paid, continuing a downward trend for the past five years that was interrupted in 2019.<sup>41</sup> And brand medicine net prices have grown in line with or below the rate of inflation for the past five years.<sup>42</sup> This trend of flat or declining net medicine prices low growth is expected to continue; IQVIA projects annual net price growth for brand-name drugs will be just 0 to -3 percent through 2025.<sup>43</sup>

The competitive market with appropriate IP protections is the engine that drives the innovative biopharmaceutical R&D ecosystem. The dynamics of the private, market-based system in the U.S. promote incentives for continued innovation and increased patient access to needed medicines while leveraging competition to achieve cost containment.

The U.S. market is structured to take maximum advantage of savings from competition while ensuring Americans have access to innovative and life-saving treatments. Today, the U.S. is the global leader in R&D related to lifesaving



treatments and cures. There are nearly 8,000 medicines in development globally, more than half of which are in development in the U.S., including hundreds for conditions like cancer and Alzheimer's disease.<sup>44</sup> The U.S. develops more new medicines than the rest of the world combined,<sup>45</sup> precisely because we reject government price setting and protect IP.

As a result, the U.S. biopharmaceutical sector serves as one of the biggest employers and investors in U.S. R&D, fueling the U.S. economy. Biopharmaceutical companies employ 800,000 Americans directly and support 4.7 million jobs nationwide.<sup>46</sup> In 2018 alone, the biopharmaceutical industry invested an estimated \$102 billion in R&D,<sup>47</sup> more than any other industry.<sup>48</sup> In fact, the biopharmaceutical industry invests on average six times more in R&D as a percentage of sales than manufacturing industries overall.<sup>49</sup> IP is designed to, and does, foster both innovation and competition. IP protections and regulatory incentives give innovator companies a degree of certainty that their IP is protected—fostering innovation—while at the same time, the specifics of the invention covered by patents are published so others can learn from it and use it as the foundation for future invention and discovery—promoting competition. This public disclosure of inventions spreads knowledge and encourages others (i.e., competitors) to invent around existing patents and find new and different ways to solve problems and develop competing products.

#### **The Nature of IP Protections for Biopharmaceutical Innovation**

The benefits of IP incentives, including both patents and statutory exclusivity, with respect to innovation are significant in the biopharmaceutical industry. In the last decade alone, the FDA has approved nearly 900 new medicines, including the first medicine to treat the underlying cause of cystic fibrosis, the first vaccine to prevent cervical cancer, and the first ever gene therapies.<sup>50</sup> With sustained investments, our scientific understanding will continue to grow, creating new opportunities for profound advances against our most complex and costly diseases.

IP protections, including both patents and statutory exclusivity, are critical incentives for innovation, given the unique attributes of the biopharmaceutical R&D process:

- The R&D process involves a high level of scientific and regulatory uncertainty, with only 12 percent of investigational medicines that reach clinical trials ultimately receiving approval from the FDA.<sup>51</sup> Patent protection helps support continued future biopharmaceutical innovation over the long term, which includes providing the opportunity to earn revenue that can also compensate for the costly failures inherent in the biopharmaceutical R&D process.<sup>52</sup>
- Because research shows that R&D-intensive industries such as biopharmaceuticals are inherently riskier than non-R&D-intensive industries due to the uncertainty around R&D endeavors, investors require higher returns to compensate for those higher risks.<sup>53</sup> Benefits from R&D investments are uncertain and, if they occur at all, are realized over an extended time horizon, all of which increases the risk of such investments. Even standard measures of profitability show that the research-based biopharmaceutical industry's profits are in line with those of many other industrial sectors.<sup>54</sup>
- The significant time horizons and costs associated with biopharmaceutical R&D ranges from 10 to 15 years to develop a new medicine and an average of \$2.6 billion dollars.<sup>55</sup> The growing cost of drug development is driven in part by increasing complexities in protocol design and manufacturing requirements, particularly for biologics. Today, clinical trials generate three times the data collected 10 years ago and clinical protocols have become significantly more complex, largely in response to regulatory expectations, contributing to growing R&D costs and challenges related to patient enrollment and retention.<sup>56</sup>
- Because certain initial patents are filed very early in the R&D process, at the time of FDA approval only half of the effective life of these patents may be left. Yet, FDA approval is not the end of innovation; rather, innovation continues throughout the biopharmaceutical life cycle.

IP protections for biopharmaceutical products are based on the concept of providing exclusive market access for a limited period as an incentive to support the substantial R&D efforts required for discovering and developing new and improved medicines. Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. Once a new medicine's patent term and any statutory exclusivity protections have expired, generic equivalents, which require minimal capital investment, can enter the market. In the absence of effective IP protections, innovative biopharmaceutical companies would be unlikely to invest in developing innovative therapies.

#### **IP Protections and Competition**

IP protections do not impede competition in the U.S.; rather, they drive companies to innovate by providing a degree of assurance that companies may earn a return on an otherwise risky and costly investment in R&D. Moreover, IP protections do not block, but instead can foster, the entry of new competitors to market during the term of the patent. Similarly, patents or exclusivity that cover new formulations do not in any way extend the patents or exclusivity on previously approved formulations, or otherwise delay or block generic copies of the earlier formulations. Patents do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents. New medicines may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). This means that drugs in the same class may have differences in effectiveness for patient subgroup populations, side effect profiles, and prices. The result is a market where products compete for patient and physician preferences as well as placement on drug formularies to the benefit of payers and patients. Since payers have strong tools to drive high generic use rates, new formulations will succeed in the marketplace only if they can demonstrate added value for patients.

It is important to keep in perspective that the term of a patent is 20 years from filing. Although a patent term adjustment (to compensate for patent office delays) or a patent term restoration (to compensate for drug approval process delays) may apply, the term of a patent cannot otherwise be extended.<sup>57</sup> Patents only provide a right to exclude as to the claimed invention. For example, once an initial compound patent expires, any competitor is free to practice that compound patent. Additional patent protection that might be obtained does not extend protection over that compound itself.

#### **Patents Support Innovation Throughout the Biopharmaceutical Lifecycle**

Patents touch nearly every facet of biopharmaceutical production and use, from the materials needed to produce a medicine, to the way it is made, to the active ingredient or component that produces its biological effect, to formulations of it, to new uses of it; the result of this breadth of innovation is that most medicines are associated with many patents.

The types of patents covering biopharmaceuticals include:

- Patents covering the active ingredient or component (the part of the medicine that produces its biological effect).
- Drug product patents, which refer to the particular form in which the medicine is delivered to a patient. New dosage forms for already FDA-approved medicines can increase patient adherence to therapy, ensure a proper dose is taken, and improve quality of life for patients who must use the medication on a prolonged basis. In turn, these innovations may result in improved health outcomes and a reduction in unnecessary hospitalizations. As an example, an injectable treatment for schizophrenia has allowed for less frequent dosing than previous forms with the potential to increase patient compliance. The long-acting form allows the medicine to remain within a therapeutic range for an extended period, helping patients better manage their disease symptoms.

- Methods of use/treatment patents. Knowledge and understanding of a medicine continue to build over time, through additional study and collection of data. This additional research can culminate in approval of new uses of medicines in different patient populations, conditions, and disease states, expanding treatment options for patients. As an example, medicines initially developed for use in rheumatoid arthritis have been shown to also help treat other autoimmune conditions that share similar molecular pathways, including Crohn's disease and ulcerative colitis. In oncology, for example, research is often under way on multiple additional indications at the time of approval of the initial indication, with post-approval clinical research often demonstrating significant clinical benefit of the therapy in a different disease, stage of disease or population.
- Methods of manufacturing patents, which cover innovations in the process or steps to manufacture increasingly more complex medicines. Advances in manufacturing processes can improve the safety and effectiveness of medicines, such as by removing potential impurities that could present safety issues (e.g., carcinogenicity, genotoxicity, immunogenicity). These innovations similarly require R&D incentivized by IP protections. In some cases, innovator firms (and, for that matter, biosimilar firms) may have developed more precise analytical methods, as well as more precise understandings about the effects of different manufacturing method changes. For R&D intensive industries, the manufacturing process is a key factor in developing new products. That's because in these industries, product and process innovation are often intertwined. Manufacturers justifiably may seek to protect these innovations, while also disclosing these processes to the public, through patents. Although biosimilar competitors may need to consider how they will proceed in light of the patents, one approach is inventing around the methods disclosed in the patent. As noted previously, prospective applicants can also choose to challenge the patents or their applicability through the process articulated in the BPCIA.

In contrast to patents that cover the composition of a new compound, new uses and new methods of manufacturing can be invented at any point in the product lifecycle, and thus patent applications for them can also be filed throughout the product lifecycle. For instance, new methods of manufacture that reduce the potential for immunogenicity are often invented years after a biologic is discovered or has obtained regulatory approval. In addition, manufacturers may invent novel methods for purifying proteins that are more efficient or allow for more precise recovery of specific proteins. Such advances in manufacturing methods should be incentivized to maximize product quality, safety, and effectiveness and ensure efficient delivery of a consistently safe and effective product to patients.

#### **Potential Barriers to Competition**

PhRMA strongly supports policies that foster a robust, competitive market for generic and biosimilar medicines while providing needed incentives for continued biopharmaceutical innovation. Robust, competitive markets for generic drugs and biosimilars will play an increasingly important role in supporting affordable care. The natural evolution of medicines is that, after an innovator undertakes the time-consuming, uncertain, and expensive development process and obtains FDA approval, it enjoys an appropriate period of IP protections, including both data protection and patent protections, following which generic or biosimilar versions, as appropriate, can be approved. Indeed, this is the very cycle that Hatch-Waxman and BPCIA were intended to encourage. The introduction of innovative therapies provides patients with new treatment options and leads to competition where there are multiple alternatives in a given therapeutic class.

There are several areas where competition could be enhanced without reducing incentives for innovation, including:

- Advancing meaningful rebate reform
- Addressing certain types of patent settlements
- A balanced approach to address "product hopping"

- Continuing to foster timely generic and biosimilar approval and market entry.

#### ***Advance Meaningful Rebate Reform***

As a result of rebates and discounts that pharmaceutical companies pay to health insurance companies, middlemen like pharmacy benefit managers (PBMs), the government, and others, net prices for brand medicines are, on average, 44 percent lower than the list price.<sup>58</sup> However, these rebates and discounts often do not reach Medicare or commercially insured patients at the pharmacy counter, particularly for patients with high deductibles and coinsurance. If insurance companies and middlemen do not pay the full price for medicines, patients should not have to either. These rebates and discounts should be shared with patients at the pharmacy counter to ensure that products compete on price and patients benefit from that competition.

#### ***Address Certain Types of Patent Settlements***

Congress enacted as part of the Hatch-Waxman Act a complex framework governing the timing of generic applications that respects IP and specifically contemplates patent litigation. Under this framework, innovator companies submit patent information to FDA for publication, or “listing,” in FDA’s Orange Book. A generic applicant needs to certify with respect to listed patents whether it seeks to market its proposed generic product prior to expiration of the patent or after expiration. If it seeks to market its product prior to patent expiration, it generally must file a “Paragraph IV certification” with FDA in which it certifies its belief that the patent is invalid or would not be infringed by the generic product, and it must notify the innovator company of that certification. The innovator company can then bring suit under a special cause of action for patent infringement that allows for litigation prior to the generic marketing its product. If the suit is brought within 45 days of the innovator receiving notice of the Paragraph IV certification, FDA cannot approve the generic application for 30 months (or sooner if the generic is successful in the litigation) so that the court can address the patent disputes prior to marketing of the generic product (although FDA continues to review the generic application).<sup>59</sup> Hatch-Waxman also provided an incentive to generics to challenge patents under the Hatch-Waxman process in the form of 180-day generic exclusivity.

In general, if the generic applicant wins in litigation, FDA can approve the generic product; but if the innovator wins, FDA cannot approve the generic product for marketing until patent expiration. There can be many generic challengers for individual products, so Hatch-Waxman can lead to a substantial amount of litigation. Like other patent infringement litigation, the parties may choose to settle the case, with such settlements generally leading to generic companies entering the market prior to patent expiration, and potentially prior to when they could have entered if the litigation had continued. Settling such litigation is not surprising given the burden of litigation and the uncertainty for both innovators and generics.

The FTC and some other stakeholders have asserted that there are anticompetitive settlements in which innovator companies have provided cash payments and generic companies have delayed marketing their products. Under the 2013 Supreme Court decision in *FTC v. Actavis*, the FTC can seek to enforce the existing law against patent settlements with cash payments under the rule of reason – a fact-based inquiry. The FTC has asserted a broader view, and there is legislation pending that would create a presumption that certain agreements are anticompetitive, including agreements entered since 2013. There have also been bills introduced in several states, and California has passed restrictive legislation.

PhRMA supports addressing patent settlements with federal legislation to ensure generic, biosimilar and innovator companies can resolve patent litigation and allow generic and biosimilar medicines to enter the market prior to expiration of innovators’ patents, without applying new policies retroactively to previous agreements or restricting companies’ ability to enter into pro-competitive agreements in the future. We are committed to working with the Committee to address concerns in this area and promote competition.

### ***A Balanced Approach to Addressing Product Hopping***

There have been situations in which companies have been held liable after taking steps in conjunction with the introduction of new versions of products that were found to be anticompetitive. Legislation is pending that would create a presumption of anticompetitive effect in situations defined as “hard switches” or “soft switches.” A “soft switch” as defined in the legislation, for instance, can include situations in which a company develops a new product and takes actions that may “unfairly disadvantage” the earlier version of the product, even though that earlier version is still marketed. The legislation, however, gives little guidance on what activities could constitute “unfairly disadvantaging” the earlier product. This could put a cloud over many types of innovations after an original FDA approval that render a medicine safer or more effective, or improve patient care or quality of life. If Congress acts, it should do so in a balanced way that supports continued improvement to medicines that bring new benefits for patients, while addressing potential anticompetitive behavior.

### ***Continuing to Foster Timely Generic and Biosimilar Approval and Market Entry***

PhRMA continues to support a robust competitive marketplace that includes the timely approval and entry of generic and biosimilar medicines. The FDA has taken meaningful steps to streamline and expedite the generic drug approval process, such as promoting more high-quality generic applications. The agency, for example, publishes a list of off-patent, off-exclusivity drugs without approved generics and has updated its internal procedures to allow expedited review for some generic drugs. The FDA has also enacted numerous guidance documents to provide clarity to biosimilar manufacturers regarding the data needed to support applications to FDA for biosimilar and interchangeable biologic products.

### **Market Distortions in the Distribution and Payment System for Prescription Medicines**

In this section, we briefly discuss three areas of market distortions that negatively impact patients which warrant further examination: misaligned incentives in the distribution and payment system for prescription medicines, distortions related to the 340B program and consolidation in hospitals, and increased shifting of costs onto patients.

### ***Misaligned Incentives in the Part D Rebate System***

The Part D program has been a resounding success since its start in 2006. According to Congressional Budget Office (CBO) estimates, total Part D costs are 45 percent (\$349 billion) lower than projected for the initial 2004 to 2013 forecast period.<sup>60</sup> The Medicare actuaries report that the Part D base beneficiary premium in 2021 is less than \$1.00 more than it was in 2006, the first year of the program’s operation.<sup>61</sup>

Powerful Part D purchasers already negotiate discounts and rebates with manufacturers. The Medicare Trustees report that “many brand-name prescription drugs carry substantial rebates,”<sup>62</sup> which have increased each year of the program.<sup>63</sup> These negotiations, on average, yield larger rebates for brand medicines in Part D than are seen in the commercial insurance market. Specifically, the Altarum Institute found that Part D plans negotiate larger rebates on brand medicines within Part D (31 percent) as compared to commercial insurance (16 percent).<sup>64</sup> CBO says Part D rebates and discounts are “somewhat larger than the average rebates observed in commercial health plans.”<sup>65</sup> And the Government Accountability Office (GAO) found that Part D plans had negotiated rebates and discounts for 99 percent of the brand medicines most commonly used by Part D beneficiaries. Further, for the top 200 brand medicines ranked by total Part D spending, GAO found that rebates and discounts nearly doubled from 2014 to 2016.<sup>66</sup>

Although these privately negotiated rebates can result in substantial savings, Part D plans still require most beneficiaries to pay cost-sharing based on the full price of their medicine, even in cases where the plan receives a substantial rebate from manufacturers. In fact, a recent analysis shows that 92 percent of Part D beneficiaries’ out-of-pocket spending is based on the list price rather than the discounted price their plans get.<sup>67</sup>

To improve patient affordability, insurers and PBMs should share more of the discounts and rebates they negotiate with biopharmaceutical companies directly with patients at the point of sale. Once medicines are researched, developed, and approved for use, the process by which prescription medicines move from biopharmaceutical manufacturers to patients involves multiple stakeholders and numerous financial transactions. This process has evolved significantly in recent years, as supply chain entities have grown to play a larger role in drug distribution and payment. Three large, sophisticated PBMs manage 77 percent of all prescriptions filled.<sup>68</sup> They use brand competition to obtain discounts from manufacturers and take full advantage of the presence of generics to drive savings. In fact, the use of generic medicines, which account for 91 percent of prescription medicines dispensed in the United States, saved nearly \$2.2 trillion between 2010 and 2019,<sup>69</sup> and these dynamics will continue to produce savings.

Competition from generics and biosimilars will result in an estimated \$128 billion reduction in U.S. brand sales through 2025.<sup>70</sup> Additionally, biosimilar competition in the biologics market will increase substantially over time as the market matures.<sup>71</sup> Between 2016 and 2020, loss of exclusivity (LOE) lowered brand spending by \$84 billion and LOE is expected to decrease brand spending by \$128 billion through 2025, with \$39 billion coming from branded biologic LOE.<sup>72</sup> There is no similar type of cost containment for other health care services.

Consolidation and increased negotiating power give middlemen like PBMs leverage to extract growing price concessions from manufacturers. The magnitude of these rebates, discounts, and other reductions in price have more than doubled since 2012, totaling over \$187 billion in 2020.<sup>73</sup> For certain medicines used to treat chronic conditions like asthma, high cholesterol, hepatitis C, and diabetes, these discounts and rebates can reduce list prices by more than 80 percent.<sup>74</sup> According to a study by the Berkeley Research Group, on average, nearly half of all spending on brand prescription medicines in 2018 went to someone other than the biopharmaceutical manufacturers who researched, developed, and manufactured the medicines.<sup>75</sup>

Even though payers often receive deep discounts on a brand medicine's price, they rarely directly pass along those savings to the patients obtaining those medicines at the pharmacy counter. Instead, health plans typically use some portion of negotiated rebates to reduce monthly premiums for all enrollees. As the actuarial firm Milliman has pointed out, this dynamic results in a system of "reverse insurance" where payers require sicker patients using brand medicines with rebates to pay more out of pocket, while rebate savings are spread out among all health plan enrollees in the form of lower premiums.<sup>76</sup> Asking sicker patients with high medicine costs to subsidize lower premiums for healthier enrollees is the opposite of how health insurance is supposed to work.

This problem is particularly striking for patients with diabetes taking insulin. Robust competition among insulin manufacturers has resulted in increasing levels of discounts and rebates that have resulted in declining net prices over the past several years.<sup>77</sup> That is because payers leverage competition among a broad range of long-, short-, rapid-acting insulin to negotiate lower prices. These dynamics lower the list price of brand diabetes medicines by 83 percent on average.<sup>78</sup> Although media reports commonly give the false impression that biopharmaceutical companies retain all revenue from list price increases, flat net price growth indicates that all or almost all of insulin list price increases are returned to payers, the government, and other medicine supply chain entities through rebates, fees, or other discounts.

While robust competition in the market has been successful in constraining net prices for insulins, medicine supply chain intermediaries have incentives to favor high list prices and large rebates, leading to affordability challenges for patients who pay cost sharing based on the list price. Helping patients access the treatments they need by passing through rebates at the point of sale to lower patient cost sharing could improve medicine adherence for conditions like diabetes, which could ultimately generate savings by reducing costly avoidable health complications. A recent study by IHS Markit found that passing through a share of rebates to Medicare Part D patients taking diabetes medicines could reduce overall health care spending (including spending in Parts A and B) for Medicare beneficiaries with diabetes by \$20 billion over the next 10 years.<sup>79</sup>

A final rule from the U.S. Department of Health and Human Services' (HHS) Office of the Inspector General (OIG)<sup>80</sup> is an important step towards an improved Part D program, by replacing protections for drug rebates with protections for passing along those discounts directly to patients. OIG reports that, on average, Medicare Part D beneficiaries who do not receive low-income subsidies (LIS) (non-LIS) would pay 10 to 19 percent less in cost sharing over the next 10 years under the revisions that would encourage upfront discounts.<sup>81</sup> And patients who take brand medicines with relatively large rebates, such as medicines for rheumatoid arthritis, would be likely to see larger-than-average reductions in out-of-pocket costs because they would now directly benefit from those negotiated rebates.<sup>82</sup>

The principles underlying the rebate rule reforms could restore incentives to favor lower net cost medicines while strengthening incentives to negotiate deep discounts on medicines. Part D plans will have strong incentives to minimize costs in the absence of retained rebates. As Milliman notes, plans would be incentivized to achieve lower net costs to minimize premium increases and maintain LIS auto-enrollment.<sup>83</sup> Actuaries have also suggested that under the changes finalized by the OIG, some manufacturers "may have more success marketing biosimilars in Part D if manufacturer rebates are eliminated," due to the incentives for plans to achieve lower net costs.<sup>84</sup>

#### ***Distortions and Lack of Competition in the Provider Market***

Hospitals are a large contributor to health care costs. In 2019, hospital care is projected to total \$1.25 trillion and represent nearly a third of health care spending; this number is expected to increase to nearly \$2 trillion by 2027.<sup>85</sup> As such, an important factor in rising health care costs is increasing consolidation and mark-ups in the cost of care delivered in the provider market. Hospitals, for example, substantially mark up new medicines. Nearly one in five hospitals marks up medicine prices 700 percent or more.<sup>86</sup> This means that if a hospital purchased a medicine for \$150, a 700 percent markup could result in patients being billed \$1,050 for that medicine. Additionally, the analysis<sup>87</sup> found that 320 hospitals – eight percent of those included in the study – marked up some medicine prices by 1,000 percent or more.

Hospital consolidation and the resulting mark-ups increase health care costs for patients and providers, but there is no evidence that this consolidation improves the quality of care.<sup>88</sup> The Medicare Payment Advisory Commission (MedPAC) recently concluded that the "preponderance of evidence suggests that hospital consolidation leads to higher prices."<sup>89</sup> The 340B program is one factor leading to more vertical provider consolidation due to the incentives 340B creates for hospitals to shift care from community-based physicians to higher-cost settings.<sup>90</sup> Congress created the 340B program to provide discounts on outpatient drugs dispensed by federal grantees and hospitals that serve large numbers of uninsured or otherwise vulnerable patients. To achieve that goal, hospitals and safety net clinics that meet certain eligibility criteria are entitled to steep discounts for medicines for eligible 340B "patients." Disproportionate share hospitals (DSH) have come to dominate sales in the 340B program and recent data shows that hospitals now account for about 80 percent of 340B sales.<sup>91</sup> Current program rules are outdated and overly broad, oftentimes allowing hospitals to make a large profit by dispensing 340B medicines that were obtained at the steeply discounted 340B ceiling price and charging patients the full list price. By doing so these hospitals fail to pass along any of the 340B discount to lower a patient's drug costs or use their profits to help increase hospital charity care.

Hospitals have also leveraged their ability to generate revenue from 340B discounts to purchase physician groups.<sup>92</sup> Once these practices are purchased, hospitals oftentimes register these outpatient clinics as 340B discounts as child sites, even if though those sites do not lower drug costs or provide any free or discounted care to a 340B patient. One economist recently testified before this same committee and stated that "it can therefore be very profitable to hospitals and physician practices for hospitals to own physician practices that provide a lot of physician-administered drugs to their patients, since the hospital obtains the drugs at a substantial discount through the 340B program, and both the discount and the revenues are captured by the combined hospital-physician practice."<sup>93</sup> These shifts in ownership and the site of treatment not only undermine community-based physician practices but also drive concentration in provider markets, leading to higher prices for payers, the government, and patients.<sup>94</sup>

Hospitals' rapid acquisition of physician practices also enables them to demand high prices from commercial payers, driving up spending for all services. From 2004 to 2011, hospital ownership of physician practices doubled from 24 percent to 49 percent.<sup>95</sup> As a result, insurers pay higher prices for equivalent services that previously were delivered in less-expensive independent physician offices.<sup>96</sup> Additionally, expansion of 340B to for-profit contract pharmacies is driving increased utilization through vertically integrated systems of pharmacies, PBMs and health plans. A report documenting this also notes that the large profits for 340B contract pharmacies may be creating additional incentives for vertical consolidation across these different types of entities and shifting 340B profits to large, for-profit corporations.<sup>97</sup> A range of changes are needed to strengthen the 340B program and ensure it no longer serves as a profit-center that fuels further health care consolidation.<sup>98</sup>

#### ***Increased Cost-Shifting to Patients***

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

In the last decade, in the commercial market, the share of patient out-of-pocket drug spending represented by coinsurance has more than doubled, while the share accounted for by deductibles has tripled.<sup>99</sup> Since 2006, deductibles for patients in employer-sponsored health plans have increased by 300 percent.<sup>100</sup> Between 2007 and 2017, patient out-of-pocket spending on coinsurance has increased 74 percent, while spending on copays has decreased.<sup>101</sup> The share of employer-sponsored health plans requiring a deductible for prescription medicines has more than doubled from 23 percent in 2012 to 52 percent in 2017.<sup>102</sup> As one recent analysis shows, patients are required to pay 11 percent of overall pharmaceutical costs versus only 2 percent of hospital inpatient costs – even though medicine can help keep patients out of the hospital.<sup>103</sup>

Deductibles and coinsurance can leave patients with high and often unpredictable costs, particularly for their medicines. Average commercially insured patient out-of-pocket costs for deductible and coinsurance claims for brand medicines are much higher than copay claims.<sup>104</sup> In 2019, half of commercially insured patients' out-of-pocket spending for brand medicines was for medicines filled while a patient was in the deductible or with coinsurance.<sup>105</sup> Patients with chronic conditions are disproportionately impacted by high out-of-pocket costs.<sup>106</sup>

In Medicare Part D, there has been a substantial increase in the use of coinsurance and complex, multi-tiered formularies. Today, 86 percent of stand-alone Part D plans (PDPs) use formularies with five coverage tiers, while 14 percent are now using a sixth tier.<sup>107</sup> The percentage of PDPs with 3 coinsurance tiers is increasing substantially, from 11 percent in 2020 to 23 percent in 2021. As a result of this shift, 62 percent of all medicines covered by PDPs are now on a coinsurance tier.<sup>108</sup>

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

Research shows that rebates paid by biopharmaceutical companies often substantially reduce the cost of brand medicines.<sup>109</sup> However, since list prices do not reflect rebates, these savings may not be directly passed on to



patients through lower cost sharing, and patients' out-of-pocket costs for prescriptions filled within the deductible or with coinsurance may be higher than they otherwise would be if they were based on the discounted cost of the medicine. Thus, the growing use of deductibles and coinsurance for medicines has exposed patients to out-of-pocket costs based on undiscounted list prices, creating affordability challenges for many, including the most vulnerable.<sup>110</sup>

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As the Committee considers policy solutions, we urge the Committee to avoid broad policies that would chill innovation, destabilize important incentives for development of new medicines, and negatively impact patient access to innovative therapies and cures. We hope the committee recognizes how IP protections enabled biopharmaceutical research companies to move quickly and effectively against COVID-19 and are critical to our ongoing efforts to increase manufacturing capacity and find new ways to fight the virus. Instead of focusing on proposals that undermine the competitive marketplace for medicines and incentives for innovation, we encourage a focus on addressing market distortions and providing pragmatic solutions, including modernizing the drug discovery and development process and removing barriers that limit paying for value. PhRMA appreciates the opportunity to testify and looks forward to continuing to engage with the Committee on these critically important issues.

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**Questions for the Record of Senator Patrick Leahy  
Subcommittee on Competition Policy, Antitrust, and Consumer Rights  
Hearing on: “A Prescription for Change: Cracking Down on Anticompetitive Conduct in  
Prescription Drug Markets”  
July 13, 2021**

**Questions for Dr. Rachel Moodie**

1. Patents should be a tool to reward innovation, and the patent process is abused when minor changes to a drug are patented and have the effect of extending patents beyond their intended 20-year term or creating an impenetrable thicket, as you so clearly explained in your testimony. I want to address steps the U.S. Patent and Trademark Office (PTO) can take to avoid issuing patents that unfairly extend drug patent terms.
  - a. **Should the PTO limit continuation patent applications, either to a certain number per original specification, or to continuations filed within a certain period of time after the original specification is filed? How would you recommend the PTO limit continuations? What effect would that limit have on patent thickets and the ability for biosimilars to enter the market?**
  - b. **As you indicated in your testimony at the hearing, continuation patents can sometimes be the lowest quality patents. Are continuation applications allowed by the PTO on a first office action more often than parent applications are allowed on a first office action? While it is currently the case that an examiner can allow an application without anyone else looking at the file, do you think it would help for the PTO to have a second person examine applications that the first examiner proposes to allow on a first office action?**
  - c. **You mentioned at the hearing that ending the option for applicants to file repetitive claims would help solve some anticompetitive harms. What are some steps the PTO could take to end repetitive claiming?**
2. You testified that one way to improve generics’ ability to compete is having better third-party tools during patent examination.
  - a. **Would it help to have more incentives, and fewer disincentives, for the public to submit relevant prior art during examination? What do you recommend as ways to improve the current incentives?**
  - b. **Would it help to have a way for the public to alert the PTO of non-prior-art issues, such as knowledge that the application is based on retracted scientific information or that the application is claiming a competitor’s existing product?**

3. At the hearing, you mentioned that inter partes reviews have been weakened recently as a tool to limit drug prices.
  - a. **Please explain what steps were taken to weaken inter partes reviews recently and how that weakening affects drug prices.**
  - b. **Based on your testimony about repetitive patent claims, would it be useful for double patenting to be a basis for inter partes reviews at the PTO?**
4. Certain products, including drugs, are cleared by the Food and Drug Administration (FDA) after the maker establishes that the products are sufficiently similar to products already on the market. At the same time, these companies are often applying for patents for the same products. In some cases, drug makers may make significantly different statements in submissions to the FDA that conflict with those made at the PTO.
  - a. **In your view, would statements made by a patent applicant to another federal agency such as the FDA be relevant to the PTO's patent examination effort?**
  - b. **Should there be improved coordination between the PTO and agencies such as the FDA to ensure that the PTO is aware of relevant statements the applicant has made in other contexts?**

**Questions for the Record of Senator Patrick Leahy**  
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**Questions for Dr. Rachel Moodie (Goode)**

1. Patents should be a tool to reward innovation, and the patent process is abused when minor changes to a drug are patented and have the effect of extending patents beyond their intended 20-year term or creating an impenetrable thicket, as you so clearly explained in your testimony. I want to address steps the U.S. Patent and Trademark Office (PTO) can take to avoid issuing patents that unfairly extend drug patent terms.
  - a. **Should the PTO limit continuation patent applications, either to a certain number per original specification, or to continuations filed within a certain period of time after the original specification is filed? How would you recommend the PTO limit continuations? What effect would that limit have on patent thickets and the ability for biosimilars to enter the market?**

**Answer:** It is true that preserving true innovation is vital to the American healthcare system, but a proper balance must be struck to foster affordability when those drugs are no longer considered innovative. One way that the USPTO could right this important balance would be to allow patent examiners to evaluate double patenting challenges by requiring that any terminal disclaimer filed by the patent holder to overcome an obviousness type double patenting challenge be recorded as a binding admission of double patenting. Alternatively, Congress could write this into legislation. The terminal disclaimer is just that, an admission that two or more patents are not patentably distinct from each other and should be enforced as such by the courts, i.e. if one patent is found to be invalid, then those patents that are tied to it through terminal disclaimers would become non-enforceable. However, by not making this distinction, those terminally disclaimed secondary patents are shielding entire patent families from scrutiny as a biosimilar manufacturer would be required to challenge each duplicate patent individually and cannot afford to do so, plus courts cannot effectively litigate scores of patents. This delays biosimilar launches. In some cases, terminally disclaimed patents make up a majority of the innovators’ patent portfolio. This practice of circumventing double-patenting through terminal disclaimers is not allowed anywhere else in the world.

Example:

### Case study: Drug X patent portfolio Clusters of US patents

- = one patent
- = a cluster of patents linked through terminal disclaimers (non patentably-distinct claims)
- = a patent family (Inpadoc standard definition)



|                   |                                       |                         |                                        |                  |                      |                      |                         |
|-------------------|---------------------------------------|-------------------------|----------------------------------------|------------------|----------------------|----------------------|-------------------------|
|                   |                                       |                         |                                        |                  |                      |                      |                         |
| Product           | Primary Indications                   | Formulation single conc | Secondary Indications                  | Purity level     | Tertiary Indications | Juvenile Indications | Formulation double conc |
| 1 invention       | 4 inventions                          | 1 invention             | 4 inventions                           | 1 invention      | 1 invention          | 1 invention          | 1 invention             |
| 10 patent cluster | 4 patent cluster + 3 distinct patents | 21 patent cluster       | 15 patent cluster + 3 distinct patents | 8 patent cluster | 2 patent cluster     | 3 patent cluster     | 4 patent cluster        |

Summary: 73 patents; 14 distinct inventions; 59 patents are non-patentably distinct

Such "obvious-type double patenting" is permissible under the US patent rules

### Case study comparison to Europe, Drug X patent portfolio in Europe

- = one patent
- = a cluster of patents linked through terminal disclaimers (non patentably-distinct claims)
- = a patent family (Inpadoc standard definition)



|                    |                     |                         |                       |                    |                      |                      |                         |
|--------------------|---------------------|-------------------------|-----------------------|--------------------|----------------------|----------------------|-------------------------|
|                    |                     |                         |                       | Patent not granted |                      | Patent not granted   | Patent not granted      |
| Product            | Primary Indications | Formulation single conc | Secondary Indications | Purity level       | Tertiary Indications | Juvenile Indications | Formulation double conc |
| 2 inventions       | 2 inventions        | 2 inventions            | 1 invention           | -                  | 1 invention          | -                    | -                       |
| 2 distinct patents | 2 distinct patents  | 2 distinct patents      | 1 distinct patent     | -                  | 1 distinct patent    | -                    | -                       |

Summary: 8 patents; 8 inventions; 0 patents are non-distinct; 0% of the portfolio is duplicative

Double patenting is not permitted by the European Patent Office



It is, however, important that originators are incentivized to continue to improve the drug after launch, which is why, each distinct invention should receive its own patent. Some of these patents are strong and should be respected as such. This policy would ensure that originators that innovate more, are rewarded for those inventions, but cannot game the patent system through double patenting. This would essentially allow these duplicates to stand and fall together based on the strength of the parent patent.

Another policy that would achieve the same goal of reducing duplicative patents within a thicket, would be to introduce legislation to cap the number of patents that can be litigated against a biosimilar. The cap could allow the patent owner to select one patent from each cluster of patents that are tied together with terminal disclaimers. In other words, the originator would litigate one patent per invention. This type of cap would incentivize originators to invest into innovation to increase the number of inventions, rather than increasing the number of obvious-type double patenting surrounding each invention.

- b. As you indicated in your testimony at the hearing, continuation patents can sometimes be the lowest quality patents. Are continuation applications allowed by the PTO on a first office action more often than parent applications are allowed on a first office action? While it is currently the case that an examiner can allow an application without anyone else looking at the file, do you think it would help for the PTO to have a second person examine applications that the first examiner proposes to allow on a first office action?**

**Answer:** As exists in many patent offices around the world, the U.S. could consider establishing a pilot program for a quality control committee in the pharmaceutical and biotechnology art units. A team of experienced examiners that approve any notice of allowance before it is sent to the patent filer could help evaluate the validity of multiple patents being filed by the same patent holder. This coupled with rebalancing the count system, which is the system used to evaluate patent examiner performance. Currently, patent examiners receive more points for granting a patent than for rejecting a patent. Under a revised count system, patent examiners would receive the same count for patent grants as for a final office action. Furthermore, by limiting requests for continued examination (RCEs) from the innovator would go along way towards ensuring that only high-quality patents are granted.

- c. You mentioned at the hearing that ending the option for applicants to file repetitive claims would help solve some anticompetitive harms. What are some steps the PTO could take to end repetitive claiming?**

**Answer:** Tightening written description rules regarding claim amendments and the filing of claims in continuation & divisional patent applications would help to correct this anticompetitive behavior. Policies should be adopted that prevent the “cherry picking” of elements from different disclosures or “laundry lists” within the specification and combine them into claims to create artificial embodiments. The USPTO could also update MPEP to include impermissible examples of broad claim language in the pharmaceutical secondary patent space. In particular, the practice of granting broad claims on pharmaceutical formulations should be restricted because such broad claims impede biosimilar companies from designing non-infringing formulations. This reduces the investment into innovation of alternative, new formulations of old drugs. Furthermore, secondary

patents having broad claims to the formulation can result in an inappropriate extension of the monopoly on the drug itself by blocking the development of non-infringing alternatives.

2. You testified that one way to improve generics' ability to compete is having better third-party tools during patent examination.

- a. **Would it help to have more incentives, and fewer disincentives, for the public to submit relevant prior art during examination? What do you recommend as ways to improve the current incentives?**

**Answer:** Currently the public is disincentivized from submitting prior art to the USPTO during patent prosecution because, in case the examiner has the discretion of whether or not to use it against the patent. Even if an examiner does not review the prior art, the document is on the record, meaning that its value in an inter partes review or post grant review is diminished. Therefore, the public would be incentivized to submit relevant prior art if the patent examiners are mandated to comment on the document. Furthermore, the deadline for submitting prior art to the USPTO should be extended.

- b. **Would it help to have a way for the public to alert the PTO of non-prior-art issues, such as knowledge that the application is based on retracted scientific information or that the application is claiming a competitor's existing product?**

**Answer:** Yes.

3. At the hearing, you mentioned that inter partes reviews have been weakened recently as a tool to limit drug prices.

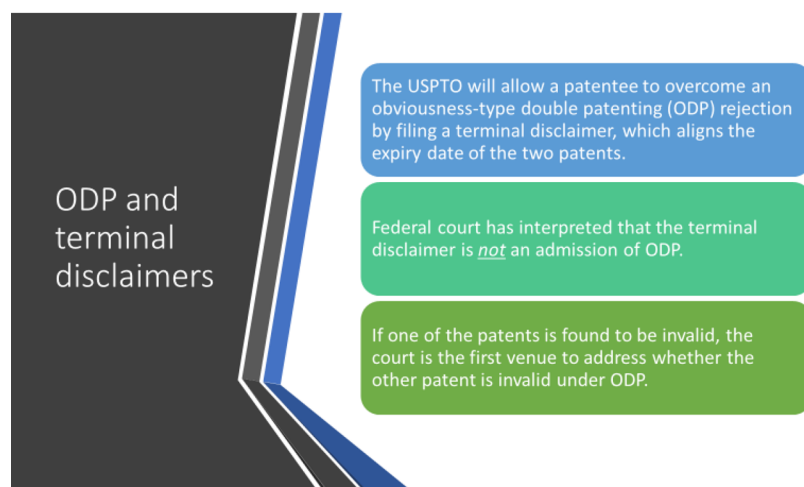
**a. Please explain what steps were taken to weaken inter partes reviews recently and how that weakening affects drug prices.**

**Answer:** There are two main issues at the PTAB level that weaken IPR as a tool, and as a result, delay biosimilar launch, and keep patients paying high prices for branded drugs. The first is that, currently, biosimilar companies do not have standing to appeal a negative IPR/PGR decision if they have not already submitted a dossier to the FDA. This rule treats legitimate biosimilar manufacturers as patent trolls, as opposed to legitimate competitors acting in good faith. This rule precludes biosimilar companies for pre-emptively clearing the path of invalid patents prior to FDA approval. This allows the patent owner to use the uncertainty of the patent situation to chill timely launches of biosimilars because the launch at risk calculation includes the threat of owing lost profit damages to the originator, which is untenable for a biosimilar manufacturer.

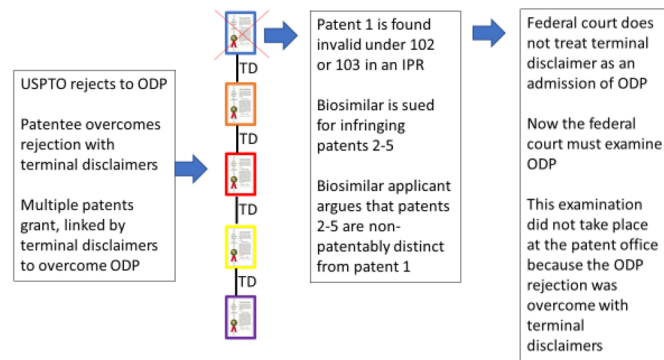
Secondly, in the last several years, the Patent Trial and Appeal Board (PTAB) has increased the number of “discretionary” denials for institution of IPRs, PGRs and ex parte reexamination. The overuse of denying institution of IPRs impacts all areas of technology and is not consistent with the expectations of Congress when they created the Leahy-Smith America Invents Act (AIA). Institution decisions are not appealable.

**b. Based on your testimony about repetitive patent claims, would it be useful for double patenting to be a basis for inter partes reviews at the PTO?**

**Answer:** As stated above, we believe that double patenting should be addressed at the patent examiner level. For example:



## Example



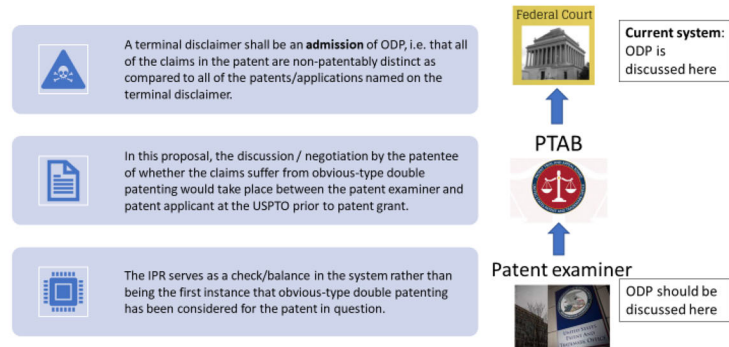
Why should ODP be added as an IPR ground

Instead of the Federal Court being the first venue to examine ODP, the USPTO would be required to consider ODP

The USPTO would have an opportunity to weigh in on ODP before the question reaches the court

The USPTO is the expert on ODP

## ODP Discussions Should Happen at the Patent Examiner Level



4. Certain products, including drugs, are cleared by the Food and Drug Administration (FDA) after the maker establishes that the products are sufficiently similar to products already on the market. At the same time, these companies are often applying for patents for the same products. In some cases, drug makers may make significantly different statements in submissions to the FDA that conflict with those made at the PTO.

- a. In your view, would statements made by a patent applicant to another federal agency such as the FDA be relevant to the PTO's patent examination effort?

**Answer:** We support FDA/USPTO coordination for this very reason. If a patent holder disclosed an invention in an FDA filing several years prior to when the patent on the same invention was filed, that patent should not be granted by the PTO examiner because it was obvious as of the number of years that patent was not filed, but was disclosed to the FDA. This is a harmful brand behavior that ensures that they will have strong patents standing at the end of their patent portfolio life which could serve to shield their weaker patents and force settlement dates beyond what is appropriate. It is not dissimilar to the "submarine patent" behavior that was corrected with legislation several years ago.

**Should there be improved coordination between the PTO and agencies such as the FDA to ensure that the PTO is aware of relevant statements the applicant has made in other contexts?**

**Answer:** Yes, we believe that this is important to eliminating barrier to biosimilar entry. For example:

| Policy ideas: FDA / USPTO Coordination                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| FDA / USPTO Coordination                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                       |
| 3a                                                                                                                                                                                                                                                                                                                                                                                                                                                 | The PTO Director shall require the inventor and patent applicant to disclose the existence of any FDA submissions related to the subject matter of the invention and confirm that the inventor or patent applicant is not aware of any inconsistent information submitted to the FDA. |
| 3b                                                                                                                                                                                                                                                                                                                                                                                                                                                 | The FDA is available to (1) answer questions from the PTO regarding the technical details of the subject matter of the pharmaceutical invention, (2) provide relevant extracts from the drug dossier (NDS, BLA) and (3) to conduct research on special problems.                      |
| <p><b>Example of how this might work in practice:</b></p> <div> <div> <div>1997:<br/>Product<br/>patent<br/>publishes</div> <div>← Same<br/>drug →</div> <div>2006:<br/>Purity level<br/>patent filed</div> </div> <ul style="list-style-type: none"> <li>FDA informs PTO that this level of purity is necessary for FDA approval of this drug.</li> <li>PTO decides that patent claims are obvious compared to the 1997 patent.</li> </ul> </div> |                                                                                                                                                                                                                                                                                       |



**Your Generics and Biosimilars Industry**

**Statement for the Record  
The Association for Accessible Medicines  
“A Prescription for Change:  
Cracking Down on Anticompetitive Conduct in Prescription Drug Markets”  
July 13, 2021**

Thank you Chairwoman Klobuchar, Ranking Member Lee and members, of the Senate Judiciary’s Subcommittee on Antitrust for holding this important hearing and for the opportunity to submit this written statement on behalf 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. Our members provide approximately 52,000 jobs at nearly 150 facilities and manufacture more than 60 billion doses of generic medicines in the United States every year.<sup>1</sup> AAM’s core mission is to improve lives by advancing timely access to affordable generic and biosimilar medications.

Over the years, AAM has worked extensively with the Senate Judiciary Committee to ensure that the patent system is appropriately balanced and that antitrust law is properly used to police truly anticompetitive behavior. We are especially grateful for this Committee’s work on addressing anticompetitive gaming of the regulatory system and in passing the bipartisan Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act. Thank you Chairwoman Klobuchar, Ranking Member Lee, and Senator Leahy for your leadership in making the CREATES Act a reality. The law is responsible for meaningful progress accelerating patient access to more affordable generic medicines.<sup>2</sup>

We are pleased that the Antitrust Subcommittee is holding today’s hearing and shining a spotlight on the anticompetitive tactics used by some brand name pharmaceutical companies to delay patient access to generic and biosimilar medicines well beyond the periods that Congress intended. In this submission, we propose six areas for reform:

- preserving procompetitive, pro-patient patent settlement agreements;
- ensuring that “skinny labeling” remains a viable FDA pathway for generic and biosimilar manufacturers to bring lower-cost medicines to market as quickly as possible;
- preventing monopolistic behavior by powerful purchasing organizations;
- prohibiting rebate traps and other anticompetitive mechanisms that deter coverage of and access to lower-cost medicines;
- prohibiting false and misleading statements about the safety and efficacy of biosimilars; and
- strengthening *inter partes* review (“IPR”) to encourage competition while preserving true innovation.

We discuss each of these proposals in greater detail below.

<sup>1</sup> AAM, “Securing Our Access & Savings: 2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report,” September 2020.

<sup>2</sup> FDA, “Office of Generic Drugs 2020 Annual Report,” February 2021. Available at: <https://www.fda.gov/drugs/generic-drugs/office-generic-drugs-2020-annual-report>.





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### I. Preserving Procompetitive Settlement Agreements

We urge the Subcommittee to focus its attention on the areas where the patent system is out of balance and systematically undermined competition. Some proposals that have been introduced in Congress are concerning because they would actually serve to **reduce** opportunities for competition in this critical area.

The first step is to do no harm. Generic medicines come to market only after the brand-name drug company has an opportunity to litigate any patents that it may have. Under the Hatch-Waxman Amendments of 1984, if the brand-name drug company wins, the generic will be kept off the market until after the last patent expires.<sup>3</sup> A generic developer that litigates all the way through trial and appeal, only to end up with that outcome, is actually in a worse position than if it had never challenged the patent in the first place. Facing uncertainty about the outcome and the possible launch date, a generic developer expends significant resources in both litigation and launch preparations without realizing any revenue.

In the vast majority of cases and particularly since the Supreme Court's decision in *FTC v. Actavis*, settlement of Hatch-Waxman litigation enables competition and benefits the public in a very tangible way: it can allow patients to access more affordable generic alternatives considerably sooner than the patents would otherwise allow. At least one analysis has found that patent settlements led to generic entry, on average, **81 months** before patent expiry.<sup>4</sup> This option is becoming all the more important as brand-name pharmaceutical companies amass larger and larger patent portfolios on each product. If **every** patent had to be litigated all the way to final judgment—with no possibility of settlement—that would create a barrier to entry and deter generic manufacturers from even trying to launch a competing product before the patent expires.

The Supreme Court's 2013 decision in *FTC v. Actavis* significantly changed the landscape for how patent settlement litigation is resolved.<sup>5</sup> Settlement agreements with "large, unjustified reverse payments" were determined to be potentially anticompetitive when combined with a market entry date well-beyond patent expiry. AAM supports the Supreme Court's decision in *Actavis*. However, recent legislative proposals go beyond the Supreme Court's decision in *Actavis* and would substantially alter a generic developer's ability to accelerate patient access to more affordable medicines and further tips the playing field to the advantage of brand-name pharmaceutical companies.

Current proposals before Congress do not simply target so called "pay-for-delay" patent settlement agreements. Many patent settlements—a potential universe of more than 200 agreements between brands and generic companies—would potentially be impacted. By deeming virtually all settlements

<sup>3</sup> 35 U.S.C. § 271(e)(4)(A).

<sup>4</sup> Patent Docs, IMS Study Shows Pro-Competitive Effects of Reverse Payment Settlement Agreements in ANDA Litigation, July 2013.

<sup>5</sup> 570 U.S. 136 (2013).





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presumptively anticompetitive, those proposals—if enacted—would severely chill the ability of generic and biosimilar developers to obtain a settlement and disincentivize their ability to challenge patents in the first place. The legislative proposals go well beyond the Supreme Court's opinion that "traditional settlement considerations, such as avoided litigation costs," do not pose the same risks as a "pay-for-delay" payment.

As the FTC has stated, "the number of settlements potentially involving "pay for delay" decreased significantly in the wake of the Actavis decision." FTC's data confirms this point —potential "pay-for-delay" deals dropped from 33 in FY2012 to 5 in FY2015 and just one in 2016.<sup>6</sup> The data are even more compelling in 2020: according to the FTC, the most recent report shows "a continued decline in use of the types of reverse-payment agreements that are most likely to harm consumers."<sup>7</sup>

In other words, the vast majority, if not all, patent litigation settlements that occur today benefit patients. Patent settlement agreements, as a result of the Supreme Court's decision in *Actavis*, ensure early generic and biosimilar competition before the patents have all expired. Patent settlement agreements provide generic developers with certainty about the generic entry date, which allows manufacturers to fulfill the promise of early entry *on* that date. As the Subcommittee takes action on the topic of today's hearing it should not *undermine* one of the ways in which our current system enables generic drug and biosimilar competition to expensive brand-name drugs.

### II. Ensuring That Skinny Labeling Remains a Viable Practice

As part of the 1984 Hatch-Waxman Amendments, Congress made the policy judgment that generic manufacturers should be able to bring lower-cost alternatives to market even if the brand-name drug manufacturer still holds patents on select methods of using a drug. This practice, known as "skinny labeling," allows a generic manufacturer to avoid patent infringement by "carving out" patented uses from its label and entering the market with its generic labeled for non-patented uses. The benefits for patients and payers are tangible—since 1984, patients and payers have saved billions of dollars by obtaining generic versions of expensive drugs for unpatented uses. Skinny labels have proven particularly important for generic competitors of blockbuster brand-name drugs where patent owners frequently seek to extend their monopolies by obtaining seriatim method-of-use patents. And they are even more important in the biologics context—brands frequently obtain many indications for diseases such as cancer, and a patent on any one such indication should not preclude competition on unpatented indications.

The "skinny labeling" pathway, however, has been called into question as a result of the recent *GSK v. Teva* case.<sup>8</sup> In *GSK v. Teva*, the Federal Circuit affirmed a \$234 million verdict for patent infringement,

<sup>6</sup> FTC, "Overview of Agreements Filed in FY2017," December 2020. Available at [https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/mma\\_report\\_fy2017.pdf](https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/mma_report_fy2017.pdf)

<sup>7</sup> <https://www.ftc.gov/news-events/press-releases/2020/12/ftc-staff-issues-fy-2017-report-branded-drug-firms-patent>

<sup>8</sup> 976 F.3d 1347 (Fed. Cir. 2020).



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including during a period of time that Teva completely carved out the patented method of use from its label. The Federal Circuit relied on the fact that Teva truthfully and accurately described its generic product as “therapeutically equivalent” to the brand-name product. Although the decision has since been vacated and is pending rehearing, it has sowed significant confusion in the industry and led to additional litigation. Indeed, at least five cases have since been filed where brand-name pharmaceutical companies have asserted patent infringement based on a carved-out label.<sup>9</sup>

The potential anticompetitive consequences—and harm to patients—from the *GSK* case are significant. Skinny labels ensure “that one patented use will not foreclose marketing a generic drug for other unpatented ones.”<sup>10</sup> Absent a strong skinny labeling practice, brand-name pharmaceutical companies will be able to use a single method of treatment patent to foreclose *all* competition from generic and biosimilar medicines. The Department of Justice has recognized the potential deleterious impact of diminished skinny labeling—as it stated to the Supreme Court, this is part of a trend where “brand-name manufacturers [have] exploit[ed] certain features of the original Hatch-Waxman scheme to prevent or delay FDA approval of generic competitors.”<sup>11</sup>

We would be happy to work with the Subcommittee to develop legislative solutions that ensure that skinny labeling remains a viable practice and that brand-name manufacturers cannot abuse the patent system to forestall generic and biosimilar competition.

### III. Preventing Monopolistic Behavior by Powerful Purchasing Organizations

Increasing consolidation in the supply chain is certainly another key threat to sustainable generic markets. Compared to the fragmented generic drug market, consolidation in the wholesale market and contractual arrangements between pharmacy chains and wholesalers have left generic manufacturers with only a small number of purchasers. The result is a market where three purchasers account for more than 90 percent of all wholesale revenue.<sup>12</sup>

As these purchasing consortia move more and more toward single-source contracts for generic drugs, it creates a dynamic where it is possible that no more than three generic manufacturers may be able to successfully market any given product. This dynamic risks future competitive success in the generic market as generic drug manufacturers may be forced to maximize economies of scale and consolidate. It is clear the significant benefits for patients of reliable access to affordable generic medicines are at risk. Notwithstanding the economic principle that more suppliers of a good or service creates lower prices for consumers, it is unclear that the new imbalance between 200 generic competitors and a handful of purchasers is sustainable.

<sup>9</sup> <https://news.bloomberglaw.com/health-law-and-business/teva-drug-label-case-spurs-fresh-litigation-as-judges-weigh-redo>

<sup>10</sup> *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 416 (2012).

<sup>11</sup> Brief of the United States, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 416 (2012).

<sup>12</sup> Fein, Adam J. Fein. The 2016-2017 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors, September 2016.



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Accordingly, this Subcommittee should be vigilant concerning the potential anticompetitive effects that may result from increasingly powerful purchasing consortia. This buyer consolidation poses a number of dangers, including smaller companies being locked out of the marketplace and critical drug shortages. Excessive consolidation of power among the purchasing consortia also presents the risk of exerting undue market power over generic suppliers, driving wholesale prices below marginal costs and reducing output. In turn, this may lead to manufacturers exiting the market, reduction of output, ceasing production of unprofitable drugs, and shortages. Such consolidation also poses a danger of elevating costs to patients and payers. In short, the ever-increasing market power of large purchasers may lead to higher prices for patients.

### IV. Prohibiting Anticompetitive Rebate Traps

The use of anticompetitive "rebate traps" by brand-name pharmaceutical companies has been well-documented. In these cases, brand-name companies threaten to remove rebates that they provide to payers unless the biosimilar is effectively excluded from the market. Some pharmaceutical companies may go so far as to threaten the rebates on a basket of products in the event that the contracted entity utilizes a biosimilar in place of the reference product.<sup>13</sup>

While a biosimilar is entering at a significant discount from the brand-name product, the "rebate trap" forces the health plan to choose to block biosimilar use or pay the full price for the brand-name product. At that point, it becomes economically infeasible for a payer to cover a biosimilar with the loss of significant rebate dollars from the brand-name company. Despite the biosimilar costing patients and Medicare less, the payer is financially incentivized to exclude the biosimilar and continue to use the brand biologic given the uncertainty of biosimilar uptake and the certainty of the brand-name biologic pulling its rebate.

These anticompetitive rebate traps have harmed patients and payers. They should be precluded, and AAM would be happy to work with the Subcommittee to develop solutions.

### V. Prohibiting Biosimilar Misinformation

As the Biden Administration recently highlighted,<sup>14</sup> intentional misinformation disseminated by brand-name manufacturers serves as one of the largest barriers to biosimilar uptake. This misinformation is intended to sow doubt among patients and prescribers regarding biosimilars' safety and efficacy, as well as construct regulatory, policy and legal roadblocks to competition.

By way of example, a brand-name biologic manufacturer recently stated that "even with the most advanced technologies, scientists can't make exact copies of biologics. That's why they're called biosimilars – they are very similar, but not identical, to the original medicines....[g]iven that biosimilars follow an abbreviated regulatory pathway in the United States, they usually receive approval based on

<sup>13</sup> Goldman, A. (2018, June 7). Walgreen and Kroger sue Johnson & Johnson over Remicade, Allege Antitrust Violation. Retrieved from <https://www.keionline.org/28114>

<sup>14</sup> Executive Order on Promoting Competition in the American Economy, July 9, 2021.



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less comprehensive data sets compared to the original medicines.”<sup>15</sup> This explicit disparagement ignores the rigorous scientific standards used by FDA to evaluate biosimilars and goes so far as to exclude the fact that biosimilars must be “highly similar to their reference products” as defined by Congress.<sup>16</sup> Such disparagement takes advantage of stakeholder—especially patient—unfamiliarity with biologic medicines including biosimilars, and the important role these medicines play in addressing serious or life-threatening conditions for patients.

To that end, AAM urges the Subcommittee to take steps to prohibit false, misleading, or otherwise deceptive statements about biosimilar products and their safety or effectiveness.

### VI. Strengthening *Inter Partes* Review

This Committee has pride of authorship over one of the most important mechanisms for ensuring patent quality: *inter partes* review (IPR) and the other post-grant review procedures that allow the Patent Office to reconsider the mistaken grant of patents that never should have issued. As a strong majority of the Supreme Court held in upholding the Judiciary Committee’s bi-partisan work, IPR “protects ‘the public’s paramount interest in seeing that patent monopolies are kept within their legitimate scope.’”<sup>17</sup>

The examination process is not by itself sufficient to serve that “paramount” public interest. The process is one-sided and limited, and provides no meaningful opportunity for interested third parties to participate. Significantly, the examiner must accomplish a number of distinct tasks during the examination process—all of which must be completed in a mere **19 hours**.<sup>18</sup>

In particular, the examiner must consider whether the claimed invention satisfies all of the provisions that Congress has included into the Patent Act, including whether the claimed invention is new and not obvious. Novelty and non-obviousness are measured against the prior art—but much of the prior art that comes before the examiner is submitted by the applicant. And the examiner’s ability to search for additional prior art—much less to apply its teachings to the application—is highly constrained. That dearth of information is magnified by the Patent Office’s “count” system—a system set up to reward productivity, not care.<sup>19</sup>

Litigation in federal district court is not an adequate forum by itself to weed out invalid patents. District court cases are slow-moving and costly. The parties generally litigate infringement as well as the invalidity of the patents. That means months or even years of fact and expert discovery. Significantly,

<sup>15</sup> Genentech. “Similar, Not the Same; The Road Ahead for Biosimilars.” <https://www.gene.com/stories/similar-not-the-same-the-road-ahead-for-biosimilars?topic=oncology>

<sup>16</sup> 42 U.S.C. 262

<sup>17</sup> *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1374 (2018) (citation omitted).

<sup>18</sup> Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application Data*, Nat’l Bureau of Econ. Research Working Paper 20337, at 7 (July 2014), <http://www.nber.org/papers/w20337.pdf>.

<sup>19</sup> Eric Blatt & Lian Huang, *USPTO Incentive Policies Influence Patentability Decisions*, available at <https://www.law360.com/articles/1052622/uspto-incentive-policies-influence-patentability-decisions>.



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the District of Delaware and the District of the New Jersey—two of the most popular forums for Hatch-Waxman litigation—have a median time to trial of 731 and 795 days, respectively.<sup>20</sup>

That is why Congress adopted legislation allowing the Patent Office to fix its own mistakes with the benefit of more time and more information. IPR allows interested parties to supply the Patent Office with important pieces of prior art that the examiner may have missed during examination. It allows invalidity issues to go before experts from within the Patent Office, rather than lay jurors or generalist federal trial judges. It also allows certain grounds of invalidity to be tested in a speedy, time-limited, and streamlined proceeding without the distraction of other issues such as infringement. And it allows a patent owner's arguments to be tested through cross-examination and the submissions of opposing experts in a way that examination does not allow.

Now more than ever, IPR is a critical tool to ensure that pharmaceutical patents are truly innovative. Brand-name drugs are protected by increasingly larger and larger patent estates. As this Committee is aware, Humira®—the bestselling drug in the United States—is the subject of more than a hundred patents and makes more money annually than all of the NFL teams combined. And many other brand-name pharmaceutical companies are following suit and developing enormous portfolios around their top-selling drugs. The effect of this trend is that litigation by generic and biosimilar drug developers to challenge some of these patents is often prohibitively expensive and risky.

IPR was designed to streamline and simplify this process, and it has indisputably worked. Indeed, many generic and biosimilar manufacturers have used IPR proceedings to successfully launch their alternatives, providing patients with earlier access to more affordable medications. For example, generic pharmaceutical companies successfully defeated the claims of a patent covering the drug Zytiga®, allowing for the launch of generic versions of the drug to treat prostate cancer.<sup>21</sup> As a result of this successful IPR, patients saved an average 81% on this life-saving medicine due to the availability of generic Zytiga®.<sup>22</sup> Over the course of four IPRs, generic pharmaceutical companies also invalidated all challenged claims of several patents covering OxyContin® in response to infringement allegations asserting over a dozen patents.<sup>23</sup> And through a series of IPRs, numerous other drug patents have been invalidated—in whole or in part—through IPR, including patents for Lantus®, Herceptin®, Rituxan®, Avastin®, and Neulasta®.<sup>24</sup>

<sup>20</sup> Pharmaceutical Patent Litigation Increases Nearly 30 Percent in 2017: Lex Machina Releases Fourth Hatch-Waxman/ANDA Litigation Report, available at <https://lexmachina.com/media/press/lex-machina-releases-fourth-hatch-waxman-anda-litigation-report/>.

<sup>21</sup> *BTG Int'l Ltd. v. Amneal Pharm. LLC*, 923 F.3d 1063 (Fed. Cir. 2019) (affirming IPR decisions).

<sup>22</sup> See AAM, Let's strengthen IPR to accelerate patient access and lower prescription drug prices.

<sup>23</sup> See *Amneal Pharmaceuticals, LLC v. Purdue Pharma, L.P. et al.*, Case Nos. IPR2016-01412, (Feb. 8, 2018), IPR2016-01413, (Jan. 17, 2018), IPR2016-01027, (Nov. 8, 2017), and IPR2016-01028, (Nov. 8, 2017).

<sup>24</sup> See AAM, Statement for the Record, Senate Judiciary Committee Hearing on the "Support Technology and Research for Our Nation's Growth and Economic Resilience Patents Act of 2019 (STRONGER)," at 2-3 (Sept. 11, 2019).



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Despite these tangible benefits for patients and payers, IPR has been steadily undermined over the past several years. In particular, the PTO has implemented rules that make it prohibitively difficult and risky for a generic or biosimilar manufacturer to file—much less succeed—in an IPR. The PTO has also given patent owners multiple bites at the apple in changing their claims throughout the proceeding—a practice that fundamentally disincentivizes IPR filings.

We would be happy to work with the Subcommittee to strengthen and restore IPR so that it promotes competition while protecting true innovation.

**Conclusion**

Patient access to biosimilar and generic medicines has never been more critical. High launch prices on new brand biologics and annual price increases on existing brand-name drugs, combined with an increasing trend of anti-competitive tactics designed to delay or prevent competition from more affordable biosimilars and generics, are pushing access to medicines out of reach for too many patients. We appreciate the Subcommittee's attention to these issues and for the opportunity to provide our views and recommendations on how best to ensure sustainable patient access to more affordable prescription medicines. We look forward to working with you to build on the success of the CREATES Act and continue to advance solutions that meaningfully reduce the cost of prescription drugs for America's patients.

## **Pharma Cheating: How Antitrust Violations by Big Pharma Costs \$74 billion a Year in Excess Medical Costs**

### **American Economic Liberties Project**

*This memo is an estimate of the impact of pharmaceutical antitrust violations on outpatient prescription drug spending.*

#### **Key Points**

- AELP reviewed the top 100 top-selling prescription drug products in Medicare Part D and Medicaid in 2019 to estimate the prevalence and impact of antitrust violations in the pharmaceutical industry.
- The analysis reveals that at least thirty (30) of the top-selling 100 prescription drugs in Part D and Medicaid in 2019 were likely impacted by anticompetitive conduct.
- The analysis estimates that anticompetitive conduct increased gross spending on the top 100 prescription drugs in Part D and Medicaid in 2019 by roughly 20%.
- If all US retail prescription drug sales were similarly impacted (20%) by anticompetitive conduct as the top 100 Part D and Medicare drugs in 2019, then the US spent an additional \$74 billion dollars on a net basis for retail prescription drugs as the result of anticompetitive conduct within the pharmaceutical industry in 2019.

#### **The State of Pharmaceutical Antitrust Reform**

The American pharmaceutical industry is structured around rules that allow firms to maintain temporary monopolies over newly introduced brand drugs. Such rules incentivize research and development by defraying the high cost of creating new drug products. These monopolies, however, are intended to be temporary. After patents and regulatory exclusivity expires, other firms are permitted to introduce equivalent versions of brand drugs and this competition between functionally equivalent drug products leads to dramatic costs reductions. This framework creates an incentive for firms to research and develop new treatments while ensuring that costs come down over time.

However, through complicated schemes like “pay-for-delay,” “product hopping,” and “rebate walls,” pharmaceutical firms have significantly increased drug prices by delaying the introduction of low-cost generic and biosimilar drugs, encouraged higher list prices that impact patients, and driven utilization of more expensive brand drugs over cheaper alternatives. These anticompetitive and illegal schemes are pervasive and have subverted the pharmaceutical development system. Members of Congress from both parties, the Biden Administration, independent agencies, and the American public now appear ready and willing to address the problem of widespread anticompetitive conduct within the pharmaceutical industry.

The extreme opacity and complexity of the US drug industry make it difficult to estimate the financial impact of these anticompetitive schemes on overall US prescription drug spending. This analysis is an attempt to fill in this gap by estimating the prevalence of antitrust violations across the top-selling 100 drug products in Part D and Medicaid and then extrapolating that rate of overspending across all US retail prescription drug spending.

Separate from questions of anticompetitive conduct, there are also political efforts to reform drug pricing directly (including H.R. 3 and similar proposed legislation in the senate), which seek to reduce pharmaceutical prices and spending by changing the way drug prices are set and negotiated.

Few appear to recognize the enormous overlap between the two issues: anticompetitive schemes are a major contributor to high drug prices and spending in the US because these schemes determine the market structure in which drug prices are negotiated. It is not ordinarily necessary to mediate high drug prices for a brand medicine if there are multiple equivalent generic or biosimilar substitutes readily available. However, anticompetitive schemes often allow pharmaceutical firms to retain their branded drug monopolies for longer than entitled and otherwise delay or deny access to competition.

In other words, the US government's failure to enforce the antitrust laws is a major reason why drug price negotiation is currently so dysfunctional. Whether federal and state governments enforce the antitrust laws against drug manufacturers and pharmaceutical benefit managers (PBMs) will determine whether the US drug system will deliver innovative drugs at reasonable prices or whether firms will continue to focus on complicated price-gouging schemes that allow them to extract billions of dollars of excess profits from decades old drugs.

### Methodology

To estimate the impact of anticompetitive conduct on US drug prices and spending, AELP collected the top 100 drug products (as defined by CMS) by gross spending in Part D and Medicaid in 2019.<sup>1</sup> For each of the top 100 products (many of which overlap between the two programs), AELP searched for and reviewed publicly available litigation documents along with other highly credible sources about the industry to determine whether each product was likely impacted by an anticompetitive scheme in 2019. AELP then estimated the likely impact of the anticompetitive schemes at issue on gross (pre-rebate) Part D and Medicaid drug spending.<sup>2</sup>

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<sup>1</sup> CMS Drug Spending, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs>.

<sup>2</sup> The purpose of this analysis is to determine the approximate scale of overspending because of anticompetitive conduct in the US pharmaceutical industry. This analysis is not intended to provide a fully defensible damages methodology for every drug product at issue, which ordinarily requires multiple economic and regulatory experts and years of litigation.



Drug products were included among those likely impacted by anticompetitive conduct in 2019 in the following circumstances:

- A brand product was expected to face generic or biosimilar competition before 2019, but that competition ultimately failed to come to market because of anticompetitive conduct.
- The brand product did face generic or biosimilar competition in 2019 but significantly less because of anticompetitive conduct.
- The brand product was a direct successor to an older brand drug product that would have lost significant market share before patients were converted over to the brand product that was successful in 2019.<sup>3</sup>
- There was evidence that prices are impacted by horizontal collusion between generic manufacturers and those prices did not appear to have returned to pre-collusion levels by 2019.
- There is publicly documented and verifiable evidence of conduct that appears to violate existing antitrust laws.

AELP next estimated the potential impact of such anticompetitive conduct on 2019 drug spending. There are two factors that determine drug spending in a particular drug market: the market share and relative prices of available drug products.

To estimate the rate of overspending, the study used default assumptions about expected price differences between brands and generics, as well as biologics and biosimilars, as well as the expected rate of conversion from brand to generic, and from biologic to biosimilar product, and then modified those default assumptions when there is evidence that the drug would have competed in an unusually competitive market, where there is market evidence that suggests a different price difference or penetration rate, or other product-specific factors.

The default assumptions included:

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of the problem of excessive drug spending because of anticompetitive conduct. This is not intended to provide a fully defensible damages methodology for every drug product at issue, which typically requires several highly paid experts and years of litigation to resolve.

<sup>3</sup> For example, Biktarvy is Gilead's successor to Truvada and Gilead publicly stated it intended to convert Truvada patients over to Biktarvy before the introduction of generic versions of Truvada. Accordingly, drug spending on Biktarvy would have been significantly less in 2019 if patients had access to Truvada in 2017. Blankenship, *Gilead's Truvada faces Teva generics assault amid Descovy switching campaign*, Fierce Pharma (Oct. 2, 2020), <https://www.fiercepharma.com/manufacturing/gilead-sciences-truvada-will-face-teva-generic-challenger-amid-descovy-switching>.

- Traditional (small molecule) generics cost roughly 80% less than brand drugs after four (4) generic competitors enter a drug market.<sup>4</sup>
- Prescriptions are dispensed as generic 97% of the time when there is a generic available.<sup>5</sup> To simplify things, this study assumes that 100% of market share would have to generic products once multiple generics were available.
- This analysis assumes a highly competitive market for biosimilars on both price and the rate of biosimilar penetration, which likely would have been the case in the absence of the anticompetitive conduct at issue.
- In a highly competitive market, biosimilars cost 45% less than equivalent brand biologic drugs.<sup>6</sup>
- In a highly competitive market, biosimilars capture 55% market share within 2 years of biosimilar entry.<sup>7</sup>

## Results

*At least thirty (30) of the top 100 Part D and Medicaid drugs in 2019 were likely impacted by anticompetitive conduct in 2019.*

| Top 100 Part D and Medicaid Drugs Likely Impacted by Anticompetitive Conduct in 2019 |                    |              |
|--------------------------------------------------------------------------------------|--------------------|--------------|
| Achzar                                                                               | Epclusa            | Odefsey      |
| Admelog Solostar                                                                     | Flovent HFA        | Proair HFA   |
| Advair Diskus                                                                        | Genvoya            | Remicade     |
| Basaglar Kwikpen U-100                                                               | Harvoni            | Restasis     |
| Biktarvy                                                                             | Humalog            | Revlimid     |
| Botox                                                                                | Humira             | Spiriva      |
| Bystolic                                                                             | Lantus             | Suboxone     |
| Combivent Respimat                                                                   | Levemir            | Truvada      |
| Copaxone                                                                             | Methylphenidate ER | Ventolin HFA |
| Descovy                                                                              | Odefsey            | Zytiga       |

<sup>4</sup> FDA, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices* (2019), <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices> (generic AMP prices are 79% less than brand with four generic producers).

<sup>5</sup> IQVIA Institute, *The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025*, at 38 (May 2021), <https://www.iqvia.com/en/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us>.

<sup>6</sup> IQVIA Institute, *Biosimilars in the United States 2020-24: Competition, Savings, and Sustainability*, at 15 (Oct. 2020), <https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024>.

<sup>7</sup> *Id.*

*There are at least thirteen (13) antitrust lawsuits and closely related groups of lawsuits regarding at least twenty-one (21) of the top 100 Part D and Medicaid drugs in 2019. The FTC appears to have brought enforcement actions in only three (3) of these thirteen (13) different cases.*

| Existing or Completed Antitrust Litigation Regarding Top 100 Medicare and Medicaid Drugs in 2019 | No. of Drugs at Issue |
|--------------------------------------------------------------------------------------------------|-----------------------|
| In re Acthar Antitrust Litigation*                                                               | 1                     |
| In re Botox Antitrust Litigation                                                                 | 1                     |
| In re Bysolic Antitrust Litigation                                                               | 1                     |
| In re Generic Pharma Antitrust Litigation                                                        | 1                     |
| In re Gilead HIV Antitrust Litigation                                                            | 5                     |
| In re Humira Antitrust Litigation                                                                | 1                     |
| In re Insulin Antitrust Litigation                                                               | 5                     |
| In re Lantus Insulin Antitrust Litigation                                                        | 1                     |
| In re Remicade Antitrust Litigation                                                              | 1                     |
| In re Restasis Antitrust Litigation                                                              | 1                     |
| In re Revlimid Antitrust Litigation                                                              | 1                     |
| In re Suboxone Antitrust Litigation                                                              | 1                     |
| In re Zytiga Antitrust Litigation                                                                | 1                     |

*The analysis found that nine (9) of the other top 100 Part D and Medicaid drugs in 2019 are implicated in antitrust violations according to publicly available materials.*

| Other Top Drugs Implicated by Credible Public Materials                           | Source                                                                                                                             | No. of Drugs |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|--------------|
| Advair Diskus; Combivent Respimat; Flovent HFA; ProAir HFA; Spiriva; Ventolin HFA | Beall, et al., <i>Is Patent "Evergreening" Restricting Access to Medicine/Device Combination Products</i> , PLoS ONE 11(2) (2016). | 6            |
| Epclusa; Harvoni                                                                  | Adam Fein, DrugChannels.net, <i>Why Part D Plans Prefer High List Prices that Raise Costs for Seniors</i> , (Jan. 22, 2020).       | 2            |
| Copaxone                                                                          | 46Brooklyn.com, <i>The Flawed Design of Medicare Part D: A Copaxone Case Study</i> (Aug. 12, 2020).                                | 1            |

*There were at least eleven (11) different types of anticompetitive schemes found among the top 100 Part D and Medicaid in 2019. The most common type of anticompetitive scheme in this analysis was illegally listing patents in the Orange Book (11), followed by Pay-for-Delay Schemes (9), exclusionary rebates (8), and then horizontal collusion (7).*

| Type of Anticompetitive Scheme by Top Drugs Impacted | No. of Drugs |
|------------------------------------------------------|--------------|
| Illegal Orange Book Listing                          | 11           |
| Pay for Delay <sup>8</sup>                           | 9            |
| Exclusionary Rebates <sup>9</sup>                    | 8            |
| Horizontal Collusion                                 | 7            |
| No Generics Agreement                                | 5            |
| Patent Fraud <sup>10</sup>                           | 4            |
| Merger monopolization                                | 2            |
| Sham Citizens Petitions                              | 2            |
| PBM Steering                                         | 1            |
| REMS Abuse                                           | 1            |
| Product Hopping                                      | 1            |

*The analysis estimates that anticompetitive conduct increased gross spending on the top 100 Part D and Medicare drugs in 2019 by approximately 20%.*

|                        | Top 100 Drug Spending 2019 | Top 100 Overcharge | Overcharge as % of Top 100 |
|------------------------|----------------------------|--------------------|----------------------------|
| <b>Medicare Part D</b> | \$104.76 B                 | \$20.13 B          | 21%                        |
| <b>Medicaid</b>        | \$34.80 B                  | \$7.37 B           | 19%                        |

*If all US retail prescription drug sales were similarly impacted (20%) by anticompetitive conduct as the top 100 Part D and Medicare drugs in 2019, then the US spent an additional \$74 billion*

<sup>8</sup> "Pay for Delay" includes geographic market allocation as a form of reverse payment.

<sup>9</sup> "Exclusionary rebates" refers to both the practice of "rebate walls" in which a manufacturer uses commercial rebates to exclude coverage of competing brand or generic/biosimilar products and the related practice of PBMs refusing to cover cheaper drugs (often identical "authorized generic" versions of brand products) because those products do not come with a rebate to the PBM.

<sup>10</sup> "Patent Fraud" refers to fraud on the patent office, sham patent litigation, and "patent thickening" in which a manufacturer obtains and enforces large numbers of patents without regard to their validity and coverage.

*dollars on a net basis for retail prescription drugs as the result of anticompetitive conduct within the pharmaceutical industry in 2019.*

|                                                            |         |
|------------------------------------------------------------|---------|
| Total 2019 Retail Prescription Drug Spending <sup>11</sup> | \$370 B |
| Est. Anticompetitive Impact on Top 100 Drugs               | 20%     |
| Est. Impact on 2019 US Retail Drug Spending                | \$74 B  |

### Limitations of This Analysis

This analysis is based on gross (pre-rebate) spending as reported to CMS and posted by CMS online for the Part D and Medicaid programs. It accordingly estimates the impact of anticompetitive based on gross spending before the impact of Part D rebates and Medicaid Drug Rebate Program (MDRP) rebates<sup>12</sup>, which are not publicly available but almost certainly distort this analysis as applied on a net basis. In other words, this analysis does not necessarily mean that Medicaid and Medicare Part D would have saved 20% on a net basis if not for the anticompetitive conduct at issue. Because the rebates at issue are secret, it is not possible to determine how the anticompetitive conduct at issue would have impacted drug spending on a net basis from publicly available information.

This analysis reviewed only the top 100 drugs from Medicare Part D and Medicaid and then extrapolates that rate and severity of anticompetitive conduct across the thousands of individual drug products covered by these programs. The rate and impact of anticompetitive conduct among the top 100 drugs in 2019 may be greater than the rate among all drugs in 2019. However, US drug spending is now heavily concentrated among the top brand products, which suggests that the top 100 brand drugs may be a reasonable proxy for the entire market.<sup>13</sup>

Additionally, the mix of drugs purchased by Medicare Part D and Medicaid is likely similar, it is not perfectly representative of all US retail prescription drug sales.

### Recommended Policy Changes Based on this Analysis

#### 1. Greatly increase enforcement resources

<sup>11</sup> CMS, National Health Expenditures 2019 Highlights, available at <https://www.cms.gov/files/document/highlights.pdf>.

<sup>12</sup> Medicaid Drug Rebate Program, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>.

<sup>13</sup> See KFF, Relatively Few Drugs Account for a Large Share of Medicare Prescription Drug Spending (April 19, 2021), <https://www.kff.org/medicare/issue-brief/relatively-few-drugs-account-for-a-large-share-of-medicare-prescription-drug-spending/> (“The 250 top-selling drugs in Medicare Part D with one manufacturer and no generic or biosimilar competition (7% of all Part D covered drugs) accounted for 60% of net total Part D spending.”).

2. Prioritize enforcement before patients have been harmed
3. Pass clear, bright-line rules and legislation that prohibits, sufficiently punishes, and deters illegal conduct without years of litigation.
4. Create pricing transparency across pharmaceutical manufacturers and pharmacy benefit managers.



**Statement for Hearing on  
“A Prescription for Change: Cracking Down on Anticompetitive Conduct in  
Prescription Drug Markets”**

**Submitted to the  
Senate Committee on the Judiciary  
Subcommittee on Competition Policy, Antitrust, and Consumer Rights**

**July 13, 2021**

Everyone should be able to get the medications they need at a cost they can afford. Rising drug prices impose a heavy burden on all Americans—a direct result of high list prices determined solely by drug companies. Too many hardworking Americans must choose between paying their bills and accessing life-saving medicines. AHIP appreciates the Subcommittee’s attention on the problem of drug manufacturers’ anticompetitive conduct in the prescription drug market. We look forward to working with the Subcommittee to advance market-based solutions that reduce drug prices by promoting competition and consumer choice, along with open and honest drug pricing.

The COVID-19 crisis has impacted all Americans and clearly illustrated the importance of access to convenient and affordable care, including lifesaving and life-sustaining medications and treatments. In a January 2021 survey conducted by Morning Consult and the Campaign for Sustainable Rx Pricing (CSRxP), 55% of Americans reported that the coronavirus pandemic has made them more concerned about prescription drug affordability.<sup>1</sup> However, this has not deterred drugmakers from raising their prices. In January 2021, drug companies raised prices for at least 582 brand-name drugs and so far in just this month, drug companies have hiked prices on another 52 brand name prescription drugs.<sup>2</sup> The conclusion is clear: Pharmaceutical companies alone set their prices—and they alone can lower them. Instead, they continue to raise prices year after year—even several times a year—making health care more expensive for everyone.

As a result of these exorbitant prices, more than 25% of Americans stated they, or both they and another family member, have been unable to afford a prescribed medication over the past year.<sup>3</sup> Americans should not have to choose between needed medications and other life essentials, such as housing or food.

While there are many factors that enable drugmakers to demand out-of-control prices, one of the most significant is their ability to engage in anti-competitive practices. While we all applaud true

<sup>1</sup> <https://www.csrxp.org/wp-content/uploads/2021/01/CSRxP-Memo-Final.pdf>

<sup>2</sup> <https://www.goodrx.com/blog/january-drug-price-hikes-2021/>

<sup>3</sup> <https://www.csrxp.org/wp-content/uploads/2021/01/CSRxP-Memo-Final.pdf>

innovations in care, including the recent successes in COVID-19 vaccine development, too many pharmaceutical innovations today also involve novel ways to extend patents beyond their intended terms. The cost of this kind of innovation takes dollars out of Americans' pockets, places care out of reach, and defers true innovation.

Prescription drugs comprise a very high percentage of medical costs, driving up Americans' health insurance premiums and the cost of health care delivered by providers whose care includes the administration of those drugs. Today, more than 21 cents of every dollar spent on health insurance premiums pays for prescription drugs—more than any other single category of expense.<sup>4</sup> At the same time, the largest drugmakers in the United States spend just 22 cents out of every dollar on research & development (R&D).<sup>5</sup> That means nearly 80 cents goes toward something other than R&D.

Research from the Congressional Budget Office confirmed that pharmaceutical R&D costs do not have a relationship to the prices drug companies set on their products.<sup>6</sup> The report states, "Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug's sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price."

In July 2021, the House Committee on Oversight and Reform released a report on drug pricing showing that leading drug companies have spent more on stock buybacks, dividends to investors, and executive compensation than on R&D.<sup>7</sup> In fact, from 2016 to 2020, the 14 leading drug companies spent \$577 billion on stock buybacks and dividends—\$56 billion more than they spent on R&D over the same period. This analysis therefore reveals that drug companies' claims that reducing U.S. prescription drug prices will harm innovation is overblown.

In September 2020, the Foundation for Research on Equal Opportunity released a study that found ballooning spending on American prescription drugs is being particularly driven by drugmakers' abuse of the patent system to undermine biologic and biosimilar competition.<sup>8</sup> The report finds that despite representing less than 1% of prescriptions in the United States, biologic drugs account for nearly half of all drug spending. Without action, the study estimates the anti-competitive nature of the biologic drug marketplace will cost American patients more than \$30 billion from 2015-2029.

Drugmakers continue to command higher and higher drug prices for longer periods of time due to gamesmanship and other abuses of the monopoly power resulting from patent protection. Legislative and regulatory action is necessary to address drug manufacturer manipulation of existing laws. We welcome the opportunity to work with the Subcommittee to advance bipartisan solutions that end these abuses and lower drug costs, premiums, employer burdens, and taxpayer expenses.

<sup>4</sup> <https://www.ahip.org/health-care-dollar/>

<sup>5</sup> [https://www.csrpxp.org/wp-content/uploads/2019/05/CSRXP\\_One\\_pager\\_III\\_FINAL-SITERELEASE.pdf](https://www.csrpxp.org/wp-content/uploads/2019/05/CSRXP_One_pager_III_FINAL-SITERELEASE.pdf)

<sup>6</sup> <https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf>

<sup>7</sup> <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf>

<sup>8</sup> <https://freopp.org/the-growing-power-of-biotech-monopolies-threatens-affordable-care-e75e36fa1529>



### Identifying and Addressing Patent Abuses to Reduce Drug Prices

Americans broadly agree lowering drug prices is an urgent challenge, with 96% of Americans saying it is “very” or “somewhat” important among all the issues facing the nation.<sup>9</sup> That includes 71% of Americans who classify lowering drug prices as “very important.”

*Leveraging new patents to extend the life of existing patents.* Pharmaceutical companies have a long history of engaging in anti-competitive patent abuse schemes to hinder generic competition and maintain high drug prices. This includes strategies to extend the patent life of their products without making clinically significant changes to the products. A recent study of prescription drugs on the market between 2005 and 2015 found that “78% of the drugs associated with new patents in the FDA’s records were not new drugs coming on the market, but existing drugs.”<sup>10</sup>

*Product hopping* describes a practice engaged in by brand drug manufacturer in which, when a product nears the end of its monopolistic patent life, the brand drug manufacturer works to move patients from the product nearing patent expiration to a patent-protected reformulation of the drug.<sup>11</sup> This practice takes two forms, through a “hard switch,” where the older product is removed from the market, and a “soft switch,” where the older product is kept on the market with the new product. In either case, this reformulation generally has no improved clinical result, does not fundamentally change the drug’s therapeutic effect, and does not provide any additional benefits to consumers. It is a lifecycle management tactic that benefits only the manufacturer at the expense of patients and the health care system, as generic savings cannot be realized if patients have been moved to a protected drug before generic competitors can enter the market.

A recent example of product hopping can be seen with Gilead’s two anti-retroviral HIV drugs—tenofovir disoproxil fumarate (TDF) and tenofovir alafenamide (TAF)—both critical therapies in treating and preventing transmission of that devastating disease. Manipulating intellectual property law and FDA regulations, Gilead was able to stagger exclusivity protections for each type of drug for the purpose of delaying the entry of generic versions of each drug and extend their patents despite both drugs having been discovered at roughly the same time. Moreover, the TAF drugs—introduced in 2016 after patent exclusivity for the TDF drugs expired—are potentially safer due to lower dosing requirements and fewer/less severe side effects, per research originally conducted by the company in 2002-2003.<sup>12</sup> Thus, HIV patients—and those at risk of contracting the virus who would be eligible to take the drug as a preventive measure—have been delayed access to a safer, more effective drug solely to extend the opportunity for Gilead to profit from their products over a greater length of time.

*Patent thickening* serves a similar purpose to *product hopping* by effectively blocking cheaper generics or biosimilars from coming to market. Patent thickening occurs when brand name drug companies create a “thicket” of patents that can dramatically extend exclusivity periods by

<sup>9</sup> <https://www.csrpxp.org/wp-content/uploads/2021/01/CSRXP-Memo-Final.pdf>

<sup>10</sup> <https://www.affordableprescriptiondrugs.org/resources/the-cost-of-brand-product-hopping/>

<sup>11</sup> <https://www.affordableprescriptiondrugs.org/resources/the-cost-of-brand-product-hopping/>

<sup>12</sup> [Intentionally Delayed Pharmaceutical Innovation Under Perverse Incentives: Gilead’s HIV Pipeline As A Case Study | Health Affairs](#)

seeking a multitude of patents for marginal aspects of the drug or biologic. A common example of this practice relates to Humira, a popular treatment for chronic inflammatory diseases such as rheumatoid arthritis and psoriasis made by AbbVie Inc. AbbVie has been granted 138 patents since Humira's approval by the Food and Drug Administration (FDA) in 2002.<sup>13</sup> Many of those patents were issued in the years close to the expiration of Humira's main patent. Even when the purpose of the patent acquisition was to harm competitors, courts have found that these thickets do not violate antitrust law.<sup>14</sup> But such court rulings have not helped hardworking American families, who lack access to biosimilars and thus are stuck paying high prices. Of note, Humira's price has almost doubled since 2012, from about \$19,000 to \$38,000<sup>15</sup> per year.<sup>16</sup>

Another way drugmakers maintain monopoly power is through *evergreening*. Evergreening occurs when a branded drugmaker makes minor changes to their drug, such as to their manufacturing process or the formulation of the drug in its injectable form, and receives approval for those changes from the FDA. As a result, drugmakers can gain new patents on the minor variations, extending their market exclusivity for an additional 20 years.<sup>17</sup>

These are just some of the anticompetitive tactics pharmaceutical companies employ to boost their profits. Market-based solutions will help crack down on drugmakers' egregious practices and increase biosimilar competition, lower prices, and enhance innovation.

### Recommendations

AHIP is committed to advancing policies that increase choice, competition and end this anti-generic/biosimilar patent gaming pursued by pharmaceutical companies. Those policies include:

#### 1. Shortening the Exclusivity Period for Biologics to Increase Biosimilars Competition

Biosimilars offer great promise for generating cost savings and increasing patient access to needed treatments and therapies. Just as with generic medications, a truly competitive biosimilars market will mean greater use of these products which, in turn, will drive down costs and increase patient access. As drugmakers are preventing competition from biosimilars by gaming the 12-year exclusivity period for biologics, Congress should consider shortening this exclusivity period to allow for earlier biosimilar competition. Non-partisan experts, such as those at the Federal Trade Commission (FTC), have concluded that the current 12-year exclusivity period is "unnecessary to promote innovation by pioneer biologic manufacturers" and could actually harm innovation in this space. By reducing the exclusivity period from 12 years to 7 years, Congress could promote greater price competition and help alleviate cost pressure for payers, patients, and consumers for biologics, which often carry extraordinarily high price tags. Moreover, a shorter exclusivity period could facilitate earlier and greater availability of biosimilars in the marketplace.

<sup>13</sup> <https://www.healthaffairs.org/doi/10.1377/hblog20210126.820337/full/>

<sup>14</sup> <https://www.natlawreview.com/article/abbvie-s-enforcement-its-patent-thicket-humira-under-bpcia-does-not-provide>

<sup>15</sup> <https://www.csrpx.org/big-pharma-earnings-watch-abbvie-3/>

<sup>16</sup> [A Humira Prescription Costs \\$38,000 A Year Because Our Patent System Is Being Abused | HuffPost](#)

<sup>17</sup> <https://freopp.org/the-growing-power-of-biotech-monopolies-threatens-affordable-care-e75e36fa1529>

## 2. Prohibit Anti-Competitive “Pay-For-Delay” Settlements that Hinder Competition in the Generics and Biosimilars Markets.

Currently, drugmakers offer patent settlements that pay generic drug companies not to bring their lower-cost alternatives to market for a certain amount of time. “Pay-for-delay” settlements block generic competitors from entering the market, allowing brand name drugmakers to continue to obtain monopoly profits and avoid competition. The FTC indicates that these “pay-for-delay” tactics by drugmakers cost Americans \$3.5 billion in higher drug costs each year.<sup>18</sup> Fully halting these anti-competitive settlements will remove a barrier to competition and expand the availability of lower-cost generic drugs and biosimilars.

## 3. Stop the “Evergreening” of Patent Protections.

Some drugmakers game the patent system to artificially prolong the exclusivity period for certain drugs and to prevent less costly generic versions from reaching the market. By making minor changes to a drug’s chemical composition or delivery mechanism (*e.g.*, an extended-release version of a previously patented drug that had to be taken twice daily), manufacturers can extend patents that otherwise would have expired. These evergreening schemes do not typically provide any meaningfully enhanced clinical benefits to patients. Instead, they are aimed at maintaining monopolistic pricing for products that are no more effective than their less expensive, generic counterparts. We look forward to working with the Subcommittee to address this issue.

## 4. Limit Product Hopping that Does Not Benefit Patients

Product hopping is frequently used in combination with Evergreening to hold patients captive to a higher-cost drug. Drugmakers using this strategy redesign a drug in a way that allows a new version to be patentable even though it does not fundamentally change the drug’s therapeutic effect. Those minor changes present an opportunity for the brand-name manufacturer to extend its monopoly potentially decades into the future. We look forward to working with the Subcommittee to address this issue.

## **Conclusion**

Americans deserve bold actions, at both the legislative and regulatory levels, to hold drugmakers accountable for the high list prices they set. The impact of high drug prices and patent abuses is felt directly by American families and businesses in the form of higher costs for needed drugs, higher premiums for health plans that pay for them, and fewer treatment choices for patients. With solutions that deliver real competition, create more choices, and ensure open and honest drug prices, the private market will have the tools it needs to deliver more affordable pharmaceutical products— while protecting and supporting innovations to deliver new treatments and cures for patients.

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<sup>18</sup> <https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay>



AMERICAN PHARMACISTS ASSOCIATION  
STATEMENT FOR THE RECORD

BEFORE THE U.S. SENATE JUDICIARY SUBCOMMITTEE ON COMPETITION POLICY,  
ANTITRUST AND CONSUMER RIGHTS

A PRESCRIPTION FOR CHANGE: CRACKING DOWN ON ANTICOMPETITIVE CONDUCT  
IN PRESCRIPTION DRUG MARKETS

TUESDAY, JULY 13, 2021



Chair Klobuchar, Ranking Member Lee, and Members of the Subcommittee, the American Pharmacists Association (APhA) is pleased to submit the following Statement for the Record for the U.S. Senate Judiciary Subcommittee on Competition Policy, Antitrust, and Consumer Rights Hearing, entitled, “A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Drug Markets.”

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care and enhance public health.

Pharmacies are where millions of Americans are first exposed to the impact of complex pharmaceutical pricing policies or confronted with changes in coverage, formularies, prior authorization, deductibles, and co-payments or co-insurance, many of which they did not know existed or understand.

Every day, pharmacists help our patients navigate through confusing and convoluted policies related to the cost and coverage of their medications and management of their out-of-pocket costs. Pharmacists are not compensated for this time or directly for most of our patient care services that support optimization of medication therapy.

Our comments focus on the following areas – cost versus value, anti-competitive actions by pharmacy benefit managers (PBMs), drug shortages, and importation concerns.

#### **Cost Versus Value**

As drugs become more expensive, complex, and personalized, the need to optimize their impact also increases. In order to get the greatest benefit from medications, patients must understand how to use their medications safely and effectively, and pharmacists are best positioned to help patients optimize the medication therapies available to them. Pharmacists have more medication-related education and training than any other health care professional. Pharmacists provide medication management services, which are especially important for patients who have complex care plans, take multiple drugs, or have chronic conditions, which disproportionately impact minority and underserved communities. Ultimately, the most expensive medication is one that is inappropriate for a patient or used incorrectly.



The COVID-19 pandemic has highlighted how accessible pharmacists are and how they can be leveraged to improve the health of communities. Pharmacists and pharmacies' lights stayed on from the start of the pandemic and have unquestionably solidified pharmacies as essential components of public health infrastructure.

Many of the new authorities and flexibilities provided related to pharmacists' patient care services during COVID-19, including pharmacists' ability to order, authorize, test, treat, and administer immunizations and therapeutics against COVID-19 and other infectious diseases are temporary federal authorizations under the Public Readiness and Emergency Preparedness Act (PREP Act),<sup>1</sup> which can be revoked at any time. **Thus, as the Committee understands, Congress needs to act immediately to ensure these pharmacist patient care services authorities are maintained as they have significantly increased patient access and improved care while lowering health care costs and saving lives.**

Unfortunately, despite that many states and Medicaid programs are turning to pharmacists to increase access to health care and address medication-related costs, Medicare Part B does not cover many of the impactful and valuable patient care services pharmacists can provide. Pharmacists are trained to do more than place medication in a container. While over 90% of Americans live within 5 miles of a community pharmacy<sup>2</sup>, many of our nation's seniors are medically underserved. As proven during the COVID-19 pandemic, pharmacists are an underutilized and accessible health care resource who can positively affect beneficiaries' care<sup>3</sup> and the entire Medicare program.

**Accordingly, APhA strongly urges the Subcommittee to include S. 1362, the *Pharmacy and Medically Underserved Areas Enhancement Act* in the Committee's legislative package to allow pharmacists to deliver vital patient care services in medically underserved areas to help break down the barriers to achieving health care equity in this country, improve patient care, health outcomes, the impact of medications,<sup>4</sup> and consequently, lower health care costs and extend the viability of the Medicare program.**

<sup>1</sup> ASPR, Expanding the COVID-19 Vaccination Workforce, July 2021, available at: <https://www.phe.gov/emergency/events/COVID19/Documents/covid19-vaccination-wrkfrc-factsheet-508.pdf>

<sup>2</sup> NCPDP Pharmacy File, ArcGIS Census Tract File, NAACDS Economics Department.

<sup>3</sup> CMS, Evidence Supporting Enhanced Medication Therapy Management, Center for Medicare and Medicaid Innovation, 2016, available at: <https://innovation.cms.gov/Files/x/mtm-evidencebase.pdf>

<sup>4</sup> See, Avalere Health, Exploring Pharmacists' Role in a Changing Healthcare Environment, May 2014, available at: <http://avalere.com/expertise/life-sciences/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment> Also, See, Avalere Health, Developing Trends in Delivery and Reimbursement of Pharmacist Services, October 2013, available at: <http://avalere.com/expertise/managed-care/insights/new-analysis-identifies-factors-that-can-facilitate-broader-reimbursement-o>



Specifically, S. 1362 would enable pharmacists to deliver Medicare Part B services that are already authorized by their respective state laws. These services include, but are not limited to:

- Medication management;
- Management of chronic conditions, such as diabetes and hypertension, and related medications;
- Cholesterol testing;
- Point of care testing (e.g., COVID-19, influenza, strep);
- Immunization screening and administration not currently covered by Medicare Parts B and D;
- Tobacco cessation services; and
- Transition of care services.

The importance of medication-related services cannot be overstated, especially in the Medicare program. Medications are the primary method of managing chronic disease that disproportionately impacts minority and underserved populations, which are involved in 80 percent of all treatment regimens. For example, regarding access to cancer medications, African Americans have the highest mortality rate of any racial and ethnic group for all cancers combined and for most major cancers,<sup>5</sup> and face greater obstacles to cancer prevention, detection, treatment, and survival. Overall, the United States spends nearly **\$672 billion** annually on medication-related problems and nonoptimized medication therapy, including nonadherence.<sup>6</sup> Accordingly, not only will this legislation increase beneficiaries' access to health care; it will help improve their outcomes—particularly those impacted by medications.

We also encourage the Subcommittee, when considering policy changes to lower drug prices, to look beyond isolated components of health care to determine cost and value. Because health coverage is frequently analyzed by the benefit type such as inpatient, outpatient, and drug coverage, a patient's overall services, costs, and outcomes may never be reviewed comprehensively. Policies cannot continue to separately consider drug and medical coverage and their related costs and outcomes if we are to achieve true value in health care. Current coverage and payment policies related to prescription drugs place incentives on the short-term, focusing on cost containment for the product rather than weighing the overall clinical benefit to the patient and the impact on their medical costs. Breaking down the many silos within our

<sup>5</sup> HHS. Office of Minority Health. Cancer and African Americans. Last Modified: 2/28/2020, available at: <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=16>

<sup>6</sup> Watanabe, Jonathan H. Et. al. Cost of Prescription Drug-Related Morbidity and Mortality. *Annals of Pharmacology*. First Published March 26, 2018, available at: <http://journals.sagepub.com/sprint/c2i12ma1d15zrN5iUay/full>





health care system will help address the billions of dollars spent on medication-related problems—many of which are preventable.<sup>7</sup>

#### PBMs

Both Congress and multiple Administrations have pointed out ongoing anti-competitive PBM practices in Medicare and Medicaid that are negatively impacting patient costs, care, and access. We would specifically like to commend Chair Klobuchar for her leadership in co-sponsoring S.2554, the Patient Right to Know Drug Prices Act (Public Law No: 115-263) that prohibits a health insurance plan or PBM from restricting a pharmacy from informing an enrollee of any difference between the out-of-pocket cost of a drug under the plan and the cost of the drug without health insurance coverage. Unfortunately, the problems do not stop there, as providers, employers, and taxpayers are also adversely affected by PBMs as well.

The PBM marketplace is highly concentrated,<sup>8</sup> (See, Appendix #1) whereby roughly three-quarters of all equivalent prescription claims are processed by only three vertically merged companies. This concentration has increased barriers to market entry, ballooned prescription drug expenditures, exacerbated cost inequities, and reduced choice for consumers and purchasers. Ample and growing data analysis clearly show increasing evidence that consolidation of PBMs with pharmacies and vertical integration in the healthcare space has led to increases in purchasers' and patients' drug prices through use of hidden "clawbacks," like direct and indirect remuneration (DIR) fees, artificially inflated list prices, price discrimination, spread pricing, mounting price shifts and administrative fees, and patient steering for brand, generic and specialty drugs and to PBM-affiliated pharmacies.

President Biden recently issued an "Executive Order [EO] on Promoting Competition in the American Economy,"<sup>9</sup> calling "on the leading antitrust agencies, the Department of Justice (DOJ) and Federal Trade Commission (FTC), to enforce the antitrust laws vigorously and recognizes that the law allows them to challenge prior bad mergers," with a focus on healthcare markets.<sup>10</sup>

<sup>7</sup> Ibid.

<sup>8</sup> Fein, Adam. Drug Channels. Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2021, The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Section 12.4.1. March 21, 2021, available at: [https://www.drugchannels.net/2021/03/drug\\_channels\\_news\\_roundup\\_march\\_2021.html](https://www.drugchannels.net/2021/03/drug_channels_news_roundup_march_2021.html)

<sup>9</sup> The White House. Executive Order on Promoting Competition in the American Economy. July 9, 2021, available at:

<https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/>

<sup>10</sup> <https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/>





The EO partners well with the new leadership at the FTC which recently voted to authorize priority investigations into vertically merged PBMs as a key enforcement priority, whom the independent anti-trust agency describes as “repeat offenders.”<sup>11</sup>

APhA would be pleased to serve as a resource to the Subcommittee to provide examples of PBM abuses to assist in the forthcoming report also included in the EO directing, “HHS to issue a comprehensive plan within 45 days to combat high prescription drug prices and price gouging.”

APhA looks forward to working with the Subcommittee, Biden Administration, and the FTC to combat the harmful impacts of vertically merged PBMs on pharmacists and our patients—consolidation which has led to increases in patients’ drug prices at the pharmacy counter through utilization of DIR fees and other “clawback” mechanisms, delaying prescribed treatments through patient steering and prior authorization, and limiting options for patients by controlling access to insurance networks.

A few of these harmful PBM practices include:

- **DIR Fees:** The Centers for Medicare and Medicaid Services (CMS) has acknowledged a notable growth in PBMs’ use of harmful DIR fees, **which have increased more than 91,500 percent between 2010 and 2019<sup>12</sup> (double the previous 45,000% increase between 2010 and 2017 in 2 years)**. Yet, CMS has failed, on multiple occasions, to address the ongoing threat to patients’ access to trusted community pharmacists. **Congress needs to act.** As the Subcommittee understands, DIR fees were originally designed to capture rebates and other mechanisms not included at the point-of-sale.<sup>13</sup> However, the term “DIR fees” have been re-defined by PBMs and are now being used beyond their original purpose to retroactively adjust pharmacies’ payment months after the sale, often resulting in reimbursement that is below the cost of drug acquisition by pharmacies. There is simply no connection between price concessions given by drug manufacturers to PBMs and the prices paid by pharmacies to their wholesalers. Thus, DIR fees “recovered” from pharmacies by PBMs are illogical (i.e., recovering money

<sup>11</sup> FTC, FTC Authorizes Investigations into Key Enforcement Priorities, July 1, 2021, available at: <https://www.ftc.gov/news-events/press-releases/2021/07/ftc-authorizes-investigations-key-enforcement-priorities>

<sup>12</sup> CMS, Justification of Estimates for Appropriations Committees, Fiscal Year 2022, May 2021, available at: <https://www.cms.gov/files/document/fy2022-cms-congressional-justification-estimates-appropriations-committees.pdf>

<sup>13</sup> See, CMS, Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. Final Rule. 83 FR 16440. April 16, 2018. Available at: <https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare>



from pharmacies that pharmacies did not “receive” in the first place). Because current point-of-sale prices or copays paid by beneficiaries can be based on the contracted price before DIR fees are extracted, many beneficiaries pay higher out-of-pocket costs for prescription drugs. CMS has cited numerous research that further suggests higher cost-sharing can impede beneficiary access and adherence to necessary medications, which leads to poorer health outcomes and higher overall medical care costs for beneficiaries and Medicare. Therefore, APhA strongly urges the members of the Subcommittee to work with their colleagues to pass the “Pharmacy DIR Reform to Reduce Senior Drug Costs Act (S. 1909),” in the Senate to move retroactive pharmacy DIR fees to the point of sale to ensure consistency throughout the Part D benefit and limit this abusive practice.

- **Artificially Inflated List Prices:** Within the prescription drug supply chain, “list prices” for prescription drugs are significantly overinflated relative to their actual cost (for a markup of about 20% or more).<sup>14</sup> PBMs use those list prices or average wholesale price (AWP), as the basis for their pricing guarantees to pharmacies and plan sponsors. AWP does not include buyer volume discounts or rebates often involved in prescription drug sales and is subject to manipulation by manufacturers or even wholesalers.<sup>15</sup> Brand name drugs have high AWP that are offset by negotiated rebates and discounts that make those net prices much lower. Generic drugs have high AWP (derived from brand drugs) that in no way reflect the actual prices pharmacies pay to acquire those drugs.<sup>16</sup> In both regards, the “actual” prices of both brand and generic drugs are hidden by PBMs from the plan sponsor, patient, and pharmacies.
- **Price Discrimination:** This is a strategy that charges customers different prices for the same product based on what the seller thinks they can get the customer to agree to. PBMs and drug manufacturers negotiate a “net price,” but the extent to which that true net price is captured by the payer (CMS/plans, etc.) depends on the payer’s access to information and negotiating leverage. As a result, PBMs pass along some discounts and rebates to some clients but choose to retain those rebates from others. Viewed from the lens of a patient, a PBM can use all their covered patient lives as a means to elicit larger rebates from drugmakers, but they can then turn around and require those same patients to pay the full list price of their medications through use of high deductible

<sup>14</sup> Thomson Reuters MicroMedex, Website. AWP Policy. Accessed October 30, 2020 at

[https://www.micromedexsolutions.com/micromedex2/4.31.0/WebHelp/RED\\_BOOK/AWP\\_Policy/AWP\\_Policy.htm](https://www.micromedexsolutions.com/micromedex2/4.31.0/WebHelp/RED_BOOK/AWP_Policy/AWP_Policy.htm)

<sup>15</sup> Cecarelli GM. Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Mechanism? National Health Policy Forum. Issue Brief. No. 775. Accessed Sept. 20, 2020 at [https://www.nhpf.org/library/issue-briefs/IB775\\_AWP\\_6-7-02.pdf](https://www.nhpf.org/library/issue-briefs/IB775_AWP_6-7-02.pdf)

<sup>16</sup> 46Brooklyn. Inside AWP: The arbitrary pricing benchmark used to pay for prescription drugs. November 8, 2018, available at: <https://www.46brooklyn.com/research/2018/11/7/visualizing-how-aint-whats-paid-awp-really-is>



plans. Hidden rebates are the key enabler allowing the drug supply chain to capture the benefits of drug price discrimination.

- **Spread Pricing:** This is the difference between the reimbursements paid to pharmacies and the rates reported back to the payer where the PBM retains the difference. Numerous studies and audits have found spread pricing amounts ballooning to excessive amounts, reaching more than \$8 per prescription in some instances. While spread pricing adds unnecessary costs for plan sponsors, it also raises anti-competitive issues, as PBMs (who often have pharmacies of their own) can directly profit off underpayments to network pharmacies. As more states eliminate spread behavior from their Medicaid managed care programs,<sup>17</sup> APhA believes CMS and other plan sponsors should follow suit.
- **Mounting Administrative Fees:** As scrutiny has mounted on costly PBM practices like DIR fees, rebate capture, and spread pricing, the industry has been able to evade cost containment efforts by recategorizing that revenue as something different or by shifting those dollars to other lesser-known layers of their vertically integrated enterprise. For example, as scrutiny grew on drug rebates, PBMs began pushing more of the drugmaker concessions to “rebate aggregators” and in addition, relabeling many of those “rebates” instead as “fees.”<sup>18</sup> And as controversy grows on the increasingly bloated DIR fees that PBMs assess on pharmacy practices, PBMs have begun diversifying and recategorizing their “clawbacks,” as “effective rates.”<sup>19</sup>
- **Specialty Steering:** Utilization distortions of the prescription drug marketplace are all about getting lucrative specialty drugs into pharmacies owned by the vertically merged insurer and/or PBM. As an example, a 2020 analysis of the Florida Medicaid program uncovered specialty drug steering issues. For pharmacy claims dispensed at retail pharmacy groups, the reported weighted average margin was \$2-\$4 per prescription. Meanwhile, claims dispensed at PBM/MCO-owned specialty pharmacies had a reported weighted average margin of up to \$200 per prescription. The study also found growing trends of expensive brand prescriptions being steered to PBM/MCO-affiliated pharmacies, and once dispensed at those affiliated pharmacies, the claims appeared to

<sup>17</sup> Milliman. Florida Agency for Health Care Administration. Pharmacy Benefit Manager Pricing Practices Affecting Statewide Medicaid Managed Care Program. December 2020, available at:

[https://cdn.vmanv.com/www.floridapharmacy.org/resource/resmgr/docs\\_2021\\_legislative\\_session/milliman\\_report.pdf](https://cdn.vmanv.com/www.floridapharmacy.org/resource/resmgr/docs_2021_legislative_session/milliman_report.pdf)

<sup>18</sup> <https://www.benefitspro.com/2021/04/15/cautionary-tale-plan-sponsors-losing-manufacturer-rebate-dollars-to-pbms-through-rebate-aggregators/?return=20210403162749>

<sup>19</sup> <https://www.frierlevitt.com/articles/service/pharmacylaw/generic-effective-rate-ger-a-new-type-of-post-sale-clawback-by-pbms/>



be more expensive than those filled at other pharmacies. The same study found that despite only accounting for 0.4% of the prescription claim volume, specialty pharmacies affiliated with MCOs and/or PBMs captured 28% of the available pharmacy dispensing margin in 2018, suggesting the growing pressure on non-MCO/PBM-affiliated pharmacy providers, as well as the lack of incentives that exist for affiliated pharmacies increased costs to the state on specialty drugs – the biggest cost driver in the state’s drug program.<sup>20</sup>

- **Network Access:** An additional problem facing some pharmacies’ ability to offer low-cost medications to patients is the inability to enter into contracts with PBMs and health plans due to the growth in narrow networks. Accordingly, APhA urges the Subcommittee to pass H.R. 2608, the “Ensuring Seniors Access to Local Pharmacies Act” that would give seniors more convenient access to discounted or “preferred” copays for prescription drugs at their pharmacy of choice. Increasing patient choice will not only improve patients’ access to benefits and services, but will also positively impact patient satisfaction and outcomes.

#### Drug Shortages

Drug shortages are another factor that can negatively affect patients in terms of cost and the availability of their treatments. APhA urges the Subcommittee to consider mechanisms to both better control the price of medications in shortage and improve tracking and prediction systems used to identify drugs in shortage. For example, FDA issued temporary guidance granting flexibility for pharmacists to compound certain necessary medications under sections 503A<sup>21</sup> and 503B<sup>22</sup> for hospitalized patients without patient-specific prescriptions to address COVID-19. Many of our members have told us FDA’s compounding flexibility is the only reason hospitals were able to keep up with patient demand. Accordingly, the recent flexibility to compound medications under both sections 503A and 503B are likely to be necessary for the foreseeable future, and we strongly urge the Subcommittee to pass legislation to codify this flexibility to address drug shortages. We believe maintaining stability within the supply chain during the global COVID-19 pandemic is crucial. We strongly urge the Subcommittee to focus on solutions that harness existing relationships with international trading partners to promote supply chain resiliency and diversity while avoiding measures that could undermine our ability to work with the international community. APhA also strongly supports the appropriate prosecution of

<sup>20</sup> 3AA, 2020 Florida Medicaid analysis.

<sup>21</sup> <https://www.fda.gov/media/137125/download>

<sup>22</sup> <https://www.fda.gov/media/137031/download>



entities that engage in price gouging and profiteering of medically necessary drug products in response to drug shortages.

#### **Importation Concerns**

Although APhA supports Congressional efforts to address patients' medication costs, APhA has significant concerns with turning to drug importation to achieve lower prices. We believe proposals to legalize importation of non-FDA approved prescription drugs is not a comprehensive solution to the complex issue of drug pricing, threatens patient safety, disrupts care, and directly conflicts with efforts by Congress and federal agencies to increase the integrity and security of the U.S. drug supply pursuant to the Drug Supply Chain Security Act (DSCSA). By commingling FDA-approved and imported versions of medicines in the marketplace, drug importation programs would create disruptions and confusion in the supply chain and may limit patient access to medications by complicating insurance coverage and reimbursement at the pharmacy. APhA is also concerned that there is no data or information that demonstrates significant cost savings to American patients from importation programs.

In addition to state or tribe-sponsored drug importation programs, APhA also opposes allowing personal drug importation as we believe that it will further fragment care and hinder the progress made by Congress to move U.S. health care delivery and payment towards coordination and value. Value-based care models and other efforts to produce cost savings and promote quality, such as outcomes-based reimbursement, will be more difficult to measure and optimize if patients receive uncoordinated care from providers outside the model's mechanisms to drive results.

Because drug importation policies effectively encourage patients to buy medications online from unknown foreign sources, APhA fears patients will be at an even greater risk of taking ineffective, adulterated, or harmful medications, including controlled medications they were not prescribed. The lack of a strong regulatory framework for internet pharmacies in certain foreign countries has led to a large number of illegitimate foreign internet pharmacies. APhA's concerns are compounded by the large number of internet "pharmacies" which have increased and become more sophisticated in recent years, making them difficult to track and permanently stop.

Obtaining safe and effective medications is only one part of appropriate medication use. It also requires a health practitioner's knowledge of the patient's complete medication profile and an understanding by the patient of how to take the medication, side effects and/or potential interactions — all of which could be negatively affected by importation. APhA believes importation of non-FDA approved drugs could hurt the very patients intended to benefit from



importation proposals. Consequently, the risks to patient safety from harmful or ineffective products or avoidable medication errors due to fractured care outweigh any potential cost-savings from drug importation proposals.

**Conclusion**

APhA would like to thank the Subcommittee for continuing to work with us and other pharmacy stakeholders by including S. 1362 in your legislative package to improve the value of prescription drugs by increasing access to pharmacist-provided patient care services in medically underserved areas to improve health care equity and reducing the harmful anti-competitive practices of PBMs on prescription drug costs for our nation's pharmacies and patients. Please contact Alicia Kerry J. Mica, Senior Lobbyist, at [AMica@aphanet.org](mailto:AMica@aphanet.org) or by phone at (202) 429-7507 as a resource as you consider these important issues.



## Appendix #1

## Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2021



1. Cigna partners with providers via its Cigna Collaborative Care program. However, Cigna does not directly own healthcare providers.  
 2. AllianceRx Walgreens Prime is jointly owned by Prime Therapeutics and Walgreens Boots Alliance.  
 3. Since 2020, Prime sources formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.  
 Source: Drug Channels Institute research; Companies are listed alphabetically by insurer name.



July 12, 2021

Senator Amy Klobuchar  
Chairwoman of Subcommittee on Competition Policy,  
Antitrust, and Consumer Rights  
224 Dirksen Senate Building  
Washington, DC 20510

**Re: A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Drug Markets, July 13, 2021, Hearing**

Dear Chairwoman Klobuchar,

We represent unions and consumer and public interest groups that work to rein in excessive prescription drug prices and are concerned about the lack of meaningful patient choice resulting from anticompetitive contracting practices and abusive step therapy policies that restrict patients' access to groundbreaking innovative therapies and lower cost medicines.<sup>1</sup> This contracting practice is known as a rebate wall or trap. We believe that rebate walls result in patients being denied access to lower cost and more efficacious drugs.

Prescription drugs can only benefit patients if they are accessible and affordable. Newly approved prescription drugs and biosimilars face numerous obstacles in obtaining commercial success in the United States. Misaligned incentives in the drug supply chain and anticompetitive conduct by branded pharmaceutical manufacturers are a significant part of the problem. Drug manufacturers have used numerous anticompetitive practices to prevent patients from obtaining important prescription drugs and biosimilars. We highlight the "next generation" of exclusionary schemes -- rebate walls, whereby certain drug manufacturers such as AbbVie structures rebates in its contracts with payors to foreclose rival prescription drug competition. This practice raises costs to patients and denies patients the treatments that they need.

In our letter to Chairwoman Maloney, we explained that rebates are not procompetitive discounts, outlined the competition concerns raised by AbbVie's rebate walls, discussed the

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<sup>1</sup> On June 16, 2021, Families USA, AFSCME, Alliance for Retired Americans, Consumer Action, Doctors for America, Treatment Action Group, UniteHere, Social Security Works, and Public Interest Research Group sent a [letter](#) to Chairwoman Maloney of the Oversight and Reform Committee thanking her for investigation of AbbVie's past anticompetitive conduct and her request for the Federal Trade Commission to investigate AbbVie's anticompetitive pharmaceutical rebate walls. Available at <https://www.thecppc.org/single-post/consumer-groups-submit-letter-to-chairwoman-maloney-thanking-her-for-her-work-on-abbvie>. On June 25, 2021, Families USA, AFSCME, SEIU, Alliance for Retired Americans, Consumer Action, Doctors for America, Social Security Works, Treatment Action Group, and Public Interest Research Group submitted [comments](#) to the FTC regarding its review of its Pharmaceutical Merger Enforcement program. Available at <https://www.regulations.gov/comment/FTC-2021-0025-0041>.



consumer and patient harm caused by them, explained how AbbVie uses rebate walls to not only protect the most popular drug in the world but to prop up its new drugs, and noted that there is increased recognition by policy makers that the Federal Trade Commission (“FTC”) should scrutinize these practices and bring enforcement actions against drug manufacturers that use these anticompetitive strategies. We would like to make this letter and the letter to Chairwoman Maloney as part of the record.

We appreciate all the work that you are doing to make prescription drug markets more competitive, and we ask the Committee to continue to encourage the FTC to actively investigate how pharmaceutical drug manufacturers use bundled rebates to exclude rival drugs from obtaining preferred access on payors’ drug formularies. We are in complete support of the letter that you, along with eight other Senators sent to the FTC regarding the AbbVie/Allergan merger recognizing that rebate walls harm competition and reduce consumer choice<sup>2</sup> and the letter that you, along with Senator Blumenthal, and Congressmen Cicilline and Jeffries sent to the GAO asking it “to conduct an assessment of the prevalence of rebate traps in pharmaceutical markets and their effects on pharmaceutical pricing, competition, and innovation.”<sup>3</sup>

More recently, Chairwoman Maloney, Chairman Nadler, and Cicilline sent a letter to the FTC requesting that the FTC open an investigation into AbbVie’s use of rebate walls.<sup>4</sup> We agree with their letter as we believe that the FTC needs to pay increased attention to AbbVie’s rebate wall because it has not only caused harm in the past but has the potential to harm competition in the future.

Again, we appreciate all the work that you are doing and hope that you continue to encourage the FTC to use all its tools to make prescription drug markets competitive.

If you have any questions, please contact me at [david.balto@dcantitrustlaw.com](mailto:david.balto@dcantitrustlaw.com) or 202-577-5424.

Sincerely,

*David A. Balto*

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<sup>2</sup> Senator Klobuchar News Release, *Klobuchar Leads Warning that Pharmaceutical Mergers May Threaten Drug Competition, Increase Prices and Reduce Patient Access*, September 17, 2019, available at <https://www.klobuchar.senate.gov/public/index.cfm/2019/9/klobuchar-leads-letter-warning-that-pharmaceutical-mergers-may-threaten-drug-competition-increase-prices-and-reduce-patient-access-to-essential-medications>.

<sup>3</sup> Senator Klobuchar News Release, *Klobuchar, Blumenthal, Cicilline, Jeffries Call on Government Accountability Office to Study Effects of “Rebate Traps” on Pharmaceutical Prices and Competition*, June 10, 2020 available at <https://www.klobuchar.senate.gov/public/index.cfm/2020/6/klobuchar-blumenthal-cicilline-jeffries-call-on-government-accountability-office-to-study-effects-of-rebate-traps-on-pharmaceutical-prices-and-competition>.

<sup>4</sup> Chairwoman Maloney, Chairman Nadler, Chairman Cicilline Send Letter Asking FTC to Open Inquiry into AbbVie, May 18, 2021 available at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-05-18\\_CBM%20Nadler%20DNC%20to%20Slaughter-FTC%20re%20AbbVie%20%28with%20enclosure%29.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-05-18_CBM%20Nadler%20DNC%20to%20Slaughter-FTC%20re%20AbbVie%20%28with%20enclosure%29.pdf).