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ENSURING AFFORDABLE & ACCESSIBLE MEDICATIONS: EXAMINING COMPETITION IN THE PRESCRIPTION DRUG MARKET

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BEFORE THE

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ENSURING AFFORDABLE & ACCESSIBLE MEDICATIONS: EXAMINING COMPETITION IN THE PRESCRIPTION DRUG MARKET

TUESDAY, MAY 21, 2024

UNITED STATES SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Committee met, pursuant to notice, at 10 a.m., in Room 226, Dirksen Senate Office Building, Hon. Richard J. Durbin, Chair of the Committee, presiding.

Present: Senators Durbin [presiding], Whitehouse, Klobuchar, Coons, Hirono, Booker, Ossoff, Welch, Butler, Graham, Grassley, Cornyn, Kennedy, and Tillis.

OPENING STATEMENT OF HON. RICHARD J. DURBIN, A U.S. SENATOR FROM THE STATE OF ILLINOIS

Chair DURBIN. This hearing of the Senate Judiciary Committee will come to order. Today the Committee will hear from a range of experts about the cost of prescription drugs in America. Americans pay the highest prescription drug prices in the world, nearly three times what people in other developed countries pay for common medications. Take the cancer drug Keytruda, which has helped extend former President Jimmy Carter's life. It has an annual list price of more than $190,000 in the United States. In Germany, the exact same drug, made by the same company, costs $89,000. Jardiance—we can all visualize—excuse me.

Senator GRAHAM. He's on a roll.

Chair DURBIN. Senator Grassley.

Voice. Give 'em hell, Grassley.

[Laughter.]

Senator GRAHAM. I've had it, too—whatever he's saying.

Chair DURBIN. I'm with Grassley. Sorry. Jardiance—you can all visualize the dancing lady in the yellow dress ad—a medicine used to treat type 2 diabetes—retails for more than $700 in the United States; $150 in Canada. The exact same drug. Prices just keep going up. In 2022, drug manufacturers raised the prices of more than 1,200 medications by an average—average—of 32 percent, 4 times the rate of inflation.

The poster child for high drug prices is insulin. It was discovered 100 years ago by Canadian researchers who surrendered their patent rights for the sum total of $1 because they believed nobody should profit from this lifesaving drug. The same thing is true of Jonas Salk and the vaccine that we use for polio. I remember that

as a kid. He surrendered his patent rights to that drug, too, because it was so important. When Eli Lilly launched its insulin product, Humalog, in 1999, a vial cost a modest $21. Over the next 20 years, Eli Lilly raised the price of Humalog more than 2 dozen times, with the cost ultimately reaching $330 for that same $21 vial. While the historic Inflation Reduction Act capped the price of insulin at $35 a month for Medicare, many patients are still paying inflated prices for a century-old drug.

The pharmaceutical industry is going to tell you that high prescription drug prices are the cost of innovation and point to billions of dollars in research and development. In fact, a government agency financed by American taxpayers, the National Institutes of Health, plays an important role in innovation and research. NIH funding contributed to 99 percent of all new drugs approved by FDA between 2010–2019, with $187 billion in taxpayer-funded research benefiting 354 of 356 new drugs. NIH is part of the solution. And too often, the prices charged by Big Pharma do not reflect a scientific advancement. Rather, they're the result of skilled lawyers manipulating the patent system and skirting our Nation's competition laws.

Take the blockbuster drug Humira, which AbbVie introduced in 2002. For more than 20 years, the company exploited intellectual property laws to build a thicket of 165 patents that allowed Humira to avoid competition. The result: $20.7 billion in revenue to AbbVie in 2021 alone and over 200 billion in revenue over Humira's 20-plus years of exclusivity. These are massive profitable drugs. I asked Blue Cross Blue Shield in Chicago, why are premiums going up so fast? The number one cause: these high-priced prescription drugs. Humira is not unique. A recent study found that the top 10 bestselling drugs in 2021 had a combined 1,429 patent applications filed, 72 percent of which were filed after the FDA approved the drug for sale.

You know what's going on if you even have a beginner course in this business. The patent system is being manipulated and used by their attorneys to extend the patents' life to avoid competition, generics, and bringing down the cost. These blockbuster drugs were covered by an average of 42 active patents. The FTC recently highlighted another page in Big Pharma's anticompetitive playbook when it challenged more than 400 patents as improperly listed in the FDA Orange Book. By listing these patents on inhalers, EpiPens, weight loss drugs, and more, their manufacturers delayed generic competition and padded profits.

The Committee has taken leadership in addressing Big Pharma's abuses. Last year, we unanimously reported five bipartisan bills that address issues ranging from anticompetitive pay-for-delay agreements and sham citizen petitions to patent thickets and product problems. This includes my bill with Senators Tillis, Coons, and Grassley to improve information sharing between the FDA and the U.S. Patent Office. This hearing will try to make it clear that our work is not done. We have things to do. Ask the American people what they think about this issue. You know what you're going to hear.

We see an average of nine ads a day for drugs on television. You cannot escape them. God only knows where else the advertising's

going. How many countries in the world allow direct-to-consumer advertising for drugs? Two: the United States and New Zealand. New Zealand, for God's sake. The only two countries in the world that allow this kind of advertising. Why do we do it? So that we can spell Xarelto and go to a doctor's office and say, I think I need a Xarelto to get well again and to skip through fields of flowers. Many doctors, instead of taking the time to argue a reason for a generic drug or no drug, instead prescribe these drugs, and as a consequence, the cost of medicine and health care goes up and up and up, and the hard-to-justify profits continue.

Before I turn to my Ranking Member, here, I want to acknowledge Senator Welch's interest in this hearing and this issue. When he first came to the Committee, we sat down and talked about his Subcommittee assignments, and he told me that this is one issue he wanted to focus on. So, at some point in the hearing this morning, I'll be surrendering the gavel to him, to continue this hearing. Thank you for being here, Senator. Senator Graham.

OPENING STATEMENT OF HON. LINDSEY O. GRAHAM, A U.S. SENATOR FROM THE STATE OF SOUTH CAROLINA

Senator GRAHAM. Thank you, Mr. Chairman. So, we've acted in the past unanimously to—there seems to be two lanes here: patent abuse, changing the patent in a small way, to extend it, delaying generic entry into the market. Every day they can keep the patent going and keep the generic out of the drugstore is a good day for them. The other is countries like Canada, same drug, a lot lower in cost. There's two ways to deal with it, I guess. What I'd like to do is let countries know that most of these drugs are developed in the United States, and the drug company has a right to get its money back. If a foreign country is basically subsidizing a drug, putting a burden on the American consumer to have to pay a higher price, I think that's an unfair trade practice. So, I'd like to go down that road.

The bottom line: This is social media all over again. We pass all these bills, we have a common view of the problem, and nothing ever happens. So, Wednesday, we're going to challenge the Senate to take up some of the social media reforms that we have reported out of this Committee unanimously. I'd like to put this in that same bucket. I mean, we're about as diverse a collected group of people you could find in the Senate, and count me in. Count me in for, like, challenging the patent system. Count me in for trying to find ways to help the American consumer versus people in other countries.

I'm very open minded about stopping abuse. What I don't want to do is kill the goose that laid the golden egg. I don't want to create a system where we stop developing new drugs that enrich our lives. I think everybody who spends money like—you know, it's like drilling for oil. Sometimes you have a dry hole, and you just—you know, you write that off. The goal is to enhance medical science and deal with sheer greed, for lack of a better word. This has to stop. I don't mind you getting your money back. I want you to make a profit. But the idea of playing games with patents needs to stop.

And I'm more open minded about the advertising than I've ever been, and, I mean, I see these ads; I don't know. Why do I need to know that? I mean, why can't I trust my doctor to—if a generic works, it works. So, let's work together, and when we pass something out of the Committee, let's go to the floor and challenge the Senate to let it go. So, this is a good hearing. I'm glad you're doing it.

Chair DURBIN. Thanks. Today we're going to welcome a consensus panel of five witnesses, who I'll introduce. Arti Rai is the Elvin Latty Distinguished Professor of Law and Co-Director of Center for Innovation at Duke. She is an internationally recognized expert in intellectual property law, innovation policy, administrative law, and health law. Adam Mossoff is a professor of law at Antonin Scalia Law School, where his research focuses on the theoretical justification for and historical protection of patents and other intellectual property rights as private property rights secured to inventors and creators.

Dr. Will Feldman is a pulmonologist, intensivist, and health services researcher at Harvard Medical School and Brigham and Women's Hospital. His research focuses on drug pricing, FDA regulation, pharmaceutical policy, and COPD outcomes. Joceyln Ulrich is the vice president of policy and research at PhRMA, Pharmaceutical Research and Manufacturers of America. At PhRMA, she leads the team responsible for policy analysis and research. David Mitchell, president and founder of Patients for Affordable Drugs—a patient advocacy organization focused on making prescription drug prices affordable for every person. He is a patient with incurable but treatable blood cancer. He depends on drugs costing hundreds of thousands of dollars a year.

So, I'd ask all the witnesses to please stand first for the administration of the oath. Please raise your right hand.

[Witnesses are sworn in.]

Chair DURBIN. Let the record reflect that the witnesses did better than the administrator of the oath and answered in the affirmative. So, we'll start with Professor Rai.

STATEMENT OF ARTI RAI, ELVIN R. LATTY DISTINGUISHED PROFESSOR OF LAW, DUKE LAW, DURHAM, NORTH CAROLINA

Professor RAI. Thank you, Chair Durbin, Ranking Member Graham, and Members of the Senate Judiciary Committee for the invitation to testify. I've worked on drug competition issues for many decades. My research is funded by nonprofit foundations and government agencies only. Today, I will discuss three aspects of the challenge, all of which relate to patents of dubious validity. Fortunately, dubious validity can be addressed through surgical responses. We need, first, greater coordination between the PTO and the FDA; second, limits on patent assertion when the patent is an obvious variant of a patent that has already been found obvious; and, third, to ensure the continued vitality of the Patent Trial and Appeals Board.

Let's begin with greater interagency coordination. Many of you have rightly been concerned about applicant statements to the FDA that are highly relevant to patent validity but that are nonetheless never brought to the attention of the PTO. These submissions can

take the form of comments made or statements made to the FDA that are flatly inconsistent with those made to the PTO. That was the scenario in *Belcher v. Hospira*, a 2021 case in which the behavior was so egregious that the Federal Circuit found a Federal—excuse me, found a Belcher executive guilty of inequitable conduct.

But my research has shown that the problem of incomplete information flow to the PTO is much more systemic. For example, manufacturing process patents represent by far the largest category of patents asserted against would-be-biosimilar competitors. Nicholson Price and I have shown that over 70 percent of these assertions involves patents with a priority filing date of more than 1 year after the originator product was marketed. For such late-filed patents, longstanding Supreme Court case law makes it clear that patent applicants should inform the PTO of commercial use that is related to or identical to the process that they seek to patent.

That is true even if—or perhaps especially if—the use is secret. The reason is straightforward. A firm that relies on secrecy for commercial advantage should not subsequently be able to extend its exclusivity further by securing a patent. The patent system is supposed to be about information that is disclosed, not kept secret. Unfortunately, applicants do not routinely disclose prior commercial use to the PTO; however, the information is known to the FDA, and therefore it is part of the executive branch's set of information. It is simply siloed. We all know about agency siloing.

One reason may be agencies' legitimate awareness of the need to maintain trade secrecy. This is very legitimate, but I think that the congressional push led by Senator Durbin is exactly what is needed to overcome agency reluctance. The Senate's Patent Agency—Interagency Coordination and Improvement Act—excuse me—sponsored by Chair Durbin recognizes that information flow from the FDA to the PTO is perfectly consistent with trade secrecy. The PTO can also help the FDA. Recently, the FTC has been active in calling out patents that are improperly listed on the Orange Book. But the FTC has to do its work very late in the day. Jorge Contreras and I have argued that the PTO could nip the problem in the bud by helping FDA ensure that irrelevant patents are never listed.

Another problem relates to terminal disclaimers filed by patent applicants to overcome examination rejections for obviousness over a prior patent they hold. Simply put, a disclaimer filing shows that the patent applicant lacks confidence that its application is nonobvious relative to its prior patent. Disclaimer patent—terminal disclaimers, excuse me, are a big deal. A recent study by Dr. William Feldman and his co-authors found that 48 percent of patents asserted against biosimilar competitors contain terminal disclosures. The PTO has recently proposed a carefully crafted rule to address this issue; however, the agency's rulemaking authority in this area might be overly narrow, and I believe a very useful revision to the patent statute would calibrate PTO's rulemaking authority in this area and harmonize it with that given to the PTO over the PTAB.

Speaking of the PTAB, there the answer is simple. Keep up the good work. My data show that the PTAB is doing an excellent job and it does not need to be interfered with. Thank you, and I look forward to your questions.

[The prepared statement of Professor Rai appears as a submission for the record.]

Chair DURBIN. Thanks, Professor Rai. Professor Mossoff.

STATEMENT OF ADAM MOSSOFF, PROFESSOR OF LAW, ANTONIN SCALIA LAW SCHOOL, GEORGE MASON UNIVERSITY, ARLINGTON, VIRGINIA

Professor MOSSOFF. Thank you. Chair Durbin, Ranking Member Graham, and Members of the Committee, thank you for this opportunity to speak with you today about how policy-driven arguments concerning patents have sown confusion and impeded evidence-based policymaking on drug prices. The causes of drug prices are complex and multidimensional, if only because the U.S. health care system is incredibly complex, itself. Yet, despite this, professors and policy activists have reduced this legal, institutional, and scientific complexity to a single cause: patents. They blame patents as the primary, if not the sole, cause of drug prices today. This is profoundly mistaken.

It's impossible to comment on the incredible number of legal and policy activities in all three branches of government today affecting drug patents, and so for the sake of brevity, I will focus on the misinterpretation and misuse of two Federal laws by those seeking to impose price controls on innovative drugs and other health care inventions, in a misguided effort to lower drug prices. The first law is the Bayh-Dole Act, and the second is a law known as Section 1498. Now, neither the Bayh-Dole Act nor Section 1498 are price control laws. This is clear in their text, function, and in their past interpretation by courts and agencies.

Congress enacted the Bayh-Dole Act in 1980 to promote commercialization of inventions that result from some upstream Federal funding. The law reaffirmed the fundamental principle in American patent law: All inventors should be secured in the fruits of their productive labors with a property right, a patent. Now, before the Bayh-Dole Act, the Federal Government actually ignored this fundamental principle and instead claimed ownership in inventions resulting from Federal funding. It offered nonexclusive licenses to any and all comers. As a result, there was no commercial development of these inventions.

The Bayh-Dole Act, importantly, changed that policy. It reaffirmed that inventors can obtain patents and then assign or license them to marketplace actors regardless of who funds and how much funding is received in the initial research. The result has been an explosion in new products and services, from new cancer drugs to the Google search algorithm to the honey crisp apple and so many others. Today, the Biden administration proposes to turn the Bayh-Dole Act on its head. A proposed new regulatory guideline twists the Bayh-Dole Act into a price control law in which funding agencies can license any resulting patent to a private company simply to drive down prices. This returns the U.S. back to the pre-Bayh-Dole era of de facto government ownership and nonexclusive licensing.

But the Bayh-Dole Act is not a price control law. It never states that price is a precondition for an inventor who obtains and then licenses or assigns a patented invention. In fact, the goal of the

Bayh-Dole Act is commercialization, as such, not low prices. Now, this is really important, because Congress knows how to enact price control laws when it wishes to do so, and it has done so many times. One of my favorite examples. The Emergency Price Control Act of 1942. Very clear in what that law does. That is not the Bayh-Dole Act. In a shortsighted effort to drive down drug prices, these new regulatory guidelines will kill this golden goose of innovation and economic growth.

The second law that is misconstrued today by those seeking to impose price controls on drug patents is Section 1498. Now, this doesn't have a name, because it's a century-old law that secures to patent owners the protections of the Takings Clause of the Fifth Amendment. It ensures a court can hear a claim for compensation when an official or government contractor uses a patent without authorization for a government use, such as the military or the Post Office. Today, price control advocates seek to turn this law on its head, as well. Now, in its text and function, Section 1498 secures the rights of patent owners against unauthorized uses of their property by the government, guaranteeing the same compensation as all other property owners. Now, some seek to turn Section 1498 into an unprecedented compulsory licensing regime in which the government promotes private companies to violate patent rights. Again, a law is being twisted to achieve shortsighted policy goals of lowering drug prices.

Today, the U.S. is a global leader in health care innovation. The biotech revolution began in the United States in the 1980's. More than 50 percent of all new drugs are invented in the United States, to this very day. Diseases like cancer, diabetes, hepatitis are no longer death sentences but are now curable or at least manageable conditions. This was all made possible by the U.S. securing reliable and effective property rights in the fruits of the labors of the innovators working in the biopharmaceutical sector: securing patents. Countless lives have been saved, lifespans increased, and quality of daily life enhanced for everyone in the world. The patent system and laws like the Bayh-Dole Act and Section 1498 made this possible. Thank you, and I look forward to your questions.

[The prepared statement of Professor Mossoff appears as a submission for the record.]

Chair DURBIN. Thank you, Professor Mossoff. Dr. Feldman, please.

STATEMENT OF WILLIAM FELDMAN, MD, DPHIL, MPH, ASSOCIATE PHYSICIAN, DIVISION OF PULMONARY AND CRITICAL CARE MEDICINE, BRIGHAM AND WOMEN'S HOSPITAL, BOSTON, MASSACHUSETTS

Dr. FELDMAN. Chair Durbin, Ranking Member Graham, and Members of the Committee, thank you for the opportunity to testify today. I became interested in pharmaceutical pricing during my medical training when I observed firsthand how patients were often unable to afford their medications, leading to decreased adherence and worse health outcomes. Much of my research today focuses on how pharmaceutical firms use patent thickets and product hops to delay generic competition and keep prices high. The U.S. Federal Government rewards pharmaceutical innovation by grant-

ing time-limited monopolies to sell prescription drugs free from generic competition. And the key here is time-limited. Once patent protection ends, generic firms can enter the market. Such competition is by far the most important tool for lowering prescription drug prices in the U.S.

Unfortunately, many brand name firms now engage in strategies designed to game the system and extend periods of market exclusivity, to the detriment of patients and payers. Consider inhalers for asthma and COPD. Millions of Americans rely on these products to help them breathe. Last year, AstraZeneca brought a product to the market called Airsupra. This product contains albuterol, first approved in 1981, and budesonide, first approved in 1994. Airsupra has patents lasting into the 2030's, and the current list price is over $500. Even with substantial rebates, we're still talking about a couple of hundred dollars for a product with active ingredients that were approved 30 to 40 years ago, and there is no hard clinical evidence to suggest that this product is any better than another AstraZeneca inhaler that has been on the market for two decades.

By no means is this criticism intended to single out one company. All of the other three major brand name inhaler manufacturers—GSK, Boehringer Ingelheim, and Teva—engage in similarly problematic strategies. For example, we have found in our research that more than half of all patents on inhalers are on the delivery devices of these products, and these patents have extended market exclusivity—these device patents—by a median of 5 years. Seventy-seven percent of these device patents fail to even mention, much less claim, the active pharmaceutical compounds in the products.

According to recent FTC action, these patents should never have been listed in the Orange Book in the first place, yet these tactics have been lucrative for inhaler manufacturers. Of the $178 billion that inhaler manufacturers earned on these products just in the U.S. from 2000–2021, more than 110 billion accrued after patents on the active ingredients had expired. That's 68 percent of revenue after patents on the active ingredients had expired. I applaud the FTC's efforts to crack down on improperly listed patents and also those of the Senate Health Committee, which launched an investigation into inhaler manufacturers earlier this year. This work is extremely important.

But inhalers are just one example of abusive patenting practices that have become rampant across the pharmaceutical system, and we need comprehensive reform. The Senate Judiciary Committee has recently moved four bipartisan bills out of Committee that, if enacted into law, could facilitate more timely generic competition. These bills focus on establishing better communication between the U.S. PTO and FDA, limiting product hops, punishing brand name firms for baseless citizens petitions, and preventing pay-for-delay settlements. I strongly support these bipartisan efforts.

I would also urge you to consider five additional measures to further advance the important work you all are doing, to facilitate more timely generic competition. First, grant the FDA the authority and resources to evaluate all patents submitted for listing in the Orange Book, to determine eligibility for inclusion. Second, require that all patents submitted to the FDA for listing in the Or-

ange Book are also concurrently submitted to the U.S. PTO for reexamination. Third, limit the number of patents that brand name manufacturers can assert to one patent per family when suing for infringement.

Fourth, grant the FDA more authority to approve generic drug device combinations that differ slightly from brand name reference products while still containing the same active ingredients and require the FDA to ensure that post-marketing surveillance studies are conducted to confirm similar outcomes between those receiving generic and brand name versions. And, finally, I would encourage Congress to increase the 180-day exclusivity periods for the first generic firms to file paragraph IV certifications on complex products like drug device combinations and decrease the automatic 30-month stays awarded to brand name firms that sue for infringement.

We should strive for a pharmaceutical system that rewards meaningful therapeutic breakthroughs—cures for hepatitis C, new MRNA vaccines—not small modifications to the plastic components of delivery devices or new tweaks to molecules that perform no better than existing therapies. Thank you for your time.

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

Chair DURBIN. Thanks, Doctor. Ms. Ulrich.

STATEMENT OF JOCELYN ULRICH, VICE PRESIDENT, POLICY & RESEARCH, PHRMA, WASHINGTON, DC

Ms. ULRICH. Chairman Durbin, Ranking Member Graham, and Members of the Committee, thank you for inviting me to participate in today's hearing. PhRMA appreciates the opportunity to discuss ways to improve the affordability and accessibility of lifesaving medicines for patients. It is no accident that the United States leads the world in the development of treatments and cures for patients. This is the direct result of our carefully designed ecosystem, built over many years through smart public policies that encourage risk-taking and collaboration.

At the core of this ecosystem are strong and reliable intellectual property protections that give companies the certainty they need to make the long-term investments required to bring new medicines to patients, as well as to improve them for additional patient benefit. In fact, the biopharmaceutical sector is one of the most research-intensive industries in the United States, spending more than 100 billion every year researching and developing new medicines for patients. This spending far outpaces the NIH's budget for drug R&D year over year.

Our members are committed to tackling the hardest, most difficult-to-treat diseases, and they make significant investments, knowing that fewer than 12 percent of potential medicines that make it into clinical trials will eventually be FDA-approved medicines. By any measure, America's IP framework has been a resounding success. Despite the long odds, biopharmaceutical companies have launched more than 750 drugs since 2000, resulting in significant progress against some of the most costly and challenging diseases.

For example, new CAR T therapies are curing children with advanced leukemia by training cells to fight the cancer, and as a result, since peaking in the early 1990's, cancer death rates have declined by 33 percent. Due to highly effective antiretroviral therapy, the HIV/AIDS death rate has declined by 91 percent, allowing HIV patients to live close-to-normal lifespans, and patients with sickle cell disease can be treated with a genome-edited cell therapy that has the potential of a functional cure for their disease. These advances not only improve patient lives but they help avoid other, more expensive health care costs. For example, between 1999 and 2012, there was a significant reduction in Medicare spending growth for cardiovascular disease, one-quarter of which was due to the greater use of cardiovascular medicines.

Importantly, our IP system not only incentivizes the development of new medicines, but it spurs competition that lowers health care costs. First, there is robust competition from other brand manufacturers. No company has a monopoly on treating a disease. Companies compete to develop the most effective treatment options for patients. For example, within a year of the first breakthrough treatment for hepatitis C, the availability of multiple competitors reduced the average price or the net cost of these medicines by nearly 80 percent.

Data also show discounts and rebates are already lowering the net costs of treatment with GLP–1s by as much as 79 percent, with more competition on the way, and eventually medicines face competition from generics and biosimilars, which drives down costs even more. On average, a drug is on the market only 13 years before facing competition from generic versions, much shorter than the patent life of 20 years, and typically drive down costs as much as 80 percent. This is what makes the marketplace for medicines unique. Similar cost containment mechanisms do not exist for any other part of the health care system.

But there are real challenges for getting more affordable options to patients. Insurance companies and their pharmacy benefit managers determine what medicines are covered, what patients pay out of pocket, and what hoops they have to jump through to access the medicines their doctor prescribes. Today, three large PBMs now comprise nearly 80 percent of the market, and each is vertically integrated with health insurers, specialty and mail-order pharmacies, and provider groups to form large health care conglomerates. And they are significantly impacting whether patients are able to benefit from biopharmaceutical innovation.

PBMs often stand in the way of patient access to lower-priced versions of medicines, routinely denying or limiting coverage. And with growing scrutiny over rebates, PBMs have leveraged their vertical integration to create new sources of revenue. PBMs are also choosing to tie patient cost-sharing to the list prices rather than the discounted prices that they themselves pay.

You'll likely hear today that the market is competitive and that abuses of the IP system and patents are the real problem. Instead, Congress should be focused on advancing policies where competition could be advanced without undermining the very foundation of the industry's ability to innovate. This includes addressing the misaligned incentives in the PBM market. Thank you for the oppor-

tunity to testify, and we look forward to working in a constructive way to ensure patient access to the medicines they need. Thank you.

[The prepared statement of Ms. Ulrich appears as a submission for the record.]

Chair DURBIN. Thanks, Ms. Ulrich. Mr. Mitchell.

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

Mr. MITCHELL. Chairman Durbin, Ranking Member Graham, Committee Members, thank you for inviting me. I'm David Mitchell. I'm the founder of Patients for Affordable Drugs. More importantly, I have an incurable blood cancer called multiple myeloma. Most patients with my diagnosis will die of it, but right now prescription drugs are keeping me alive. My doctors have me on a four-drug combination with a list price of more than $1 million a year. Just one of my oral drugs, a drug called Pomalyst, is priced at more than $22,000 for 21 capsules in this little bottle that I have to buy 13 times a year. And because Medicare beneficiaries like me pay our costs based on list price, I spent more than $16,500 out of pocket last year, just for Pomalyst.

The Inflation Reduction Act changed that. This year, an out-of-pocket spending limit began to take effect, and my cost is $3,326. Next year, the limit will drop to $2,000, and no one on Part D will pay more than that. For me and other patients like me who have to take very expensive drugs to stay alive, it is life changing. The drugs are keeping my cancer at bay, but their efficacy is waning, and eventually I will need a new treatment—and one after that.

So I care deeply about innovation and new drug development. Without it, I'm going to die sooner than I hope to. That's why this hearing is so important. Our patent system was put in place to incentivize and reward risk in investment in new treatments that can save my life and the lives of others. But too often, drug companies are instead investing in a legal strategy, using patents not to reward innovation but to block competition. In one recent 10-year period, 74 percent of new drug patents were issued for drugs already on the market. Of the roughly 100 bestselling drugs, nearly 80 percent obtained an additional patent to extend their monopoly. Partly as a result, we pay more than four times what other wealthy nations pay for the exact same brand name drugs. Thirty percent of Americans say they struggle to afford their medications.

Let's look at another drug I take to prevent blood clots and stroke, Eliquis. In 2023, it was the most expensive drug for Medicare, at $12.6 billion. Its maker, Bristol Myers Squibb, has applied for 48 patents and been granted 27, blocking competition in this country. The list price for a 30-day supply in the U.S. is about 600 bucks. In Canada, where there is a generic on the market, the price is about $75. We need to restore balance to our broken drug patent system so it does incentivize and reward true innovation instead of being used to block competition. The FTC is moving on this problem, as the chairman pointed out, challenging more than 300 junk patents, as many as 400, that are listed in the Orange Book. And Congress can act to help now. Bipartisan bills to address the principal abuses of our patent system by drug companies have cleared

Committee and are ready for passage in the Senate. They deal with pay-for-delay, patent thicketing, and product hopping. There are two more bills to improve FDA practices that will speed generics to market. They stop the abusive citizen petitions and allow the FDA to share important information with generic manufacturers to help them get to market more quickly.

Now, while the headwaters of our drug price problems are the list prices set by drug companies, as Ms. Ulrich pointed out, there are other reforms needed downstream in the supply chain. Pharmacy benefit managers are black boxes that cut secret, often mutually beneficial, deals with drug companies, and none of it is transparent. We need to increase transparency and curb anticompetitive practices by PBMs. There are bipartisan bills in both the House and Senate to accomplish these goals.

I am here today to ask you all to pass all of these bills, which will allow competition and market forces to lower drug prices for millions of Americans, regardless of how they pay for their drugs. These bills also save money for taxpayers, and we're pushing, along with dozens of allies, for inclusion in any year-end health care package that may be negotiated. And in a city riven by political division, these bills are thoroughly and completely bipartisan. Together, you can pass them. Please don't let this opportunity to help millions of Americans slip away. I look forward to answering your question. Thank you.

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

Chair DURBIN. Mr. Mitchell, thank you very much. There'll be rounds of questions from the Members, 5 minutes each. I'll start and then turn the gavel over to Senator Welch.

Dr. Feldman, since you're the only medical doctor on the panel, I'm going to ask you an obvious question. The legal system in America basically says that in order to have a prescription drug, you need a doctor to write a prescription. So, a doctor's judgment is involved in that administration of that very basic principle. So, my question to you is this. We know the pharmaceutical industry spends $6 billion a year, the size of the entire FDA budget, to fill the airwaves with brand name drug ads. That way, patients cannot only pronounce Xarelto—maybe even spell it—but they can also tell their doctors that's the blood thinner they want.

So, the pharmaceutical industry must believe that that's good enough, to inform the consumer of the benefits of this drug and some of the dangers of the drug, at one time, but to basically get them to the point where they go to the doctor and say, I want Xarelto. Then the doctor, in our system, has to make a professional judgment: Is that the right drug for this patient? Is there a better drug? Clearly, Pharma believes that the consumer suggestion is going to be pretty powerful in this equation. So, I don't want to say this in a negative fashion, but I'm going to. Are doctors complicit with Pharma in prescribing overpriced drugs because they don't have enough time or inclination to debate the issue?

Dr. FELDMAN. Thank you. You know, I think doctors—you know, clearly, as you said, pharmaceutical companies are spending this money on advertising because they think it works and because, to some extent, it does work. I do think that some doctors—I know

some doctors receive money from pharmaceutical companies for prescribing certain types of medications. And so I do worry that some physicians are complicit in this, to an extent.

Chair DURBIN. Well, they're gatekeepers in this process, and if they aren't there, I don't know who would police the ranks in terms of that. Ms. Ulrich, when you hear over and over and over and over again the fact that a basic drug being sold to Americans is at a price that is dramatically higher than you're selling the same drug in your industry in other countries, do you just shrug it off and say, that's just the luck of the draw? Or is it the fact that Americans are being asked to pay for the innovation and the costs and the profits, whereas other countries basically put their foot down and say, this is greed, and we're going to stop you?

Ms. ULRICH. Thank you, Senator Durbin, for that question. I first would point out that, when we're looking at comparisons of U.S. funding, medicines are about the same share of overall health care spending as European countries. So, when you're looking at the actual relative contribution of spending on medicines, it's similar. In addition, I would point out that comparisons are often looking at list prices. And as I spoke about in my testimony, we know that there are significant amounts of rebates being paid to PBMs and others in the supply chain that are not accounted for when we're doing those cross-country comparisons.

Chair DURBIN. Well, let me say this about your suggestion. If I put one hand over a flame on the stove and the other hand in a freezer, on the average I should be just fine. But life doesn't work that way. And say on the average other countries are just about as expensive as the United States; the list prices are dramatically different. One hundred percent different. Why would you do that to the American consumers, when you're American companies?

Ms. ULRICH. Well, I would also point out that Americans get access to those medicines much faster than those countries, as well. Eighty-five percent of globally approved new medicines are available to patients in the U.S. versus about 40 percent in the EU countries. In cancer medications, European patients are getting access 2 years later, on average. So, patients are benefiting from that innovation, as well.

Chair DURBIN. Mr. Mitchell, what do you think?

Mr. MITCHELL. Oh, I think that drug companies file first here because we are the largest market in the world, with the highest prices in the world. And they come here because the FDA is pretty easy to work with, and it's a high quality drug approval agency. And so they come here. They apply first, to get access to the market, but also they can take a lot of their filing work and take it abroad. It's interesting to note—because the IRA was raised earlier—that even after the IRA is fully implemented, we will still be the largest market in the world, with the highest prices in the world, and they are still going to file first here. And it's because it's in their business interest to do so.

Chair DURBIN. Senator Graham.

Senator GRAHAM. Thank you, Mr. Chairman. So, Mr. Mossoff, you said 50 percent of all the new drugs are made in America; is that right? Or developed here?

Professor MOSSOFF. Yes. It's actually more than 50 percent.

Senator GRAHAM. Do you agree with that, Ms. Ulrich?

Ms. ULRICH.

[Nods in the affirmative.]

Senator GRAHAM. Okay. Why is that?

Professor MOSSOFF. So, and very much—it's a great question, and thank——

Senator GRAHAM. Are we smarter, or what's the deal?

Professor MOSSOFF. And very much I believe it has to do with the patent system, in the sense that the United States innovatively took the position, starting from the very beginning of the country, that they would secure next-generation technologies and they would protect them as property rights.

Senator GRAHAM. So, patents are a good thing?

Professor MOSSOFF. Patents are a driver of economic growth, of new——

Senator GRAHAM. Okay.

Professor MOSSOFF [continuing]. Innovation. Yes.

Senator GRAHAM. Okay. I agree with that. Now, is patent abuse a problem when it comes to drugs?

Professor MOSSOFF. So, there's a lot of rhetoric about, you know, whether their abuse exists.

Senator GRAHAM. I'm not talking about the words; the actions.

Professor MOSSOFF. Yes. Yes. So, it's very difficult to sometimes find actual evidence. So, for instance, you see evidence of abuse. Are there some cases? Yes, because in every legal system and every area of life, there's going to be some bad actors.

Senator GRAHAM. So, Dr. Feldman, do you believe there's gaming of the patent system by pharmaceutical companies?

Dr. FELDMAN. I think there's no question. You know——

Senator GRAHAM. See, I'm with you on this one.

Dr. FELDMAN. You look at—I don't think it's sort of finding a needle in a haystack. Everywhere we——

Senator GRAHAM. Yes.

Dr. FELDMAN [continuing]. Look; every study we do——

Senator GRAHAM. Yes.

Dr. FELDMAN [continuing]. We find gaming. We look at——

Senator GRAHAM. Yes.

Dr. FELDMAN [continuing]. Drug device combinations. I talked about inhalers. We see the same thing on GLP–1 receptor agonists like Ozempic and——

Senator GRAHAM. Yes. So, I'm with you on that. So, I want to keep, like, the patent system in place, because it's good. I just think the problem is real, in terms of patent abuse, the games that people play. Senator Grassley's, you know, pay-to-delay, that kind of stuff. So, count me in on trying to fix that without killing the golden—the egg laid by the goose. Ms. Ulrich, you talked about PBMs. What percentage of costs do you think could be attributed to them?

Ms. ULRICH. I'm sorry, I don't have a number, but I can tell you that, you know, with 80 percent being controlled by 3 in the vertically integrated entities, that there's extreme market pressure being controlled by those 3 entities.

Senator GRAHAM. Okay. So, that'd be a good place for us to look, to create some competition, right?

Ms. ULRICH. I agree.

Senator GRAHAM. Do you agree that there is patent abuse in your industry?

Ms. ULRICH. You know, PhRMA is not in support of anticompetitive behaviors, and——

Senator GRAHAM. Well, that's not the question. Do you agree there's patent abuse in your industry?

Ms. ULRICH. Well, I believe that there are controls in place to handle that, when there is——

Senator GRAHAM. So, you don't think there's a problem?

Ms. ULRICH. I think that the courts and FTC has——

Senator GRAHAM. So, wait——

Ms. ULRICH [continuing]. The authority to deal with it.

Senator GRAHAM [continuing]. A minute. Wait a minute. You don't think there's a problem with pharmaceutical companies playing games with patents to keep generics out of the market?

Ms. ULRICH. I think that the system has the correct checks and balances in place to deal with it.

Senator GRAHAM. So, you think it's working?

Ms. ULRICH. I think it's working.

Senator GRAHAM. Yes. Well, I don't. Mr. Mitchell, you're on the receiving end of all this. One, I hope the next drug comes along quickly——

Mr. MITCHELL. Thank you.

Senator GRAHAM [continuing]. Because there're a lot of people like you, in different areas of our society, depending on Ms. Ulrich—I mean, I'm not saying—I'm trying to say new drugs are good; gaming the system, bad. PBMs need to be better controlled. Is that a good summary?

Mr. MITCHELL. I'd say so.

Senator GRAHAM. Okay. Now, let's go to foreign countries. If a drug is a lot cheaper in a foreign country because of government action in that country to subsidize the drug, would you consider that an unfair trade practice, Professor Mossoff?

Professor MOSSOFF. Potentially, yes. I mean, one of the problems with the cost of high drugs in this country is that other—all—this is the last country in the world, as far as I'm aware, that drug manufacturers and drug innovators can set the price in the marketplace at a price that they would seek to sell it at. All——

Senator GRAHAM. Yes. I think——

Professor MOSSOFF [continuing]. Other systems have single-payer systems.

Senator GRAHAM. Professor, do you consider that a potential unfair trade practice?

Professor RAI. Thank you for the question. It could be, yes. I mean, I do think that it is the case—I'm not an international trade expert, but it is the case that——

Senator GRAHAM. So—Okay, so——

Professor RAI. Yes.

Senator GRAHAM [continuing]. Here's what I'd like to do, as a Committee, here. Focus on the fact that some countries actually do lower the prices through government action that we prohibit here. For all the reasons you said, that makes our consumers have to absorb more of the R&D. That, to me, needs to be part of the con-

versation. To me, that is an unfair trade practice. Does that make sense to you, Mr. Mitchell?

Mr. MITCHELL. Respectfully, Senator, I disagree. I don't think their prices are too low. I think our prices are too high. And the reason their prices——

Senator GRAHAM. Well, but——

Mr. MITCHELL [continuing]. Are low—one reason is that we're the only nation in the world that permits drug companies to dictate prices to its citizens; the only nation on the planet. Every other country negotiates. We only began——

Senator GRAHAM. Yes.

Mr. MITCHELL [continuing]. To negotiate this year, and we will negotiate over a total of 60 drugs out of about 4,000. But——

Senator GRAHAM. I don't——

Mr. MITCHELL [continuing]. We should do more negotiating.

Senator GRAHAM. Yes. I understand, to a point. The question is, what role of the government here? And I'll let you go. I wish you well. What role should the government play in this is a very important decision to make. And when a country is having governmental policies that make our consumers pay more for the R&D we all need, I'm going to go after those countries. Thank you.

Senator Welch, [presiding.] Senator Whitehouse.

Senator WHITEHOUSE. Thank you, Chairman Welch. Good to be with all of you. I know we've talked a fair amount about drug ads. Obviously, like everybody else, I see a lot of them on my television. As best I can tell, they provide the public no health care value whatsoever. They provide sales and marketing value for the companies that are paying for the ads. And as best I can tell, what the marketing strategy is, is to convince everybody that all these drugs are a cure for loneliness.

[Laughter.]

Senator WHITEHOUSE. I don't know if you've noticed, but the person always starts off alone, and then they tell you about the drug, and then they're with friends or they're, instead of alone on the dock, out on the lake with their family in the canoe. And the mental communication, the message, is, this drug will make you less alone and lonely. And then, of course, you don't even listen to all the horrible things that the drug is going to do to you, in the rapid, fast-paced, legally driven script at the end. It's a very peculiar piece of propaganda art, and I would love to understand more about how it's made to work.

But the ads that I really want to talk about are other ads, and that has to do with Big Pharma's role funding dark money political pressure and ads. Pharmaceutical and health product companies put over $372 million into lobbying Congress and Federal agencies in 2022—a third of a billion. They deployed over 1,600 lobbyists, 3 times the number of Members of Congress. Now, it's hard to keep track of dark money spending compared to lobbying, because that's the whole purpose of using dark money funding channels, but an investigation by Issue One showed Pharma contributed more than $34.5 million to the House GOP-aligned dark money group, American Action Network, since 2010. Thirty-five million dollars is enough to get the attention of House Republican leadership, I think.

In 2022 alone, Pharma gave a record 7.5 million to American Action Network, which spent millions on advertising in 2022 opposing our drug pricing reform efforts and specifically the ones that made it into the IRA. Pharma donates to the Koch-and Trump-affiliated dark money organizations Americans for Prosperity, Americans for Tax Reform, and America First policies. A summary by The Washington Post in 2021 was pretty good: Congress Members who supported legislation to curb the cost of prescription drugs faced "massive months-long advertising, lobbying, and political donation blitz undertaken by the pharmaceutical industry and its allies, to kill a Democratic proposal to lower the cost of prescription drugs by empowering the Federal Government to negotiate their prices."

And, obviously, particularly the political donation blitz and the advertising blitz have a lot to do with putting those political ads up on TV, which I think are disconcerting to folks in America, because when it's your TV, and there's a message coming in to you across your TV, and it's paid for by a group with a name like Americans for Peace and Puppies and Prosperity, and you know perfectly well that there is no such group that provides any real service or any real product—they're just there to mask who's really trying to communication with you—it's creepy as hell.

And I think we need to fix that, and I would like to encourage all of you to do whatever you can to encourage the pharmaceutical industry to at least be transparent in its spending. Don't use Americans for Prosperity or some of these other front groups as intermediaries. If you really think this opinion that you're offering into people's living rooms is worth it, own it. And I'll leave it at that. Actually, let me ask Mr. Mitchell, what do you think are the sort of red flags that we should be looking at, where anticompetitive use of the patent system is signaled as opposed to pro-innovation use of the patent system?

Mr. MITCHELL. Well, anytime you have a drug like Humira that, as the Chairman pointed out in his opening remarks, had 165 patents on it—and I remember the day Senator Cornyn spoke to the chairman of Humira in a hearing and couldn't get a straight answer from him on how many patents there were on Humira—those patents, which began to expire in Europe in 2018, led to prices in Europe that were 15 percent of the prices that we paid in this country until the Humira competition finally hit the market last year. So, look for the number of patents. Look at what's happening abroad. Did they give away a little bit of the market in Europe in order to protect their market here from competitors? There are signs to look for.

Senator WHITEHOUSE. Thank you very much.

Senator WELCH. Senator Grassley.

Senator GRASSLEY. If you heard what Mr. Mitchell said, you're going to hear it again. So, I have this question about some bills that we've already passed out of this Committee that I think lead to anticompetitive practices in prescription drugs, as well as the availability of lower-priced generic alternatives. We focus on pay-for-delay deals, citizen petitions abuse, product hopping and evergreening and unfair PBM practices. And so these bills kind of come out with these names in this Committee: Prescription Pricing for the People Act, the Preserve Access to Affordable Generics and

Biosimilars Act, Stop STALLING Act, the Affordable Prescriptions for Patients Act, and the Interagency Patent Coordination and Improvement Act.

And it's frustrating that these bills move and become law—why they have not, I don't know. I hope that we can break the logjam for the benefits. And, Mr. Mitchell, you made that very clear. So, I was going to ask you, as one of three people here—so I'm going to focus on Professor Rai and Dr. Feldman. Do you believe that these bills that I've mentioned will help promote competition and lower drug costs?

Professor RAI. Thank you for the question. Yes, I do believe they will. I don't know that I would agree with the particulars of every single bill, but I've already endorsed heartily the Interagency Coordination Act, and I believe that the bills for product hopping, in particular, could be very useful, as well. There's also a bill on patent thickets that I think could prove very useful. So, yes, overall, absolutely.

Dr. FELDMAN. I agree. I think every bill that we are talking about today—all these bipartisan bills—would help address the problem. To me, there is no silver bullet. I wish there was one solution that could solve all of our problems, but I really think the work this Committee is doing around all of these issues—around better communication with the U.S. PTO and FDA, around citizen petitions, pay-for-delay settlement—we really have to be going after every single issue, to make incremental progress on what think is a real problem for our health care system.

Senator GRASSLEY. Yes. Ms. Ulrich, you made very clear in your answer to a question that the 3 biggest PBMs have 80 percent of the market, so I don't need to ask you to explain that further, but I'd like to zero in on a bill that Senator Cantwell and I have focused, called the Pharmacy Benefit Manager Transparency Act, to prevent unfair anticompetitive practices by PBMs and bring about greater transparency. Specifically, our bill would prohibit deceptive pricing schemes and arbitrary clawbacks of payments made to pharmacies. The bill would also require PBMs to report to the FTC how much money that they make through spread pricing and pharmacy fees. Do you believe that this bill would help address competition concerns and lower the price of drugs for patients?

Ms. ULRICH. Yes, thank you, Senator Grassley. We believe in—we support the principles of that bill, but I would defer to my other colleagues who are more engaged on PBM policy more directly, to answer you fully. And we would be happy to engage with you further on that.

Senator GRASSLEY. Okay. Thank you very much. I would go to Ms. Ulrich and Professor Mossoff. I'd like you to answer questions about the Federal Government investing $50 billion in health care research in this Fiscal Year alone. On top of that, we know the pharmaceutical industry invests 80 to 90 annually on research and development. Universities, pharmaceutical entities, biotech startups, small inventors, and other stakeholders are all engaged in innovation to find cures and produce lifesaving drugs. So, Professor Mossoff, how do we build on this work so that we can find the next miracle drug without breaking patients' pocketbooks? What kind of incentives spur investment in R&D?

Professor MOSSOFF. I think that, as a general principle, we should continue to retain the system that has made possible the biotech revolution and all of these incredible new drug treatments, which is reliable and effective patent rights that are secured to the innovators, that they can deploy in the marketplace. The data that I have on the funding shows that, at least as of 2018, you had private R&D funding of around 129 billion, which, as Ms. Ulrich said, dwarfs, you know, the 40 billion or so by NIH. So, it's not true, what many people believe, that the government funds all drug development or all drug discoveries.

In fact, one study done in 2021 of just the grants by the NIH in the year 2000—there were 23,230 NIH grants in the year 2000, and those were linked to only 18 FDA-approved medicines by 2020. So, what, you know, you have is a continuing process in which the NIH funds very far upstream initial research, right, the basic research, and then once the university researchers figure out that this is something that might be important, they get a patent; the university licenses it to a biotech company or they create a startup and get venture capital financing.

And that's what accounts for the $2.6 billion, on average, that goes into drug development ultimately that leads to an FDA-approved therapeutic treatment in the marketplace. And we should continue to ensure that that can happen by ensuring that the Bayh-Dole Act is not changed and that it continues to function in the way that it has functioned very successfully in the past 30 or 40 years in this incredible R&D pipeline that's been developed—as I said, rooted in this system of property rights to innovators that we have had in this country for 200 years.

Senator GRASSLEY. I'll submit questions for answer in writing. Thank you.

Senator WELCH. Thank you. Senator Hirono.

Senator HIRONO. Thank you, Mr. Chairman. Thank you all for testifying. I know that every time we compare pharmaceutical prices, we are told that Europeans pay far, far, less, but I do acknowledge, as you said, Professor Mossoff, that our health care system is very complicated. You're the only person on the panel who happened to mention that other nations have single-payer systems. In our country, adding to the cost of health care is depending on how you get injured and what system is kicking in to take care of you. We have the VA, the largest health care program in the country; we have private insurance; we have Medicare; we have Medicaid. In Hawaii, depending on if you get hurt in an auto injury, then that's another system.

So, I think that, you know, there is no single bullet, and for us to just—I realize that the patent system abuses is part of the problem, but for us to sit here and just point our fingers at the patent system is not going to resolve in the kind of non-silver bullet that we also acknowledge. And, in fact, Professor Mossoff, would you like to just very briefly go over why the payer system we have in our country—if you have any information on how much that adds to the cost of health care in our country, I would appreciate your thoughts.

Professor MOSSOFF. Thank you for the question, Senator. I don't have any specific data on the total cost of all of the different com-

plex institutions, public and private, that exist in our health care system, except for the fact that I know generally, as a scholar, it is incredibly complex, and it makes other systems look very simple and basic.

Senator HIRONO. Yes. And I think that if we really wanted to get control over the United States having the highest health care costs in the country, we should look at the payer systems that we have in place, but that's not what our focus is right now. It is clear that we do have abuses in the patent system, and I think it is important for us to very carefully target the abuses, as opposed to passing legislation that is going to be overbroad. Would you say that some of the bills that we have passed out of this Committee precisely target the abuses in the patent system? Anybody—wants to weigh in on this? I think you're familiar with some of the bills that have emerged from this Committee.

Voice. So——

Dr. FELDMAN. I think the bills are targeted effectively. The bills target citizen petitions. They target pay-for-delay settlements. There are very specific things that these bills go after, that I think would undoubtedly improve some of the patent gamesmanship that we've seen, but I don't think these bills go far enough. I think there are numerous other targeted solutions that are simple and would help improve things. For——

Senator HIRONO. Such as?

Dr. FELDMAN. Such as, have the FDA review every patent that gets submitted to the Orange Book. The FDA currently serves in a purely ministerial role. It doesn't look at the patents. The companies can submit whatever they want. So, give the FDA the authority and the resources to review those patents. Force manufacturers, when they submit patents for listing in the Orange Book—submit them for re-examination to the U.S. PTO. Very simple, but making sure that these patents that are listed in the Orange Book aren't——

Senator HIRONO. Would the——

Dr. FELDMAN [continuing]. Being listed——

Senator HIRONO. Excuse me.

Dr. FELDMAN [continuing]. Improperly.

Senator HIRONO. Would the rest of you agree that those are some so-called simple changes, where there's more collaboration as well as the information sharing between PTO and FTC, for example?

Professor RAI. FDA and——

Senator HIRONO. Oh, FDA.

Professor RAI [continuing]. PTO. Yes. Absolutely. I think that—and also, Professor—Dr. Feldman's point about the FDA's ministerial—so-called ministerial role could be fixed really readily and inexpensively if the FDA and PTO collaborated on every patent that was listed on the Orange Book, to ensure that it's properly listed. This is a gap in the system that has existed for decades, and it's really unclear, to me, at least, why this gap has not been filled.

Senator HIRONO. Thank you for that suggestion. I have a question for Dr. Feldman. Last year, insulin prices were cut dramatically after surpassing the rate of inflation year after year. In a paper last year, you catalog "The Rise and Fall of the Insulin Pricing Bubble." I'm not talking about the situation where the legisla-

tion capped the insulin costs for Medicare. This has to do with insulin's cost for everybody else. Can you give us some insight into why prices rose so high, why they fell so dramatically, and whether that experience points the way toward possible policy solutions we can use for other high or overpriced pharmaceuticals?

Dr. FELDMAN. Thank you for the question, Senator. The reason why the prices of insulin rose so dramatically is because the three large insulin manufacturers obtained numerous patents to limit competition. They raised prices year after year, many, many, many times the original prices of these products. And the reason why prices came down so suddenly is that a rule in Medicaid lifted the cap on rebates, on penalties that these companies were going to have to pay. So, previously it was capped at 100 percent, where, if a patient used one of these old insulin products in Medicaid, because they had raised prices faster than the rate of inflation, year after year, they had to pay these very large penalties that were capped at 100 percent. They are no longer capped at 100 percent, and so insulin manufacturers responded by dropping their list prices.

Senator HIRONO. So, there are other ways that we can lower drug prices by, for example, impacting what PBMs are getting. Is that part of the approach that we should consider?

Dr. FELDMAN. I think we absolutely should consider legislation that addresses PBMs. I think some of the things we've talked about here today, like spread pricing, the lack of transparency—all of these contribute to higher prices in the system. But I would say just on this question about insulin prices and why they came down so dramatically, it's a rule that forced manufacturers to pay penalties for raising list prices greater than the rate of inflation. And so I think with the IRA we will see similar types of penalties, moving forward. And, you know, I think, again, we need action on—with the pharmaceutical companies, and we also need action with PBMs.

Senator HIRONO. Thank you. Thank you, Mr. Chairman.

Senator WELCH. Senator Kennedy.

Senator KENNEDY. Thank you, Mr. Chairman. With me today, Mr. Chairman, are two interns in my office, Ms. Anna Kate Luke and Quinn Eisenfeld, and I wanted to recognize them today. They're sitting behind me.

Mr. Mitchell, I'm sorry about your health challenges. You made a very impassioned plea for us to consider the various bills that have come out of this Committee. Why do you think the full Senate hasn't taken them up?

Mr. MITCHELL. I think you've been busy with some other things.

Senator KENNEDY. You really think that's the reason?

Mr. MITCHELL. Part of the reason, I think, yes, is that the Senate has been busy with many other things. I do think that there is an appetite on both sides of the aisle to——

Senator KENNEDY. Well——

Mr. MITCHELL [continuing]. Advance these bills, maybe in the lame duck session.

Senator KENNEDY. Respectfully, I think you're wrong.

Mr. MITCHELL. Tell me.

Senator KENNEDY. Okay. The majority leader controls the floor of the U.S. Senate. Whether that majority leader is a Republican or a Democrat, one person controls what the entire United States Senate can consider. And I don't mean to pick on Senator Schumer. He's my friend. He is exercising the power that we have ceded to him. If Republicans were in the majority, I feel pretty confident in saying that our majority leader, Senator McConnell, would exercise the same power.

Do you think the Senate ought to establish a new rule that all Senators are equal, and some aren't more equal than others, and that if a Senator can demonstrate that he or she has 60 votes to pass a bill—perhaps through the number of co-sponsors, though that wouldn't be the only way—that that Senator should have the right to bring the bill to the floor of the United States Senate and allow Senators, in front of God and country and their constituents, to vote on it?

Mr. MITCHELL. Senator, you're way over my pay grade.

Senator KENNEDY. Okay. You don't have an opinion on that?

Mr. MITCHELL. No.

Senator KENNEDY. Professor, you're an attorney. Do you have an opinion? You don't want to make Senator Schumer mad. Does that concern you?

Professor RAI. That's an excellent question. It does seem to me that that level of control could be not optimal, the level of control exercised by one person as——

Senator KENNEDY. You're a professor, right?

Professor RAI. I am a professor.

Senator KENNEDY. Not optimal?

Professor RAI. Correct.

Senator KENNEDY. Yes. In the real world, we say it sucks.

[Laughter.]

Senator KENNEDY. I came here today to learn, and I have learned a lot. But here's what I'm trying to understand. Professor, is your contention that, because of the patent abuse—your words, not mine—that pharmaceutical drug companies are making obscene profits in the United States?

Professor RAI. Thank you for the question, sir. I don't think it's obscene. I think that, as many people have pointed out, in the United States we do fund research and development for the whole world, and that's a very, very knotty problem, so that's a challenge that I think we all need to take on. I do think that patent abuse contributes to lack of innovation, which might seem counterintuitive, but I'll tell you why.

Senator KENNEDY. Okay.

Professor RAI. Because if you——

Senator KENNEDY. Let me stop you for a second, because I'm going to run out of time. You use the term, patent abuse. You're obviously using it in a pejorative sense. Is this patent abuse illegal?

Professor RAI. It is not currently illegal, but there are mechanisms that we could readily employ to curtail it.

Senator KENNEDY. If we passed a bill?

Professor RAI. If we passed bills. There's also a lot that agencies can do right now, using their current powers.

Senator KENNEDY. So, why don't they?

Professor RAI. They don't because I think that Congress doesn't adequately push them to do it. So, you need to hold oversight hearings, hauling up the FDA and the PTO, asking them why they don't cooperate more, including on the sort of thing that they can already do, which is exchange information, including trade secret information——

Senator KENNEDY. So, you think the problem——

Professor RAI [continuing]. Protected by trade secrecy law.

Senator KENNEDY. You think the problem is in part within our administrative agencies, like the FTC or——

Professor RAI. The FTC is, I think, doing a cleanup job on the back end, but the FTC can only work on the back end. Recall that the FTC's jurisdiction is antitrust. That's after all the bad stuff has already happened. They try to clean up on the back end. We need to nip the problem in the bud, on the——

Senator KENNEDY. What about——

Professor RAI [continuing]. Front end.

Senator KENNEDY [continuing]. The FDA?

Professor RAI. FDA can help, and the PTO can help.

Senator KENNEDY. Is the FDA doing a bad job with controlling patent abuse?

Professor RAI. The FDA considers its role ministerial. I think——

Senator KENNEDY. But are they doing a bad job, in your opinion? Come on——

Professor RAI. I think they could——

Senator KENNEDY [continuing]. Professor, we're trying to find solutions here. Don't dance around on me. Tell me what you think.

Professor RAI. I think they could do more.

Senator KENNEDY. Okay. I'm gone way over. Thanks for your indulgence, Mr. Chairman.

Senator WELCH. Thank you. I want to thank my colleagues for the work that you've done, and I do hope, Senator Kennedy, that we get those bills on the floor and have a chance to vote on them. You've done a lot of work on that, Senator Cornyn, and I'm very supportive of what you've done.

Senator KENNEDY. Well, I've suggested a way, Mr. Chairman, that we can get them on the floor, that—I'm not trying to step on——

Senator WELCH. Talk to your friend, the majority leader.

Senator KENNEDY. I'm not trying to step on Senator Schumer's toes, by any stretch. The door——

Senator WELCH. Let's go back to the issue here.

Senator KENNEDY [continuing]. Swings both ways.

Senator WELCH. Thank you. You know, the bottom line here is the cost of health care in this country is killing folks. It is such a brutal, punitive burden on everyone, and that's for citizens in all of our States, folks who are having trouble paying the rent or they're having trouble paying for groceries. They can't afford—they can't even dream about owning a house. And when I was visiting with some employers in Vermont this week, they told me that the cost of a family plan for an employee is $40,000. That's 20 bucks an hour. All right? And the biggest driver in health care costs are Pharma costs, prescription drugs. And whether you want to call it

abuse or gaming, the fact is, people can't afford it, and it is not sustainable.

And the reality, too, is that Pharma's got a pretty sweet deal. It's got a guaranteed market, with Medicare, with Medicaid, with the VA. It's got employer-sponsored health care, and our employers in Vermont and around the country—they really care about having good health care for their employees. That's important to them. And then they've got the taxpayer-funded research, which is often the hardest, most risky research, that the NIH does, that elemental research, as opposed to the—about marketing and what devices and how to package it. And then, of course, you've got the patent system that we're talking about today, where there needs to be reform. And there's been a lot of bipartisan effort here on this Committee to do it.

Let me just ask a few questions. Dr. Feldman, let's talk about Ozempic—yes. Am I pronouncing that right?

Dr. FELDMAN. Yes.

Senator WELCH. Yes. What I understand is that you have done research, a lot, on this particular drug, and that you—as we know, it costs 936 bucks a month in the U.S., only 147 in Canada, and $83 in France. That's a huge expense for our employers and for our taxpayers. And last year Novo Nordisk made 13.9 billion in sales from Ozempic, 60 percent coming from the U.S. So, we're just paying an enormous amount. But on the patents—and you have researched this, I understand—there's 25 patents, and only 4 are for an active ingredient. Can you just explain what that means?

Dr. FELDMAN. Yes. That's exactly right. So, over the years, Novo Nordisk has obtained and listed in the Orange Book 25 patents on this drug.

Senator WELCH. And how many for the active ingredients?

Dr. FELDMAN. And so 21 are on the delivery device. On the delivery device: the injector pen technology that is used for patients to self-administer the medication. The other four patents are non-device patents: two on the active ingredients and then two on methods of use or formulations. And so I think it's a perfect illustration of the problem. You have 25 patents; 21 on these delivery devices. The FTC has said, these patents should never have been listed in the Orange Book in the first place, and, you know, the brand name firms already are suing for infringement. They're litigating these brands.

Senator WELCH. Okay. So, I have a bill that I introduced with Senator Klobuchar and Senator Braun to streamline the drug patent litigation by limiting the number of terminally disclaimed patents a drug company can assert. And the U.S. Patent Office, as you mentioned, Professor Rai, instituted a rule. But that legislation that would essentially limit that thicket—can you comment on your view on that legislation and how it would be helpful or not?

Dr. FELDMAN. Yes. I think it's a great piece of legislation. The idea is that currently the Patent Office is required to reject patents that are obvious follow-ons from other patents, but companies can use these terminal disclaimers, which say, okay, the patent will expire at the same time as other patents.

Senator WELCH. Right. Thank you.

Dr. FELDMAN. And I think by limiting litigation on these patents to one per family, I think it could promote——

Senator WELCH. Thank you.

Dr. FELDMAN [continuing]. Timely competition.

Senator WELCH. And, Professor Ulrich, you know, I listened carefully to your testimony, and it's the same testimony I've been listening to for over a decade, and that is, the sky is falling if we do anything that will interfere with the magic of Pharma. But do you know how much the top 15 biggest drug companies reported in revenue in the first quarter of 2024? There's 173 billion? Does that sound about right?

Ms. ULRICH. I'm sorry, I don't have that figure in front of me.

Senator WELCH. Well, it's 173 billion. And of that, about 14 percent—25 billion—was spent on research. By the way, that isn't specified as to whether it's for a new molecule or a combination of an active ingredient or marketing. Novo brought in 9.5 billion in the first quarter and spent only 1.2 billion on R&D. Do you know how much Novo spent on shareholder dividends and buybacks? Yes. Four and a half billion dollars. So, there is a question here, with the advertising expenditures, with the shareholder buybacks and the dividends. Is there room for companies to consider maybe giving the consumers and the taxpayers a fairer price?

Professor Rai, a recent study at the University of Texas focused on improving the patent approval process found that if the patent examiners were given more time to examine the secondary patent applications, it could save consumers up to $5 billion. Could you comment on that?

Professor RAI. Absolutely. That study was conducted by a PhD scientist and a PhD economist, one of whom is at Duke. And it is an impeccable study. I think that it's bulletproof, and examiners need to be given more time. What that means, however, is that the Patent Office will have to raise fees, because it is entirely fee funded. I think that's a very wise use of the patent agency's fee-setting authority.

Senator WELCH. Thank you. Senator Cornyn.

Senator CORNYN. Thank you, Mr. Chairman. Listening to the testimony today reminded me of a quote from H.L. Mencken, who said that for every complex problem, there's a solution that's simple, neat, and wrong. So, that may be why I find myself agreeing with all of you, bits and pieces of what you say, but also disagree with all of you in other respects. But let me see if I can find some common ground here.

So, I'm a big believer in our patent system, and I believe the exclusivity that is provided to people who discover new lifesaving drugs ought to be protected. But at the same time, I'm angry when I look at the abuse of the patent system by filing as many as 165 patents for something like Humira. And, Dr. Feldman, when you mentioned that some of these patents have nothing to do with the active ingredients in the drug but rather the delivery devices—in other words, you take a pill as opposed to some aerosol you inhale or whatever—that this then prevents these incredible lifesaving drugs from being more readily available and affordable to Americans.

But at the same time, I recognize that if there wasn't the promise of a big financial payoff for the people that do this research—and I think somebody mentioned 12 percent—Ms. Ulrich, maybe that was you—actual success rate—so, that means that 78 or—excuse me, 88 percent of the drugs investigated actually fail, which is one reason why Pharma spends so much money on R&D, hoping to hit gold, I guess, for that 12 percent. So, I find myself sort of torn, back and forth, and maybe that's the reason why we are where we are.

But I do agree with Senator Kennedy. Senator Schumer could put these bills on the floor today, if he wanted to. And, Mr. Mitchell, you're being way too kind in terms of how busy you think we are here. We're working about two and a half days a week and hardly breaking a sweat, so we have a lot more room to grow and capacity to deal with important problems like this. And taking up and passing bipartisan bills would be pretty remarkable. And in addition to the ones we've talked about here, the Finance Committee has done a lot of work, Ms. Ulrich, on the pharmacy benefit managers that you addressed.

The 20-year patent system does not—there's a problem, I think—and you tell me if it's a problem, Ms. Ulrich. So, you get 20 years' exclusivity, but you may not have a full 20 years of exclusivity because you can't actually sell the drug until the FDA approves it. So, there's a lag time, frequently. And I think you said effectively the 20 years is 13 years; is that correct?

Ms. ULRICH. Yes, for small molecule drugs it's around 13 years on average.

Senator CORNYN. I know that Hatch-Waxman, many years ago, tried to sort of figure out how to deal with that, but it strikes me as that may be some area where we ought to be able to give patentholders the effective use of their patents longer, by making sure that the period of the exclusivity ran from the time that it actually was available to be sold, as opposed to when it's patented. But that maybe is another discussion for another day.

Mr. Mitchell, do you—let me just say I, too, wish you well. I'm glad we live in a country where you can get access to lifesaving drugs. What I've always been told, though, is that the way that some of these countries, like in Europe, for example, that have national health care systems, deal with this is they restrict the formulary—that is, the drugs that are actually available. Do you know whether the drugs that you take, that are saving your life, would be available to you if you lived, for example, in Europe? My understanding is——

Mr. MITCHELL. Most——

Senator CORNYN [continuing]. The EU only has about 40 percent——

Mr. MITCHELL. I'd have to check country by country, but for the most part, the principal medications for myeloma are available abroad. I do think there's an important issue that you're touching on, and Professor Rai started to talk about it, and that is very important to me, as someone who needs innovation. Patent abuse inhibits innovation. If drug companies can raise prices on old drugs that should have competition but don't, and they can raise them at

will, then they have much less incentive to invest in the risky innovative work that can produce new drugs that can extend life.

Senator CORNYN. You and I are of one mind on that.

Mr. MITCHELL. And so I don't want to just——

Senator CORNYN. The Chairman's going to cut me off because my time is up. Let me ask one last question. Does the fact that, according to the most recent figures I've seen, that 40 percent of the active ingredients in the drugs that Americans consume in this country come from China—does that concern you? After COVID, we became very concerned about supply chain vulnerability, and it strikes me that's a vulnerability. Is that not a problem, or is that a problem? Anybody have a view on that?

Professor RAI. It is a problem. Yes.

Senator CORNYN. It seems like it.

Professor RAI. Yes.

Senator CORNYN. I would think so. And——

Professor RAI. Indeed, it is.

Senator CORNYN [continuing]. Maybe there'd be a way for us to do more of that producing——

Professor RAI. Well, the FDA needs more resources.

Senator CORNYN [continuing]. More of those active ingredients here in America. I'm sure it's a financial decision.

Professor RAI. The FDA needs more resources.

Senator CORNYN. Okay. Thank you.

Senator WELCH. Senator Coons.

Senator COONS. Thank you, Chairman Welch. And I am sorry that I had two other Committee hearings at the same moment. I know this has been an important and robust conversation about a matter of great significance to all of us. I agree with my colleagues that we have to do more to reduce the very high price of prescription drugs in the United States. They remain too high for my own constituents. In fact, it's often the first thing I hear from in town halls, and I do think the Inflation Reduction Act has made dramatic process in this direction. There's more yet to be done, and I'm hoping we can still get more done in this Congress.

I do believe that there are other factors than patents at work, in terms of high prescription drug prices, and as we've discussed, my core concern is that the patent system applies to a very wide range of products and goods, not just pharmaceuticals. And so what reforms or changes are made in order to pursue reduction in drug prices I hope do not harm the foundation of the patent system, that protects everything from roof shingles to batteries to electric vehicles to paint coatings—I mean, thousands and thousands of innovative products and services.

So, let me, if I might, first just ask a question. Professor Mossoff, as I was leaving to the other hearing, you were talking about Bayh-Dole march-in rights, and I don't get the sense that you've come back to that at all. The core issue I had with the direction that NIST went in allowing pricing for Bayh-Dole march-in rights is it doesn't just apply to prescription drugs. It applies to everything. So, any company who invents or any researcher who invents anything is now potentially open to the Federal Government saying, I want that, and I don't agree with the price you're setting for it. Is that accurate?

Professor MOSSOFF. Yes. It's entirely accurate.

Senator COONS. And are there breakthroughs in other sectors unrelated to pharmaceutical or therapeutics or vaccines where you think having a price-based march-in right regime would put innovation at risk?

Professor MOSSOFF. Oh, certainly. I think, you know, every sector of the innovation economy, from high tech to even areas of the manufacturing base, are threatened by this. It completely destabilizes patents as property rights, when you cannot rely on this with certainty, going forward, that the government won't step in at any particular point in time, decide arbitrarily you're charging too high of a price, and therefore interfere with your ability to contract in the market——

Senator COONS. Is there——

Professor MOSSOFF [continuing]. Your product.

Senator COONS [continuing]. Compelling evidence that the highest priced prescription drugs or majority prescription drugs would actually have their prices brought down by having march-in rights available to the Federal Government?

Professor MOSSOFF. Thank you for that question, because that's an excellent question. And the actual studies show that actually very few percentage of prescription drugs are actually covered by the Bayh-Dole Act. It's around approximately 1 percent is the last number that I saw. And so you would not see any effect in prescription drug prices with the adoption of this radical systemic change to the patent system, where you would have the ability of any government agency to march in and to dictate prices in the private market on any product or service.

Senator COONS. One of the five bipartisan bills I think that is ready for action is one related to PBMs, Senator Grassley's Prescription Pricing for the People Act, which would provide transparency about anticompetitive practices by PBMs. I'd be interested in whether I missed a compelling conversation about PBMs and their role in the marketplace. Dr. Feldman, if you would, do the existing PBM structures make any sense, in your view? And what role, if any, do they play in keeping prices unnaturally high for U.S. consumers?

Dr. FELDMAN. Thank you for the question, Senator. The short answer to your question is, they make no sense. I think that the current PBM structures make no sense. We have a system that rewards these high rebates—so, high list prices, high rebates that ultimately affect out-of-pocket costs for patients, that—for folks who don't have insurance, they don't have access to these rebates. You have spread pricing, where PBMs are collecting more than they're actually charging the pharmacies; keeping the difference. So, I think there are a lot of problems with PBMs.

There's fundamentally a lack of transparency that makes it very hard for researchers, like several of us up here, to do our work, because we don't know what the actual prices of these drugs cost. So, I think the bill out of your Committee—there are several bills that address bad behavior from PBMs; are important. I will say PBMs are negotiating discounts, and so whatever legislation you all pursue, you don't want it to undermine the ability to get discounts, but

I'm in full agreement—to go back to—the very simple answer is, it is not a functioning system.

Senator COONS. It's a very complex, multistep system, where the numbers of steps between innovation and manufacturing and price at the prescription counter has a whole series of steps. Last, I'm a co-sponsor of Senator Durbin's Interagency Patent Coordination and Improvement Act and could not agree more that better communication between FDA and PTO can help improve a patent examiner's finding of prior art.

I agree with you, Professor. PTO needs to raise its fees in order to give examiners more time to do a more thorough job. Patent quality is something I would hope we all agree on. I'd just be interested in whether you think there's either other agencies the PTO director ought to be coordinating with or there's more we could do to improve collaboration between the PTO and the FDA. And I recognize I'm over my time.

Professor RAI. So, yes to everything you're saying, and there's a laundry list of other agencies that the PTO could collaborate with, but since we're focused on drug pricing, I think FDA is the most important one.

Senator COONS. Thank you. Thank you for this hearing.

Senator WELCH. Thank you.

Senator COONS. I look forward to following up with you.

Senator WELCH. Thank you very much. Senator Ossoff.

Senator OSSOFF. Thank you, Mr. Chairman, and thank you to our panelists for joining us today. And, Professor Mossoff, we should perhaps determine whether we're distant cousins.

[Laughter.]

Senator OSSOFF. I am grateful to you all for your expertise. Dr. Feldman, I want to discuss with you the prices that Georgians are paying for inhalers: children on Medicaid, seniors on Medicare, and everybody in between. First, I just want to note generally the prices that Georgians are paying for prescriptions are outrageous.

The stories that come to me in my office are shocking, from a constituent who, right now, is having difficulty making ends meet and affording cancer treatment, who watched their own friend die from being unable to afford cancer treatment; a veteran in Georgia who right now is having to scrape together thousands of dollars per month in order to afford leukemia treatment; kids and seniors with asthma or COPD who are having to pay exorbitant prices for inhalers; medical devices across the board. And the tremendous lobbying power of the pharmaceutical industry is a major driver of the outrageous prices that Americans pay. And of course there's a balance that we have to strike between making sure that research and development and innovation are rewarded and the interests of patients and consumers, but this country is not getting the balance right.

We made big progress, capping the cost of insulin for seniors on Medicare Part D at $35 a month, finally empowering Medicare to undertake some negotiation with Pharma over prices, but we have a long way to go. And let's talk for a moment, Dr. Feldman, about inhalers. And I know that some voluntary caps are now in place, but Medicare, Medicaid—still not participating in that. You've seen countless patients—you're a pulmonologist, correct?

Dr. FELDMAN. That's right.

Senator OSSOFF. And so you've seen countless patients dealing with serious life-threatening asthma and COPD. Is that right?

Dr. FELDMAN. That's correct.

Senator OSSOFF. How long have inhalers been on the market?

Dr. FELDMAN. The first metered-dose inhaler was approved by the FDA in 1956.

Senator OSSOFF. 1956. In the last few decades, have the active ingredients in these devices substantially changed?

Dr. FELDMAN. No. Since 1986, there have been no inhalers for asthma or COPD with a new mechanism of action. That means, of the dozens upon dozens of brand name inhalers that've been approved, not a single one has an active ingredient that is fundamentally different from other active ingredients in the same class.

Senator OSSOFF. For three and a half decades, you're saying, the active ingredients have been basically the same?

Dr. FELDMAN. That's right. Some tweaks to the molecules where you get new active ingredients in—but in the same class, and so fundamentally no major breakthroughs in terms of managing these diseases, from inhalers.

Senator OSSOFF. So, why are so many Georgians and so many Americans still paying hundreds of dollars for these devices?

Dr. FELDMAN. I think it comes back to really what we're focused on in this hearing today, which is these problematic patenting practices, product hops, where companies are taking decades-old active ingredients, getting patent protection for the delivery devices, for other aspects of the products, and it allows them to keep prices high by limiting generic competition.

Senator OSSOFF. So, product hopping or device hopping—just for the folks tuned in from Georgia, define that in a nutshell.

Dr. FELDMAN. That's where you take the same ingredient or set of ingredients and put them from an old delivery device into a new delivery device that may be no better than the earlier one, but it does have new patents. So, it allows you to move people from an old device to a new device, if you're a brand name company, earn a lot more revenue by doing so but to no benefit for patients.

Senator OSSOFF. And so that patent, based upon no innovation of the underlying medicine, some nominal innovation of a device, then boxes out competitors, generics, and helps keep prices high, right?

Dr. FELDMAN. That's exactly right.

Senator OSSOFF. Now, I do want to note some manufacturers have agreed to cap out-of-pocket costs for inhalers. Does that apply to Medicaid or Medicare?

Dr. FELDMAN. It does not. Those caps do not apply to Medicare and Medicaid.

Senator OSSOFF. So, for a kid on PeachCare in Georgia; for a senior—and I think, according to my notes here, one in nine Medicare beneficiaries have COPD—those caps don't apply?

Dr. FELDMAN. That's correct.

Senator OSSOFF. Where else do we see this practice of device hopping or product hopping?

Dr. FELDMAN. We see it, really, for all drug device combinations. What are drug device combinations? Those include products like in-

sulin pens, inhalers, EpiPens, GLP–1 receptor agonists, that Senator Welch was asking about. So, it seems like kind of a niche set of products, but in fact, if you look at the top 50 drugs by Medicare spending in 2022, by gross spending, 40 percent are actually drug device combinations.

Senator OSSOFF. Yes. Just about every family in Georgia has had to think, at some point, about—do I need to carry around an EpiPen for my child who has an allergy? Do I need to purchase an inhaler for my child with asthma or for a grandparent suffering from COPD? And yet these abusive practices, where there's not innovation on the underlying drug but there's some nominal change in the product, is boxing out competition and keeping prices high. And this is, Mr. Chairman, a place where I hope we can achieve some bipartisan consensus, to make progress for Georgians who are struggling for these basic medical products. Thank you, Dr. Feldman.

Dr. FELDMAN. Thank you.

Senator WELCH. Senator Butler.

Senator BUTLER. Thank you so much, Chairman, and thank you to all of you for coming. It's an incredibly important issue for Americans all over the country, particularly for folks living in my State, and so I appreciate all the work that you all are doing here. Couple questions, just really quickly.

I think I want to direct this question, if it's okay, to you, Dr. Feldman. Across our country, many families are choosing now between putting food on the table and purchasing those lifesaving health care drugs and medication—all the things that we have been talking about throughout today's hearing—paying nearly three times as much on prescription drugs compared to families in peer countries. Dr. Feldman, as a physician, how have you seen high prescription drug costs not only impact patients but affect the livelihood and financial stability of the full family?

Dr. FELDMAN. Thank you for that question. I have. You know, we often think about, as physicians, how these high out-of-pocket costs affect that patient. Are they going to take the medication? You know, I spend a lot of my time—when I'm practicing, I work in the medical intensive care unit. We admitted a patient recently who had diabetes and was there with DKA, diabetic ketoacidosis, which can be a fatal complication of not taking your insulin. I asked her what happened, and she said, I just couldn't afford my insulin. And I think as physicians we're laser focused on the problems for the patient, but there is no question that every dollar that is spent on those high out-of-pocket costs for patients mean a dollar less that they can spend on getting food, clothing for their kids, for their loved ones. So, I think it's an important point that we probably don't think enough about.

Senator BUTLER. I appreciate you acknowledging it. You're right; there's lots of conversation among practitioners about the patient complying with the medication orders and managing their health. And the unintended consequences that making those choices have across the full family then also potential lead to the, you know, young person not being able to sort of have the resources to meet their sort of full impact in life. So, I appreciate you talking about it. Are there particular populations that you think that are dis-

proportionately touched by these kinds of financial burdens, just in the patient population that you've seen or experienced that we need to be thinking about specifically?

Dr. FELDMAN. All of the issues that we're talking about today have disproportionate effects on the most disadvantaged members of our society. Where do we see the highest rates of asthma, of COPD, of diabetes? It's in already disadvantaged groups of patients. And I think a big motivation for my work is trying to address these problems, to resolve some of these disparities. You know, we've talked a lot about different proposals. It can feel very lofty, a lot of these conversations we're having about the patent system. At the end of the day, we're talking about expensive medications for people who can't afford them and it disproportionately hurting certain members of our society in ways that I think are problematic.

Senator BUTLER. And this is a line of questioning that I wanted to get to, because I do think that there are a lot of—there's a lot of complexity, as was noted in the first witness's offerings. There's a lot of complexity to the systems and the laws, as we're—and consequences, intentional and unintentional, around the bureaucracy, and so often we can lose sight of the people, as we try to navigate the morass of the process. And so I wanted to make sure that, for those who are taking, you know, an hour to watch C–SPAN, whose issue—but whose lives are very much impacted by the cost of medication—that we give them an opportunity to remind ourselves that, at the end of the day, this is about the American people as opposed to the complexity of the process. And so if there was one patient that you could offer their story for consideration, I'd love to give you my last 10 seconds to talk about and offer that one story.

Dr. FELDMAN. Yes. You know, I'm thinking about a patient that I saw when I was a fellow in pulmonary medicine. And, you know, it's hard to talk about costs with patients. A lot of patients are embarrassed. People don't want to talk about the fact that they can't afford their medications. But I remember talking with her, and rather than using inhalers, which are more convenient, which she could not afford, she was using—cobbling together therapies via a nebulizer, which is not something we've talked about, but it's basically where the ingredients are sold separately. And they can work, but it just—her story sticks out in my mind because, Number one, it was hard for her to talk about; Number two, she couldn't use the medications that we prescribed. She had to use a medication that takes longer to administer; you have to do it at home.

And, you know, it's exactly like I was saying before. The most disadvantaged members of society are the ones who are affected by these patent games. I think if we want to address racial disparities, socioeconomic disparities, we have a lot to do in this country, but everything we're talking about here today is a way of doing that.

Senator BUTLER. Thank you, Mr. Chairman.

Senator WELCH. Senator Klobuchar.

Senator KLOBUCHAR. Thank you very much, Mr. Chair, and thank you for the work that we've done together on the negotiation—Medicare prices. We're so pleased. I was hearing you talk, Mr. Mitchell, about Eliquis, one of the drugs, as you know, that's

now being negotiated, of the ten blockbusters, with many more to come.

I want to start, though, with one of the issues—a bill that still hasn't passed, that Senator Grassley and I have been working on for a really long time, which I know he mentioned, pay-for-delay. And as you know, Mr. Mitchell, anticompetitive pay-for-delay settlement, where a branded Pharma company pays off a generic or biosimilar company to delay the introduction of the competing drug product, is, sadly, a common practice. Our bill—it's called Preserve Access to Affordable Generics and Biosimilars Act—strikes a balance between targeting anticompetitive settlements while allowing procompetitive patent settlements to proceed and saving an estimated 1.6 billion—1.6 billion—over 10 years. Mr. Mitchell, you mentioned the drug that you depend on, Revlimid, that was caught up in a pay-for-delay settlement, as I understand. How did that affect the cost of the drug for you personally? How do pay-for-delay deals keep the cost of prescription drugs high for patients, generally?

Mr. MITCHELL. I took Revlimid for five and a half years, and during the time I took the drug, both the price—underlying price—and my out-of-pocket rose dramatically. By the way, Revlimid was the second-most expensive drug for Medicare, until it began to have competition in the last year—to treat only 39,000 patients: the second-most expensive drug for Medicare, at $5.4 billion.

When the drug company that owns the patent decided to let competition come on the market, it limited the generics to a lower market share, 10 percent each for the first two competitors. If you have a limited market share as part of the deal, you will not lower your price because you cannot gain market share. What happens then is the brand drug company and the two generics, in the case of Revlimid, shared the monopoly, and the price didn't come down. This is a pay-for-delay deal. This is making an arrangement to say, we won't fight you in court; instead, we'll give you a market share limited deal, and you will make a whole lot of money for a few years while we delay real competition.

Senator KLOBUCHAR. Very good description. Thank you. Turning to another issue that has been discussed today—that's sham FDA petitions. Dr. Feldman, this practice risks delaying the approval of generic drugs and biosimilars and poses unnecessary burdens on FDA resources, to add to everything else, when they have so much to do. Senator Grassley, again, 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. CBO estimates that the bill would save taxpayers 400 million over 10 years. As you know, both of these bills have gone through this Committee on a voice vote. Which types of entities file the majority of citizen petitions challenging FDA approval of generic or biosimilars, Dr. Feldman?

Dr. FELDMAN. Brand name drug companies.

Senator KLOBUCHAR. Okay. And can you elaborate on the harms to patients and competition caused when Pharma companies use a citizen petition process to delay entry of competing drugs?

Dr. FELDMAN. Yes.

Senator KLOBUCHAR. I just find it ironic, indeed, when it's a citizen petition process, and the citizens are getting screwed by it, but continue on.

Dr. FELDMAN. I have felt that same irony, myself. So, first of all, we should say that companies are doing this because every day of delay for some of these blockbuster drugs can be worth millions or tens of millions of dollars for the company. So, there's a strong incentive to do this. And basically what happens is the brand name pharmas will wait until the right moment to put a question to the FDA to request that they not approve a generic medication. And it slows things down. And every day that we slow things down is more revenue for the brand name manufacturers, but it's one less day that patients get access to generic drugs. And we know that generic drugs are the number one way to lower prices in this country. It is a way to bring down costs for patients. So, I think it's a good bill, and as you said, these are not citizen petitions. They are put out there by the companies for economic gain.

Senator KLOBUCHAR. Last, Professor Rai, the price of 25 brand name medications that Medicare spends the most on—some of which are negotiated, of course, right now or in negotiations—have, on average, tripled in price since they hit the market. You have written that Medicare price negotiations will promote the entry of new drugs by reducing the incentives for brand drug companies to engage in anticompetitive patent strategies that can allow for these price increases.

So, this is kind of where our Medicare negotiations, that is almost an outcome of all of this bad activity, sort of hits the road and combines with this patent problem. How will requiring drug companies to negotiate prices with Medicare—as I said, with more on the road—despite lawsuits going on right now all over the country to try to stop us, which seems unbelievable to me, given that Congress is the one that made the deal, and Congress can change a deal—how will requiring drug companies to negotiate prices with Medicare deter Pharma companies from playing patent life-cycle games to preserve high prices and facilitate entry of competitors and further reduce prices?

Professor RAI. So, I think the Inflation Reduction Act is one of the most important patent reforms of the 21st Century, and the reason is this. It finally places a time limit, at least for Medicare, on how long you can extend an old drug, which means that you have to come up with new drugs, truly new drugs. And that is a game changer, it seems to me, and I wish it was only—more than ten drugs, and it is increasing, fortunately, but I think that's how it spurs innovation. And Dr. Feldman noted this, as well, or Mr. Mitchell noted this point, as well—that it spurs innovation, to prevent patent abuse.

Senator KLOBUCHAR. Very good. Thank you. I'll turn it back to the Chair.

Senator WELCH. Thank you. Thank you very much, Senator Klobuchar. Senator Tillis.

Senator TILLIS. Thank you, Mr. Chairman. And I apologize for not being here sooner. I am under the weather. I have tested; I do not have COVID. But I wanted to make sure the room was cleared before I came in to speak, but this is clearly a hearing I needed

to come to, based on the work that we do on the Intellectual Property Subcommittee. I have been watching the hearing. I want to associate myself with the comments from my Chair and colleague on the Intellectual Property Subcommittee, Senator Coons. I am a really boring person, because I really try to do my best to not be sensational, to be fact based, to drive my decisions. It's one of the reasons why I'm shocked that I've actually won the elections that I've run, because I tend to want to get into the nitty, gritty details.

So, I'm only going to spend a few minutes, and then hopefully—do you need to get that? Kidding. He's my staff. I want to talk—Number one, the Inflation Reduction Act was heralded as a great thing. There're actually some good things in the Inflation Reduction Act. I don't necessarily hear a lot of people lauding the fact that we've had a double-digit reduction in small molecule research, and we've actually even had board meetings where investors have been told, we're de-emphasizing this. Does anybody disagree that the Inflation Reduction Act—the decisions in there around drug pricing—does anybody think that there isn't a nexus between that and the reduction in small molecule research? And of course I'm going to first go to the person who's from North Carolina here. Professor?

Professor RAI. So, thank you for that question. I'm so glad you followed-on from Senator Klobuchar on that question. I believe that small molecules need greater incentives, and the way to do that is to establish parity between small molecules——

Senator TILLIS. Okay. I understand that, but——

Professor RAI [continuing]. And biologics.

Senator TILLIS [continuing]. I'm getting to the fundamental question: Do you agree or disagree that there appears to be a nexus between the well intentioned drug pricing policies in the Inflation Reduction Act and a reduction in investment in small molecule research?

Professor RAI. So, I have no idea why the IRA——

Senator TILLIS. Yes.

Professor RAI [continuing]. Limited small molecule——

Senator TILLIS. Mr. Mossoff, could——

Professor RAI [continuing]. To 9 years——

Senator TILLIS [continuing]. You opine on that?

Professor RAI [continuing]. Versus 13 years for biologics.

Professor MOSSOFF. I think it makes complete sense that if you impose what is essentially effectively a price control system——

Senator TILLIS. Yes.

Professor MOSSOFF [continuing]. On the sale of drugs, that price controls destroy and undermine——

Senator TILLIS. Yes.

Professor MOSSOFF [continuing]. Markets. This is well established in economics.

Senator TILLIS. Could I ask a more—Ms. Ulrich, can—we saw drug prices listed here, and they're unacceptably high, but is that a drug price that was set by the pharmaceutical company, or is that what happens through the sausage meal value chain that starts with an investigational—a promising compound, an investigational new drug, clinical trial monitoring, manufacturing, pharmacy benefit managers, insurance companies, doctors, and a pa-

tient? Which one of those is true? A big, bad pharmaceutical company sets their price, or that whole sausage factory occurs before you know what the price is?

Ms. ULRICH. Well, thank you, Senator Tillis. We would agree that there is a large sausage-making process, but largely——

Senator TILLIS. So, if you want——

Ms. ULRICH [continuing]. It's composed by PBMs.

Senator TILLIS [continuing]. The sausage to taste differently, you've got to have all the components in the——

Ms. ULRICH. That's right.

Senator TILLIS [continuing]. Value chain at the table, right?

Ms. ULRICH. That's right.

Senator TILLIS. Right. So, how on earth can we give a pass to the pharmacy benefit managers, when we're taking a look at the end price of a drug and try to figure out why it costs what it costs? Right? Now, the other thing—and Mr. Mitchell, I wish you the very best. You've got a more aggressive disease, but I too have an incurable, potentially fatal disease that I don't have to manage with drugs now, but I understand a modicum of what you're going through, and I'm sure it must be challenging for you and your family.

But I do believe that there was a point made here that's very important: The price of that drug, through your health care system, that's not available in a formulary in other countries, is zero, and the reason for that is because you can't get the drug. Now, I know your answer to that question—that there are certain jurisdictions where you do have access to it, but there are some where you don't. Again, trying to get back to the facts, folks—we can't say we want to be just like fill-in-the-blank country, if fill-in-the-blank country doesn't give you that option through their single-payer health system.

Mr. MITCHELL. I think——

Senator TILLIS. Then you come here.

Mr. MITCHELL [continuing]. Senator Tillis—to remember that we use formularies in this country.

Senator TILLIS. Yes.

Mr. MITCHELL. Most employer-provided plans use formularies. The VA uses a formulary.

Senator TILLIS. I agree.

Mr. MITCHELL. And so it's——

Senator TILLIS. I'm getting more to the—I think we're being simplistic when we say we want to be just like fill-in-the-blank. If we want to be just like fill-in-the-blank, then let's have our litigation systems just like other countries; let's have medical malpractice policies very similar. There are so many things that make us dissimilar that we've just got to be realistic about how far we're willing to go.

But more importantly—I've been here for 10 years. The substance of this hearing is not materially different than the substance of hearings that I had in my first Congress here. So, why is it—you all make great points, and I agree with a lot of what you say. I agree, with qualifications, on other ones. I wanted to talk about the I–MAK, for example, Professor Mossoff. I'm not going to go too far over my time; I know I'm extending the hearing. But just get-

ting data from the I–MAK, to a point—I'm trying to get the U.S. PTO and the FDA just to take that information, distill it into something meaningful, because I believe today—and, Professor, I think we may disagree—that people are using it conveniently to build their case.

But look, folks, I've been here for 10 years, now. We're not making progress. If anything, we've taken steps back because of well-intentioned provisions in the Inflation Reduction Act. We at least know that we are reducing incentives to invest and take risk. The majority of these projects, like—I was in the tech space, so we knew that when we made a—well, I was in research and development. So, we knew that the majority of the ones that we're going forward with were going to be successful. It was just a technological change for, you know, products that we were going to make commercially available. Some of these things are billion-dollar investments that get put on ice after a while. I'm thinking about the much publicized Alzheimer's drug.

I don't want to reduce innovation in this country, because people's lives are in the balance. Potentially a cure for the disease that you're going through; a cure for the disease that I'm challenged with—and so I feel very, very strongly that we need to stop talking past each other, finding one link in the value chain that we naively think is the way you solve this problem, and all agree that there are ways to increase availability and decrease the cost of prescription drugs—but it's not the simplistic approach to take in only one link in the chain at a time. And I would love, Mr. Chair, to find a damned drug that I could put up there that everybody is demonizing and start from the beginning, the entire investment, the whole history of the patent protection for that drug, the end user price, so that we could really start getting past these lovely discussions we have, once a Congress, maybe twice a Congress, and into something meaningful that helps the patient, who is the only person I care about: how we can save more of you, how we can do it on a more affordable basis.

And we've got to start getting people to stop talking past each other, to get it done, or, Mr. Chair, I look forward to the next Congress having a hearing that's substantially the same information with substantially no progress. We've only taken steps back in the 10-years that I've been here. We haven't really made major leaps forward. Thank you, Mr. Chair.

Senator WELCH. Thank you. Senator Booker.

Senator BOOKER. I want to thank the panelists for being here today. I really appreciated your testimony and the common-sense input that you had. Mr. Mitchell, I was really moved by your testimony, frankly, because it's testimony I hear all the time, everywhere I go. About half of Americans take at least one prescription drug. For seniors, it's upwards of 80 percent of seniors are taking a prescription drug. And it is outrageous that about a quarter of Americans really have a difficult time affording those drugs, often for critical, lifesaving needs.

I am stunned that we live in a world where the same drug can be sold, you know, two to four times higher. That means Americans are often paying four times as much. And it is stunning, when I hear people telling me what they do to cope. They delay refills.

They ration their drugs. They are just forgoing taking the drugs. And what's fascinating to me is most people don't understand this often creates higher costs within our system.

When a diabetic goes into diabetic shock, I know what that's like, because being a mayor, having a lot of my people end up in hospital emergency rooms because they were reducing their drug—they were rationing their insulin drug costs and ending up in a hospital emergency room, driving up the costs of our health care system. It is so outrageous to live in a nation that is the wealthiest nation on the planet Earth and have so many Americans suffering daily, making the most difficult decisions between paying rent, kids' tuition, food on the table, or taking their prescription drug.

Now, I disagree with my colleague, because we've actually done some good things. The Biden administration has allowed Medicare to be able to negotiate prices for the first time. Insulin—I was just down in South Carolina, getting wild applause when we reminded people that the President and this Congress have capped insulin costs at $35 for people on Medicare. And for me, I was talking to a predominantly African-American audience. Blacks are twice as likely than white Americans to forgo taking a prescription drug that they need. And next year, out-of-pocket costs for Medicare Part D will be capped at $2,000.

So, I don't think we're wasting our time here, but I'm very frustrated to see how much lobbying money comes down here to try to stop us from doing things that are common sense. We can balance being the innovation capital of the world and having affordable prescription drugs for Americans. These are not counter. But right now I see games being played, gross profits being made because people are working the system. This is why I've introduced legislation that I've written, co-written; I've joined colleagues.

We're about to reintroduce the Prescription Drug Affordability and Access Act in the coming months. Last Congress, I joined Senator Sanders and Senator Casey to introduce the Affordable and Safe Prescription Drug Importation Act. I'm proud to have joined my colleagues on this Committee, Senators Grassley and Klobuchar, on their Preserve Access to Affordable Generics and Biosimilars Act and the Stop STALLING Act. These are common-sense pieces of legislation that can make an extraordinarily big difference.

I cannot tell you, Mr. Mitchell, how frustratingly common it is for me to be grabbed by somebody, when I'm out and about in multiple States, for them to tell me their stories. When I ran for President, I had people bring to me their bills, to show me what they were paying out of pocket. And then I'll never forget, in New Hampshire, the same person showing me their salary and explaining to me why they're putting their health in danger every single month because it does not add up.

And so, Mr. Chairman, I know I'm spending more of my time speaking now, but when I read the testimonies and listened to some of the testimoneys today, there are just common-sense things that we could do to relieve this pressure, to save lives, to keep people out of emergency rooms, to keep families together and healthy. I just want to say, for the conclusion, the question Ms. Rai—and, Professor, I'm pronouncing that right? Rai?

Professor RAI. No, Rai.

Senator BOOKER. Rai. I thought I had it right.

Professor RAI. You got it right. Yes.

Senator BOOKER. Thank you. Ms. Rai. Like, I really think that President Biden is being an extraordinary actor in this space, and they're in the process, the Biden administration, of finalizing a proposed framework for exercising march-in rights on government-funded inventions, including prescription drugs that are priced out of reach for patients, despite having been invented at public universities, with public money, Federal grants, taxpayer dollars.

And that's the thing that often frustrates me the most, because taxpayers are investing in these inventions, and then they're paying—they get no discount. They get no big—because of our country, but then they look at other nations, and these drugs that we invented, with our taxpayer dollars, are so much lower. So, I just want to hear your thoughts on this framework and on the prospect of the Biden administration using these rights to license generic competition on drugs that are priced two or three times, or more, than prices drug corporations charge in our peer nations.

Professor RAI. So, I'm glad you asked that question. Thank you, Senator Booker. I think the NIST guidance is actually much more careful and modest than some of the critics would have it be. It's very carefully designed to target situations of price gouging, essentially, not the situations that have been discussed earlier, where, you know, for example, you need recoupment of your R&D costs for something legitimate, but rather situations of the sort where there is price gouging going on. And the NIST guidance is very careful to say price is a factor to consider. And agencies, just to be clear, have never used march-in rights. They've had march-in rights from the beginning. NIST has had march-in rights from the beginning; never been used. This is just a gentle nudge to suggest that sometimes, just sometimes, price could be a factor.

Senator BOOKER. Thank you. And I'm just going to say, because there's an elephant in this room that we have not talked about, politicians—Senators and Congresspeople—should not be taking campaign contributions from industries that we regulate. It just shouldn't.

I think I was the fourth Senator to say, no corporate PAC dollars; no Pharma C-suite money; no oil company money. I really think there's a problem in this institution with corporations coming here and throwing millions, if not hundreds of millions, of dollars into campaign war chests; and Citizens United, which allows dark money to be spent without any accountability or transparency—to not think that this is a major part of this problem and that we should pass laws to prevent that, or everyone should take a similar pledge—I really think that is an inhibitor to solving problems that have so frustrated Americans for so long and that seem to have such—as some of the commentary here—such obvious solutions, to drive down prices. Mr. Chairman, thank you for the latitude.

Senator WELCH. Thank you, Senator Booker. I want to thank the witnesses. You know, one of the extraordinary opportunities you have in this job is to hear from people like you, who have spent your careers studying things that are hard to learn about, and you shared that information with us, and hopefully it'll result in some

action. But I just want to express my gratitude to each of you for the commitment you've made in your lives to, really, public service research and work.

The hearing record will remain open for 1 week, for statements to be submitted to the record, and questions for the record may be submitted by Senators by 5 p.m. on Tuesday, May 28.

Senator WELCH. Thank you all very much, and the hearing is adjourned.

[Whereupon, at 12:11 p.m., the hearing was adjourned.]

[Additional material submitted for the record follows.]

APPENDIX

Submitted by Chair Durbin:

Submitted by Senator Coons:

Submitted by Senator Tillis:

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PATENT THICKETS AND PRODUCT HOPS: HOW CONGRESS COULD REWARD LEGITIMATE INNOVATION WHILE FACILITATING MORE TIMELY GENERIC COMPETITION

Testimony of:

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United States Senate
Judiciary Committee
Tuesday, May 21, 2024
Washington, D.C.

Summary of major points

- Brand-name prescription drug manufacturers receive **time-limited government-granted rights** to sell their products free from direct generic competition, and generic firms can then enter the market once patent protection ends. This system is designed to reward innovation while ensuring that patients and payers ultimately benefit from access to low-cost therapies.

- Brand-name firms undermine this system by engaging in **strategies aimed at extending periods of market exclusivity** and delaying generic competition. Firms often obtain numerous patents not just on active pharmaceutical compounds but on peripheral features of their products such as formulations and delivery devices (establishing large **patent thickets**), and they make minor modifications to existing therapies that offer minimal or no clinical advantage (**product hops**).

- **Drug-device combinations** are particularly susceptible to patent thickets and product hops and represent a growing share of pharmaceutical spending. Recent research has found that inhalers for asthma and chronic obstructive pulmonary disease and glucagon-like peptide-1 (GLP-1) receptor agonists for diabetes and weight loss have been subject to especially problematic strategies aimed at limiting generic competition. More than half of all patents on these products, for example, are on the delivery devices, not the active ingredients.

- The Senate Judiciary Committee has recently moved **4 bipartisan bills** out of Committee that would help reduce barriers to generic entry. These bills would improve collaboration between the Food and Drug Administration (FDA) and US Patent and Trademark Office (USPTO), limit product hops, punish manufacturers for baseless citizen petitions, and strengthen the Federal Trade Commission's (FTC) authority to challenge pay-for-delay settlements.

- Several additional reforms would help advance the Committee's work aimed at facilitating timely generic competition. Congress should take the following steps:
    - Grant the FDA the **authority and resources to evaluate all patents submitted for listing in the Orange Book** to determine eligibility for inclusion.
    - Require that patents submitted to the FDA for listing in the Orange Book are also submitted to the USPTO for **re-examination**.
    - **Limit the number of patents that brand-name manufacturers can assert** to one patent per family when suing for infringement.
    - Grant the FDA **more resources and flexibility to approve generic drug-device combinations that differ slightly from brand-name reference products** (while still containing the same active ingredients) and require the FDA to ensure that **post-marketing surveillance studies** are conducted to confirm similar outcomes for patients receiving generic and brand-name versions.
    - **Increase the 180-day exclusivity periods** for the first generic firms to file paragraph IV certifications on complex products like drug-device combinations and **decrease the 30-month stays** awarded to brand-name firms that sue for infringement.

Chair Durbin, Ranking Member Graham, and Members of the Committee:

My name is William Feldman. I am pulmonologist, ICU physician, and health policy researcher at Harvard Medical School and Brigham and Women's Hospital, where I have joint appointments in the Division of Pulmonary and Critical Care Medicine and the Division of Pharmacoepidemiology and Pharmacoeconomics. I am a faculty member in the Program On Regulation, Therapeutics, And Law (PORTAL), one of the largest non-industry-funded research centers in the US devoted to pharmaceutical use, costs, regulation, and outcomes. I also serve as co-chair of the Ethics Committee at Brigham and Women's Hospital, and I teach and mentor trainees from Harvard College, Harvard Medical School, and the residency and fellowship programs at the Harvard teaching hospitals.

I became interested in pharmaceutical pricing during my medical training when I observed firsthand how patients were often unable to afford their medications, leading to decreased adherence and worse outcomes. When I started my pulmonary fellowship in 2017, there was not a single generic inhaler for asthma or chronic obstructive pulmonary disease (COPD) on the US market out of dozens of brand-name versions that had been approved since 1956, when the first metered-dose inhalers entered the US market.[1] Over the past several years, I have embarked on a series of research studies with colleagues to understand how pharmaceutical firms have used the patent system to limit generic competition and preserve market exclusivity while keeping prices high.

I am honored to talk with you all today about this research and what we can do to improve competition for the benefit of patients. I will begin by providing a brief background of different strategies that manufacturers employ to delay generic competition. I will then discuss one type of pharmaceutical product that has proven especially vulnerable to patent abuses: drug-device combinations, which contain active pharmaceutical compounds sold together with their delivery devices.[2] My comments will focus on inhalers and glucagon-like peptide-1 (GLP-1) receptor agonists, two of the largest classes of drug-device combinations now sold in the US. I will then briefly turn to other pharmaceutical products (besides drug-device combinations) and will offer a set of policy reforms that could help facilitate generic entry for small-molecule drugs across the pharmaceutical system.

1. How brand-name firms seek to delay generic competition

The US government grants time-limited rights for brand-name pharmaceutical firms to sell prescription drugs free from direct generic competition, and generic firms can then enter the market once patent protection ends. Such competition is, by far, the most important tool for lowering prescription drug prices in the US. Although approximately 80% of prescriptions are filled for generic drugs, these prescriptions account for just 20% of total spending.[3] As each

[1] Stein SW, Thiel CG. The History of Therapeutic Aerosols: A Chronological Review. J Aerosol Med Pulm Drug Deliv. 2017 Feb;30(1):20-41.
[2] US Food and Drug Administration. Combination Products. Available online from: https://www.fda.gov/combination-products. Accessed May 17, 2024.
[3] US Department of Health and Human Services. Assistant Secretary for Planning and Evaluation. Trends in Prescription Drug Spending, 2016-2021. September 2022. Available from:

new generic competitor enters the US market, prices tend to drop and eventually approach the costs of production.[4] This system is designed to promote innovation while ensuring that patients and payers ultimately benefit from access to low-cost therapy.

Key to the function of our prescription drug market is *timely* generic competition. The government permits monopoly pricing *for a period* before allowing the free market to operate. Unfortunately, many brand-name firms undermine this system by engaging in strategies designed to extend periods of market exclusivity and delay generic competition. These strategies not only harm patients, but they raise health care costs for us all through higher insurance premiums and taxes that fund federal health programs like Medicare and Medicaid.

Patent thickets

One key tactic that brand-name manufacturers employ to delay generic competition is erecting large thickets of patents.[5] Many of these patents do not cover active pharmaceutical compounds (otherwise known as primary patents) but cover peripheral features such as alternative formulations and methods of use (secondary patents) and delivery devices (tertiary patents).[6] They may also be continuations of earlier patents that disclose no new inventions; indeed, we have found that a majority of pharmaceutical patents now listed with the FDA are continuations and not original patents.[7] Brand-name firms augment large patent portfolios by adding numerous patents after FDA approval and, in many cases, timing these additions to create uncertainty for competitors just as FDA-granted "regulatory" exclusivities are set to expire.[8] Some of these strategies increase the *density* of patent portfolios (the number of patents on a given product) while others increase their *duration* (the time from approval until expiration of the last-to-expire patent).

For small-molecule drugs, which I'll be focusing on today, companies list their key patents in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book). Maximizing both the density and duration of patent portfolios on brand-name drugs can be effective for pharmaceutical companies, because the FDA cannot approve generic drugs for marketing until patents in the Orange Book on these drugs expire or are successfully challenged.[9] The FDA does not review what gets listed in the Orange Book but instead serves

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https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf. Accessed May 17, 2024.

[4] Dave CV, Hartzema A, Kesselheim AS. Prices of Generic Drugs Associated with Numbers of Manufacturers. N Engl J Med. 2017 Dec 28;377(26):2597-2598.

[5] Feldman R. May your drug price be evergreen. J Law Biosci. 2018 Dec 7;5(3):590-647.

[6] Beall RF, Kesselheim AS. Tertiary patenting on drug-device combination products in the United States. Nat Biotechnol. 2018 Feb 6;36(2):142-145.

[7] Tu SS, Kesselheim AS, Wetherbee K, Feldman WB. Changes in the Number of Continuation Patents on Drugs Approved by the FDA. JAMA. 2023 Aug 1;330(5):469-470.

[8] Horrow C, Gabriele SME, Tu SS, Sarpatwari A, Kesselheim AS. Patent Portfolios Protecting 10 Top-Selling Prescription Drugs. JAMA Intern Med. 2024 May 13:e240836.

[9] US Food and Drug Administration. Patent Certifications and Suitability Petitions. Available from: https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions. Accessed May 17, 2024.

in a "purely ministerial" role, listing patents that manufacturers choose for submission.[10] When generic firms challenge FDA-listed patents (via what is known as paragraph IV certifications), brand-name firms that sue for infringement within 45 days can receive an automatic 30-month stay while litigation resolves. The large patent thickets created by brand-name pharmaceutical companies often tie up generic firms in costly legal battles and deter generic firms from challenging patents in the first place.

Product hops

A second type of strategy that manufacturers employ to limit generic competition is developing new products that are closely related to originators (reformulations) yet sufficiently different to receive new patents. For example, manufacturers may move an active ingredient from one delivery device (e.g., an inhaler) to another with extended patent protection even if the new device offers minimal added clinical benefit to patients—or none at all. Pharmaceutical firms may combine two existing drugs into a single pill with new patent protection or release new strengths, salts, or esters (e.g., metoprolol tartrate rather than metoprolol succinate), or single enantiomers of racemic mixtures (e.g., esomeprazole rather than omeprazole).[11] These reformulations are considered hard product hops when the original drug is discontinued altogether and soft product hops when both versions remain on the market but the company seeks to move patients to newer products to reduce generic uptake of older versions.[12]

Although some product hops result in formulations that are more convenient for patients, many offer little to no meaningful clinical advantage over existing products. For example, in the largest systematic review to date of single enantiomer vs. racemic mixture drugs, the majority of randomized controlled trials found no differences in efficacy or safety between the two.[13] More importantly, the financial rewards of these small tweaks often far outstrip the benefits to patients, sometimes rivalling those bestowed on transformative new therapeutic breakthroughs.

Incremental innovation

Manufacturers rely on these strategies—increasing the density and duration of patents and making small tweaks to existing products—to protect revenue streams. These strategies not only undermine the very rationale for time-limited, government-granted monopolies, but they divert resources away from investment in more meaningful therapeutic advances.

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[10] US Food and Drug Administration. The Listing of Patent Information in the Orange Book. Available from: https://www.fda.gov/media/155200/download. Accessed May 17, 2024.
[11] Darrow JJ, Chong JE, Kesselheim AS. Reconsidering the scope of US state laws allowing pharmacist substitution of generic drugs. BMJ. 2020 Jun 23;369:m2236.
[12] Gowda V, Beall RF, Kesselheim AS, Sarpatwari A. Identifying potential prescription drug product hopping. Nat Biotechnol. 2021 Apr;39(4):414-417.
[13] Long AS, Zhang AD, Meyer CE, Egilman AC, Ross JS, Wallach JD. Evaluation of Trials Comparing Single-Enantiomer Drugs to Their Racemic Precursors: A Systematic Review. JAMA Netw Open. 2021;4(5):e215731.

2. The particular challenges posed by drug-device combinations

Drug-device combinations, which include products like inhalers, insulin pens, GLP-1 receptor agonists, and epinephrine pens are especially susceptible to patent thickets and product hops.[14] They also represent a growing share of pharmaceutical spending. Of the 50 products with the highest 2022 gross Medicare Part D spending, 20 (40%) were drug-device combinations.[15] These include blockbuster drugs like Trelegy Ellipta (fluticasone-umeclidinium-vilanterol) and Symbicort (budesonide-formoterol) for asthma and COPD and Ozempic (semaglutide) and Lantus SoloStar (insulin glargine) for diabetes. Although manufacturers have engaged in harmful patenting behavior on a variety of products, I will focus on two of the largest classes of drug-device combinations—inhalers and GLP-1 receptor agonists—to illustrate key problems that threaten the function of our pharmaceutical system.

Inhalers for asthma and COPD

More than 27 million people in the US have asthma[16] and nearly 12 million have COPD.[17] Patients with both conditions rely on maintenance inhalers for daily use and rescue inhalers to manage acute symptoms.[18] List prices for these products can run more than $600 per month and, although payers negotiate rebates to lower costs for payers, net prices are still substantially higher than prices in other countries.[19] Because out-of-pocket costs are often tied to list prices and because those without insurance do not pay insurer-negotiated rates, high list prices can also threaten affordability for patients. For many years, spending on inhalers has represented approximately 3-5% of net spending on retail prescription drugs in Medicare.[20]

In research analyzing all 53 brand-name inhalers approved for asthma and COPD by the FDA from 1986 to 2020, we observed several worrisome features regarding the tactics employed by manufacturers to preserve market exclusivity.[21]

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[14] Sinha M., Costly Gadgets: Barriers to Market Entry and Price Competition for Generic Drug-Device Combinations in the United States. 23 Minn. J.L. Sci. & Tech. 293 (2022).
[15] Center for Medicare and Medicaid Services. Medicare Part D Spending by Drug. Available from: https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug. Accessed May 17, 2024.
[16] Asthma and Allergy Foundation of America. Asthma Facts. Available from: https://aafa.org/asthma/asthma-facts/. Accessed May 17, 2024.
[17] American Lung Association. COPD Trends Brief: Prevalence. Available from: https://www.lung.org/research/trends-in-lung-disease/copd-trends-brief/copd-prevalence. Accessed May 17, 2024.
[18] Global Initiative for Chronic Obstructive Lung Disease (GOLD). 2024 GOLD Report. Available from: https://goldcopd.org/2024-gold-report/. Accessed May 17, 2024. Global Initiative for Asthma (GINA). 2023 GINA Report, Global Strategy for Asthma Management and Prevention. Available from: https://ginasthma.org/2023-gina-main-report/. Accessed May 17, 2024.
[19] NAVLIN database. Available online from: https://data.navlin.com/alspc/. Accessed May 17, 2024.
[20] Feldman WB, Gagne JJ, Kesselheim AS. Trends in Medicare Part D Inhaler Spending: 2012-2018. Ann Am Thorac Soc. 2021 Mar;18(3):548-550.
[21] Feldman WB, Bloomfield D, Beall RF, Kesselheim AS. Patents And Regulatory Exclusivities On Inhalers For Asthma And COPD, 1986-2020. Health Aff (Millwood). 2022 Jun;41(6):787-796. Demkowicz BJ, Tu SS, Kesselheim AS, Carrier MA, Feldman WB. Patenting Strategies on Inhaler Delivery Devices. Chest. 2023 Aug;164(2):450-460.

1. New products in old classes: Firms have not managed to find new therapeutic breakthroughs for inhaled medications to treat asthma and COPD. Instead, they have copied drugs in the same therapeutic classes. The last inhaler to reach the market with a new mechanism of action was Atrovent (ipratropium) in 1986. Since then, every inhaler to receive FDA approval has contained active ingredients with the same mechanisms of action already present in other inhaled products sold in the US.

2. Large patent thickets: Manufacturers have released inhalers with an increasing number of patents on their products. The median number of patents at the time of approval rose from 2 in the first decade of our study (with a median of 0 device patents) to 11 in the final decade (with a median of 7 device patents).

3. Patents added after FDA approval: Inhaler manufacturers filed patents after FDA approval for 25 (47%) products, including 12 cases in which the new patents extended periods of market exclusivity (by a median of 6 years).

4. Numerous device patents: Overall, device patents represented more than half of all patents listed on inhalers in the cohort. These device patents were on small plastic components of inhalers such as dose counters, filters, and nozzles. In some cases, the only patents listed on the product were on the delivery devices. Boehringer Ingelheim, for example, listed 25 patents on Combivent (albuterol-ipratropium) when the drug was approved in 2011, every single one of which was on the delivery device. This product, which contains albuterol (first approved in 1981) and ipratropium (first approved in 1986) still faces no generic competition.

5. *Features of device patents*: Many of these device patents were entirely disconnected from the drugs on which they were listed, making no mention of active pharmaceutical compounds, therapeutic classes, methods of use, or other features in their claims that might connect the patent to the drug. Companies are only permitted to list patents in the Orange Book that cover a drug (either a drug substance or drug product) or method of use.[22] A 2020 court case found that Sanofi had improperly listed a patent on the drive mechanism of an insulin injector pen because the patent made no mention (much less claimed) insulin or even the indication (diabetes).[23] In recent work, we applied a similar logic to analyze inhaler device patents and found that 77% made no mention of any active ingredients or molecular structures; 72% made no mention of any active ingredients, molecular structures, therapeutic classes, indications, device names, or the lungs.[24] Twenty-five inhalers had a device-only patent as the last-to-expire patent (with no mention of active ingredients), and these device-only patents extended periods of expected protection by a median of 8 years beyond other patents.

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[22] Congressional Research Service. Patent Listing in FDA's Orange Book. Available from: https://crsreports.congress.gov/product/pdf/IF/IF12644. Accessed May 17, 2024.
[23] *In re Lantus Direct Purchaser Antitrust Litig.*, 512 F. Supp. 3d 106 (D. Mass. 2020).
[24] Demkowicz BJ, Tu SS, Kesselheim AS, Carrier MA, Feldman WB. Patenting Strategies on Inhaler Delivery Devices. Chest. 2023 Aug;164(2):450-460.

The FTC has recently identified hundreds of patents that have been impermissibly listed in the Orange Book.[25] The *majority* of these patents are device-only patents listed on inhalers for asthma and COPD. These patents increase the density of patent portfolios, which make challenges more difficult, and increase the duration of protection, which make challenges necessary in the first place. Indeed, in an analysis of litigation following paragraph IV challenges on inhalers, we found that more than half of all litigated patents were on delivery devices.[26] Brand-name firms are not just listing device patents, but they are building litigation strategies around these patents to keep generic competitors off the market.

6. Device hopping: Inhaler manufacturers have also engaged in extensive device hopping—or shifting active ingredients from one delivery device to another with new patent protection. Manufacturers of 15 different originator inhalers in our study pursued this strategy, leading to 19 follow-ons. Some of these device hops were related to a ban on chlorofluorocarbons (CFC), which went into effect for pharmaceutical products from 2009 to 2013.[27] However, many of these device hops were unrelated to the ban. For example, GlaxoSmithKline released 5 different fluticasone products from 1996 to 2014: CFC-containing Flovent (1996) and then CFC-free Flovent Rotadisk (1988), Flovent Diskus (2000), Flovent HFA (2004), and Arnuity Ellipta (2014). Boehringer Ingelheim released two different CFC-free tiotropium inhalers: Spiriva HandiHaler (2004) and Spiriva Respimat (2014). By moving molecules to delivery devices with new patents, manufacturers can extend streams of revenue. The median duration of expected protection on products in our cohort with device hops was 28 years for the product lines, from approval of the first product to the last-to-expire patent listed for follow-ons.

These practices have been very lucrative for inhaler manufacturers. From 2000 to 2021, manufacturers earned more than $178 billion on inhalers in the US, including $67 billion (38%) when patents on active ingredients were active, and $111 billion (62%) when these patents had expired.[28] Some of the biggest blockbuster inhalers have earned staggering sums when only secondary and tertiary patents were active: Advair: $42 billion; Symbicort: $16 billion; Flovent: $12 billion; ProAir: $8 billion; Spiriva: $5 billion. In some cases, including AstraZeneca's Symbicort and Teva's ProAir, *all* manufacturer revenue accrued after primary patent expiration, as these patents had expired before product launch.

Without legislative reform, these practices are likely to continue. The Senate Committee on Health, Education, Labor, and Pensions launched an investigation in January 2024 examining

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[25] US Federal Trade Commission. FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book. Available from: https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book. Accessed May 17, 2024. US Federal Trade Commission. FTC Expands Patent Listing Challenges, Targeting More than 300 Junk Listings for Diabetes, Weight Loss, Asthma, and COPD Drugs. Available from: https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma. Accessed May 17, 2024.
[26] Reddy S, Beall RF, Tu SS, Kesselheim AS, Feldman WB. Patent Challenges and Litigation on Inhalers for Asthma and COPD. Health Aff (Millwood). 2023 Mar;42(3):398-406.
[27] Wouters OJ, Feldman WB, Tu SS. Product Hopping in the Drug Industry – Lessons from Albuterol. N Engl J Med. 2022 Sep 29;387(13):1153-1156.
[28] Feldman WB, Tu SS, Alhiary R, Kesselheim AS, Wouters OJ. Manufacturer Revenue on Inhalers After Expiration of Primary Patents, 2000-2021. JAMA. 2023 Jan 3;329(1):87-89.

potentially anticompetitive practices by inhaler manufacturers over the last several decades.[29] This work builds on important action taken by the FTC to crack down on impermissibly listed device patents on inhalers. In response, 3 of the 4 major inhaler manufacturers announced that they would voluntarily cap out-of-pocket costs at $35.[30] While this is an important step for millions of Americans with asthma and COPD, it does not address the underlying problems that have limited generic competition, nor will it necessarily translate into less spending by payers as long as the same harmful patenting practices can continue.

GLP-1 receptor agonists for diabetes, weight loss, cardiovascular disease

GLP-1 receptor agonists have shown remarkable promise for the treatment of diabetes, weight loss, and cardiovascular disease. But these drugs remain out of reach for many patients. List prices can run more than $1,000 per month and, even with large manufacturer rebates for payers,[31] net prices are still substantially higher than in other countries,[32] raising alarms about looming unmanageable budgetary impacts for US payers, including Medicare.

GLP-1 manufacturers appear to be relying on a similar playbook as inhaler manufacturers—establishing large thickets of patents, many of which are centered on delivery devices. This should not be surprising, because the two largest GLP-1 manufacturers, Novo Nordisk and Eli Lilly, used the very same strategies on insulin pens over the last 3 decades. We found that half of all patents on insulin products approved from 1986 to 2019 were on the delivery devices of these products, and 85% of these patents made no mention of insulin in their claims.[33] The FTC has not targeted delivery device patents on insulin products because they are no longer listed in the Orange Book (they are now regulated as a biologics rather than small-molecule drugs).

In other work, we identified several concerning trends on GLP-1s:[34]

1. Large patent thickets: Among 10 GLP-1 receptor agonists approved from 2005 to 2021, manufacturers listed a median of 20 patents per product, including a median of 17 before FDA approval and 2 added after FDA approval. The median period of expected protection on each product is more than 18 years. Because many of these products were recently approved, we

[29] Tirrell M. Bernie Sanders, Senate Democrats open investigation into price of asthma inhalers. CNN. January 8, 2024. Available from: https://www.cnn.com/2024/01/08/health/senate-democrats-investigate-price-of-asthma-inhalers/index.html. Accessed May 17, 2024.
[30] Becker Z. GSK joins AstraZeneca, Boehringer in capping US out-of-pocket inhaler prices at $35 per month. Fierce Pharma. March 21, 2024. Available online from: https://www.fiercepharma.com/pharma/gsk-latest-inhaler-maker-commit-35-out-pocket-price-cap-us-following-peers-boehringer. Accessed May 17, 2024.
[31] Hernandez I, Sullivan SD. Net prices of new antiobesity medications. Obesity (Silver Spring). 2024 Mar;32(3):472-475.
[32] NAVLIN database. Available online from: https://data.navlin.com/alspc/. Accessed May 17, 2024.
[33] Olsen A, Beall RF, Knox RP, Tu SS, Kesselheim AS, Feldman WB. Patents and regulatory exclusivities on FDA-approved insulin products: A longitudinal database study, 1986-2019. PLoS Med. 2023 Nov 16;20(11):e1004309.
[34] Alhiary R, Kesselheim AS, Gabriele S, Beall RF, Tu SS, Feldman WB. Patents and Regulatory Exclusivities on GLP-1 Receptor Agonists. JAMA. 2023 Aug 15;330(7):650-657. Alhiary R, Gabriele S, Kesselheim AS, Tu SS, Feldman WB. Delivery Device Patents on GLP-1 Receptor Agonists. JAMA. 2024 Mar 5;331(9):794-796.

are likely to see increasing numbers of patents added to the products in the coming years absent regulatory reform.

2. Numerous device patents: Manufacturers listed 188 patents on GLP-1 drug-device combinations, including 107 (57%) on the delivery devices.

3. Features of device patents: Not a single device patent on GLP-1 receptor agonists mentioned their active ingredients, molecular structures, therapeutic class, or device name. Only 1 patent (listed on 3 separate products) mentioned an indication (diabetes). In April of this year, the FTC announced a second round of improperly listed patents, including numerous device-only patents on GLP-1 receptor agonists.[35]

4. Litigation strategies: Although many GLP-1 receptor agonists have only recently been approved, we found that generic firms have already filed at least 30 paragraph IV challenges on 5 different products. Brand-name firms sued for infringement in these cases on 70 patents, 40 of which (57%) were device-only patents that should likely not have been listed in the Orange Book in the first place. As with inhalers, device patents form a core part of litigation strategies that brand-name firms employ to delay generic competition.

3. Other pharmaceutical products

Although drug-device combinations are perhaps the best exemplars of how pharmaceutical patenting practices have gone astray in the US health care system, brand-name firms employ similar strategies on other types of products. Research from our group has shown that the number of patents per new drug approval increased by more than two-thirds from 2000 to 2015.[36] Another study looking at drugs approved from 2005-2015 found that, among 106 top-selling drugs, manufacturers added patents after FDA approval that extended the duration of protection on 70% of products.[37] Recent research on 10 top-selling pharmaceuticals in 2021 found that approximately two-thirds of all issued patents on these products were filed after FDA approval and fewer than 20% had composition-of-matter claims.[38]

4. Proposals for Reform

Addressing the problems of patent thickets and product hops across the pharmaceutical system will require a multipronged strategy that includes the FDA, USPTO, and FTC. The Senate Judiciary Committee has recently moved 4 bipartisan bills out of Committee that, if enacted into law, would facilitate more timely generic competition.

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[35] US Federal Trade Commission. FTC Expands Patent Listing Challenges, Targeting More than 300 Junk Listings for Diabetes, Weight Loss, Asthma, and COPD Drugs. Available from: https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma. Accessed May 17, 2024.
[36] Tu SS, Kesselheim AS, Wetherbee K, Feldman WB. Changes in the Number of Continuation Patents on Drugs Approved by the FDA. JAMA. 2023 Aug 1;330(5):469-470.
[37] Feldman R. May your drug price be evergreen. J Law Biosci. 2018 Dec 7;5(3):590-647.
[38] Horrow C, Gabriele SME, Tu SS, Sarpatwari A, Kesselheim AS. Patent Portfolios Protecting 10 Top-Selling Prescription Drugs. JAMA Intern Med. 2024 May 13:e240836.

Senate Judiciary Committee bills

1. Improving the quality of issued patents: The Interagency Patent Coordination and Improvement Act 2023 (sponsored by Senator Durbin) would establish a formal task force to improve communication between the USPTO and FDA. Better communication could, among other things, help ensure that patentability standards are met at the USPTO and prevent invalid patents from being issued in the first place. Once issued, a patent is legally presumed to be valid and is therefore challenging to overturn in court, which emphasizes the importance of ensuring that the correct standards are applied in the first place.

2. Limiting product hops: The Affordable Prescriptions for Patients Act of 2023 (sponsored by Senator Cornyn) would authorize the FTC to enforce a prohibition on product hops that occur just after brand-name firms receive notification of generic drug applications up until 3 years after generic approval. Although product hops may occur well ahead of generic drug applications, this bill could help limit at least some forms of product hopping designed to stifle generic competition.

3. *Punishing brand-name firms for baseless citizen petitions*: The Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics (Stop STALLING) Act (sponsored by Senator Klobuchar) would fine firms that bring baseless citizen petitions up to $50,000 each day that the FDA spends reviewing the petition. Prior research has shown that brand-name firms often file citizens petitions to delay FDA review of generic drug applications, and the vast majority of these petitions are denied.[39] By deterring frivolous citizen petitions, this bill could help the FDA approve generic drug applications in a more expeditious manner.

4. Preventing pay-for-delay settlements: The Preserve Access to Affordable Generic and Biosimilars Act (sponsored by Senator Klobuchar) would give the FTC more authority to challenge anticompetitive pay-for-delay settlement agreements. Preventing these types of reverse payment agreements could avoid the long delays that are now commonly seen between paragraph IV filings and generic entry.

Other proposals

While all 4 bills offer meaningful improvements, several additional reforms could help further advance the Committee's work aimed at facilitating timely generic competition. I would encourage the Committee to consider the following:

1. Orange Book listings: Congress should require the FDA to release more comprehensive guidance on the types of patents that can be listed in the Orange Book and give the FDA the

[39] Carrier MA, Wander D. Citizen Petitions: An Empirical Study, Cardozo L Rev. 2012;34:249-252. Carrier MA, Minniti C. Citizen Petitions: Long, Late-Filed, and At-Last Denied. Am. U. L. Rev. 66(2):305-352. Sachs R, Walentynowicz M, Frank RG, Adler L. The FDA Could do More to Promote Generic Competition: Here's How. June 14, 2022. Available from: https://healthpolicy.usc.edu/research/the-fda-could-do-more-to-promote-generic-competition-heres-how/. Accessed May 17, 2024.

resources and authority to review all submitted patents to determine eligibility for listing in the Orange Book. Although the FDA has expressed reluctance to take on this role given limited patent expertise and few resources to conduct the work,[40] an expanded role may be feasible with appropriate funding and close collaboration with the USPTO.

2. Re-examination: Congress could require manufacturers that submit patents for listing in the Orange Book to simultaneously submit these patents for re-examination by the USPTO. Given the stakes for the health care system of invalid patents, routine reexamination would help ensure that only truly patentable innovations appear in the Orange Book.[41]

3. Litigation: Congress should limit the number of patents that brand-name firms can assert when suing for infringement following patent challenges. One approach, for example, would limit litigation to one patent per family among patents joined by terminal disclaimers.[42]

4. Generic approval standards: Congress should grant the FDA more authority to approve complex generic drugs like drug-device combinations that differ in slight ways from brand-name reference products containing the same active pharmaceutical compounds. This would enable generic firms to more easily design products that avoid infringing brand-name patents. Congress should couple such a law with a requirement that the FDA review post-marketing data on outcomes to further ensure clinical comparability between the generic and brand-name drugs.

5. Incentives for patent challenges: To increase incentives for generic firms to bring paragraph IV certifications on complex drugs, Congress should increase the 180-day exclusivity period awarded to first-to-file generic firms. By the same token, to decrease the incentives for brand-name firms to file baseless litigation following paragraph IV certifications, Congress should reduce the length of automatic 30-month stays.

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[40] US Government Accountability Office. Generic Drugs: Stakeholder Views on FDA's Information on Patents. March 15, 2023. Available from: https://www.gao.gov/products/gao-23-105477. Accessed May 17, 2024.
[41] Tu SS. FDA Reexamination: Increased Communication between the FDA and USPTO to improve patent quality. Hous. L. Rev. 2022;60:403-465.
[42] Welsh, Braun, and Klobuchar Introduce Bipartisan Legislation to Streamline Drug Patent Litigation, Lower Cost of Prescription Drugs. January 12, 2024. Available from: https://www.welch.senate.gov/welch-braun-and-klobuchar-introduce-bipartisan-legislation-to-streamline-drug-patent-litigation-lower-cost-of-prescription-drugs/. Accessed May 17, 2024.

PATIENTS FOR AFFORDABLE DRUGS NOW™

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

before the

U.S. Senate Committee on the Judiciary

for a hearing on

"Ensuring Affordable & Accessible Medications:
Examining Competition in the Prescription Drug Market"

May 21, 2024

Chairman Durbin, Ranking Member Graham, members of the committee. Thank you for inviting me to testify today at this important hearing examining how we can lower prescription drug prices by curbing the rampant anticompetitive conduct in prescription drug markets that is hurting patients, consumers, and taxpayers across America.

Section I. Background and Introduction

My name is David Mitchell. I am the founder of Patients For Affordable Drugs NOW. We are the only national patient advocacy organization focused exclusively on policies to lower prescription drug prices. We are independent, bipartisan and we don't accept funding from any organizations that profit from the development or distribution of prescription drugs.

Since we launched a little over seven years ago, more than 35,000[1] patients across all 50 states have shared stories with us of their struggles to pay high drug prices. And we have built a community of more than three-quarters of a million patients and allies supporting policies to lower drug prices.

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

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[1] (2024, February). Patients For Affordable Drugs Map. *Patients For Affordable Drugs*. https://map.patientsforaffordabledrugs.org/

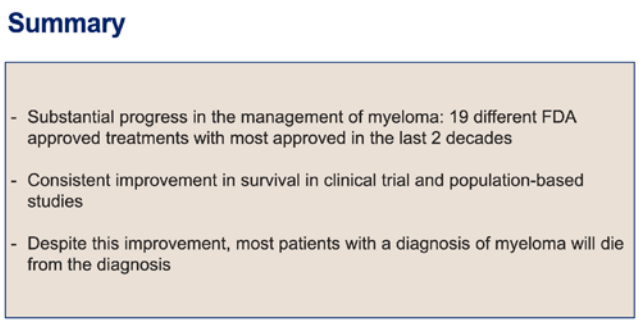
My oncologists currently have me on a four-drug combination of infused and oral cancer medications. These four drugs carry a combined list price of more than $1 million per year. Just one of my oral drugs, called Pomalyst, is priced at more than $22,400 for 21 capsules, which I must buy every 28 days. And because Medicare beneficiaries like me pay our out-of-pocket costs based on list price, I spent more than $16,500 out-of-pocket last year — just for Pomalyst. To help manage the cost of my infused drugs, I spend another $3,980 per year to purchase a Part B supplement. And of course, I have the base costs of Medicare to pay as well.

But the Inflation Reduction Act has changed that equation completely. After paying more than $16,000 last year because there was no out-of-pocket maximum in Part D, I am paying only $3,326 this year as an out-of-pocket cap began to phase in. Next year, the maximum anyone on Medicare will pay annually for drugs is $2,000. Our patients who have been unfortunate enough to contract a disease or condition requiring expensive drugs are elated–they say it is life-changing. Judy from Maine wrote to us a few weeks ago saying:

> "I have to admit that I was still a bit skeptical about the Medicare changes until today. In January my copay for Enbrel was $2,150.83. In February it was $1,141.86. Today it was zero. I was thrilled, as was the staff at the pharmacy."

That's just one story. There are many more like that.

Here on this slide is the state of my disease today. This slide below is from a presentation[2] to the FDA's Oncologic Drugs Advisory Committee on March 15 of this year on the state of multiple myeloma in the U.S. Please note the last point.



[2] Mailankody, Sham. (2024, March). Meeting of the Oncologic Drugs Advisory Committee (ODAC). *US Food and Drug Administration.* https://www.youtube.com/watch?v=VSjdGeeXb40. At 49:03

The last point is always sobering to reflect on: "Despite this improvement, most patients with a diagnosis of myeloma will die from the diagnosis." Yet, I am a very lucky man — the drugs are currently keeping my cancer at bay, and I tolerate them pretty well. But with multiple myeloma, nothing works forever. This is why innovation is so important to me. And it goes to the heart of the reason for this hearing:

We rely on patents to incentivize and reward innovation. We give drug companies limited-time monopolies to charge whatever they like in order to ensure a rich reward for the development of innovative new drugs. We need that innovation. I need it personally. But drugs don't work if people can't afford them. And too often drug companies abuse the current patent system, not to reward innovation, but to block competition that would lower prices as the patent laws intend. The bipartisan bills that are the focus of today's hearing aim to address that abuse and restore the intended balance.

For me personally, the point is: I need innovative new 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 not a plea for sympathy–it's just an unfortunate fact.

But my more than 13-year journey as a cancer patient has taught me that our current system which relies on competition and market forces to lower drug prices after a period of monopoly pricing is not working. I'm here to ask each of you to fix it.

Section II. The High Prices Americans Pay For Drugs and Need For Further Reforms

Drugs are too expensive in the United States. Americans pay more than four times what people in other wealthy nations pay for the exact same brand-name drugs. Even after applying estimated rebates to arrive at net prices, Americans are still paying more than three times what people in other wealthy nations pay for the same brand-name drugs.[3]

Consequently, about three in ten Americans report having difficulty affording their medications.[4] 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.[5]

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[3] Mulcahy, A., Schwam, D., and Lovejoy, S. (2024, February). International Prescription Drug Price Comparisons: Estimates Using 2022 Data. *RAND Corporation.* https://www.rand.org/pubs/research_reports/RRA788-3.html

[4] Kirzinger, A., Montero, A., Sparks, G., Valdes, I., Hamel, L. (2023, August). Public Opinion on Prescription Drugs and Their Prices. *KFF.* https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/

[5] Nguyen, A. (2021, March). 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/

High drug prices disproportionately harm communities of color. One in two Latinos in the United States takes a prescription medication, and more than 20 percent are uninsured.[6] Black and Latino adults aged 65 and older were more likely to report difficulty affording prescription medications than White adults. Further, 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.[7]

As expensive as my drugs are, even with Medicare out-of-pocket caps taking effect, I never lose sight of the fact that roughly 26 million Americans don't have any health insurance at all and are exposed to the full list price of the medications they need.[8]

The reality is that people struggle to pay these high prices with and without insurance.

Americans have been demanding relief for years. A KFF poll in July of 2023 found three out of four Americans said there is not enough government intervention when it comes to limiting the price of prescription drugs. That includes 82 percent of Democrats, 67 percent of Independents, and 68 percent of Republicans.[9] In the wake of the enactment of the Inflation Reduction Act which is helping millions of people by lowering prices and making drugs more affordable–Americans want more done.

Section III. The Need for Patent Reform

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 it undertook. Our patent system was created 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.

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[6] (2021, January). A Vicious Cycle of Health Inequity: How High Prescription Prices Hurt Latino Health and Prosperity. *UnidosUS Action Fund.* https://www.lowerdrugpricesnow.org/wp-content/uploads/UNIDOS-RX-REPORT-Vicious-Cycle.pdf

[7] (2020, December). High Prescription Drug Prices Perpetuate Systemic Racism. We Can Change It. *Patients For Affordable Drugs Now.* https://patientsforaffordabledrugsnow.org/2020/12/14/drug-pricing-systemic-racism/

[8] (2023, November). The Share of Americans Without Health Insurance in 2022 Matched A Record Low. *Peter G. Peterson Foundation.* https://www.pgpf.org/blog/2023/11/the-share-of-americans-without-health-insurance-in-2022-matched-a-record-low

[9] Kirzinger, A., Montero, A., Sparks, G., Valdes, I., Hamel, L. (2023, August). Public Opinion on Prescription Drugs and Their Prices. *KFF.* https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices//

Neither new patents nor new drugs equal new innovation. Worse, in too many cases, manufacturers are abusing America's patent and exclusivity system –not to reward innovation – but to prevent free-market competition and block affordable generic and biosimilar drugs from coming to market.

Between 2005 and 2015, 74 percent of the new drug patents issued were for drugs already on the market.[10] A second study of the ten top-selling drugs in 2021 corroborated that number.[11] Of the roughly 100 best-selling drugs in another study, nearly 80 percent obtained an additional patent to extend their monopoly period.[12]

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

There are a variety of strategies used by drug corporations to extend monopolies, including product hopping, evergreening, patent thicketing, pay-for-delay deals, and abuse of the U.S. Food and Drug Administration (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 in one study was not five years or even the seven years allowed for orphan drugs. Instead, it was 12.4 years.[13]

Product Hopping

Let's start with product hopping. This tactic occurs when a brand-name company switches a patient population from an older product whose patent is coming to an end and facing imminent 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 may even be as simple as changing a product from a tablet to a capsule.

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[10] Koons, C. (2017, November). Most New Drug Patents Are for Old Remedies, Research Shows. *Bloomberg.* https://www.bloomberg.com/news/articles/2017-11-01/most-new-drug-patents-are-for-old-remedies-research-shows
[11] Horrow, C., Gabriele, S., Sean Tu, S., et al. (2024, May). Patent Portfolios Protecting 10 Top-Selling Prescription Drugs. *JAMA Intern Med.* https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2818277
[12] Feldman, R. (2018, December). May your drug price be evergreen. *Journal of Law and the Biosciences.* https://academic.oup.com/jlb/article/5/3/590/5232981?login=true
[13] Wang B., Liu J., & Kesselheim A.S. (2015, April). Variations in time of market exclusivity among top-selling prescription drugs in the United States. *JAMA Internal Medicine 2015;175(4):635-637* https://pubmed.ncbi.nlm.nih.gov/25664700/

This switching takes two forms. 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 keeps the older product on the market, but engages in aggressive marketing to prescribers and patients, urging them to switch to the newer formulation.[14] 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 reformulated drug were to reduce this type of side effect, it might well meet an appropriate standard for 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, which treat opioid dependence and high cholesterol respectively. 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 160 mg tabs and I broke it in half for the 80 mg 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 Thickets

Patent thicketing is a tactic similarly designed to undermine market competition at the expense of patients. This strategy occurs when drug companies file dozens of non-innovative patents in order to create an impenetrable "thicket" around a drug product forcing a prospective generic or biosimilar competitor to litigate through each of the patents in order to gain market entry.

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[14] Jones, G. H., Carrier, M. A., Silver, R. T., & Kantarjian, H. (2016, March). *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/

Let's look at another drug I take to prevent blood clots and stroke–Eliquis. In 2021, it was the most expensive drug for Medicare at $12.6 billion.[15] Its maker-Bristol Myers Squibb (BMS) has applied for 48 patents and been granted 27, blocking competition in this country for 40 years.[16] The list price for a 30-day supply in the U.S. is about $600. The cost in Canada–where there is a generic on the market–is less than $75.[17]

The encouraging news is that there are multiple bills before the Senate designed to close loopholes in our patent system that are harming patients. All have bipartisan support. Many have already cleared this committee on strong bipartisan votes.

- P4ADNOW supports S. 150, the "Affordable Prescriptions for Patients Act of 2023," which cracks down on patent thickets in the biologic market and is projected to save hundreds of millions of dollars. There is also a new bipartisan bill-S. 3583-which has not cleared committee and we support that bill as well.

- S. 150 also addresses product hopping. When combined with the legislation's patent thicket provisions, the bill could save $1 billion.[18]

- Pay-for-delay continues to be a problem,[19] despite the Actavis decision.[20] This tactic occurs when brand-name drug companies provide something of value to a potential competitor to induce them to delay selling a generic version of a drug, therefore keeping it off the market in order for the brand-name drug to maintain a monopoly for longer. P4ADNOW has endorsed S. 142, a bipartisan bill to curb pay-for-delay agreements that the nonpartisan Congressional Budget Office (CBO) estimates could save $600 million.[21]

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[15] Bunis, D. (2023, July). 10 Prescription Drugs That Medicare Spends The Most On. *AARP.* https://www.aarp.org/politics-society/advocacy/info-2023/most-expensive-medicare-rx-drugs.html

[16] (2018, August). Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices. *I-MAK.* https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf

[17] Lovelace, B. (2024, February). Pharma CEOs grilled by senators over sky-high drug prices. *NBC News.* https://www.nbcnews.com/health/health-news/pharma-ceos-grilled-senators-sky-high-drug-prices-rcna137993

[18] (2022, June). Cost Estimate for S. 1435. *Congressional Budget Office.* https://www.cbo.gov/system/files/2022-06/s1435.pdf

[19] Vaheesan, S. (2023, June). Antitrust Has a Generic-Drug Problem. *The Atlantic.* https://www.google.com/url?q=https://www.theatlantic.com/ideas/archive/2023/06/pharmaceutical-generic-drugs-pay-for-delay/674410/&sa=D&source=docs&ust=1715629121705021&usg=AOvVaw0WjVJ5dgLHD_YfvUT5DPGv

[20] The Actavis Supreme Court decision held that "Governments and private parties may bring lawsuits against brand-name drug manufacturers to challenge the drug companies' payments to would-be competitors who make generic substitutes to keep the generic substitutes out of the market, but those payments are not presumptively illegal." (See: Federal Trade Commission v. Actavis. *SCOTUSblog.*) https://www.scotusblog.com/case-files/cases/federal-trade-commission-v-watson-pharmaceuticals-inc/)

[21] (2024, March). Cost Estimate for S. 142. *Congressional Budget Office.* https://www.cbo.gov/system/files/2024-03/s142.pdf

- 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 citizen petition process has been co-opted by corporations looking to block competition. Brand-name drug makers were behind 92 percent 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,[22] which were without scientific merit and filed for the sole purpose of delaying generic competition, keeping prices high for patients. P4ADNOW supports both S. 148 and S. 1067 which will reform this process, promote generic competition, and save millions of dollars.

- Current FDA policies prohibit the agency from disclosing information generic companies need in order to speed approval of new generic competitors. P4ADNOW supports S. 775 which will increase transparency and facilitate generic entry. This bill is projected to save more than $800 million.[23]

- P4ADNOW also supports S. 79 which will establish a task force between the United States Patent and Trademark Office (USPTO) and FDA in order to improve communication in the implementation of each agency's patent-related activities.

- P4ADNOW also supports the bipartisan bill S. 1250 - the *Drug-price Transparency for Consumers Act of 2023*- which is led by Chairman Durbin and Senator Grassley, and supported by Senators from both sides of the aisle. It will provide useful information to consumers by including prices on prescription drug advertising. And don't fall for the "no one pays list" argument against the bill; two-thirds of Americans pay for some or all of their out-of-pocket costs *based on list price*. List price matters greatly to us.

To achieve true innovation at prices that are affordable over the long haul, we must reform our patent and exclusivity system so that it is once again focused on driving innovation that saves lives, not driving high prices that make lifesaving drugs unaffordable to those whose lives depend on them.

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[22] Carrier, M. and Minniti, C. (2017). Citizen Petitions: Long, Late-Filed, and At-Last Denied. *American University Law Review 66:2 Article 1.* https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1956&context=aulr

[23] (2023, December). Cost Estimate for H.R. 5378. *Congressional Budget Office.* https://www.cbo.gov/system/files/2023-12/hr5378-DS-and-Revs_12-2023.pdf Sec. 201.

Section IV. What Else Should We Do? Reform Pharmacy Benefit Managers (PBMs)

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. We need to increase transparency and curb anticompetitive practices by PBMs.

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 the Big Three PBMs–Cigna, Optum Rx, and CVS Health–in control of 80 percent of the $633 billion in U.S. spending on drugs, that is more than half a trillion dollars flowing through just those three entities annually.[24, 25] And vertical integration uniting all three major PBMs with insurers only increases their market power. Opaque practices with that kind of money involved are a bad way to run a railroad.[26] It's time for transparency to ensure PBMs are operating in the best interests of patients and consumers.

It's not just about transparency either. 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."[27]

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[24]Mikulic, M. (2023, May). Market share of the top pharmacy benefit managers in the U.S. prescription market in 2022. *Statista.* https://www.statista.com/statistics/239976/us-prescription-market-share-of-top-pharmacy-benefit-managers/

[25]Tichy M. E., Hoffman, J., Tadrous, M. et al. (2023, July). National trends in prescription drug expenditures and projections for 2023. *Am J Health Syst Pharm.* https://pubmed.ncbi.nlm.nih.gov/37094296/

[26](2019, March). The Prescription Drug Landscape, Explored. *Pew Charitable Trusts.* https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored

[27]Cohen, J. (2021, March). Rebate Walls Stifle Prescription Drug Competition. *Forbes.* https://www.forbes.com/sites/joshuacohen/2021/03/01/rebate-walls-stifle-prescription-drug-competition/?sh=1ccc940366ae

Let's be clear: These rebate 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 which has been built to benefit those who profit from it at the expense of those it is supposed to serve.

P4ADNOW supports reforming the practices of PBMs, including transparency requirements in order to 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 managers. In our ideal world, PBMs would have a fiduciary responsibility to patients and all beneficiaries, and all reforms would put patients at the center. While none of the PBM bills go as far as we would like, each takes important steps in the right direction and would make meaningful and important progress in the regulation and oversight of PBMs. We support key provisions of bills that have cleared the Finance Committee on unanimous or near-unanimous bipartisan votes:

- Modernizing and Ensuring PBM Accountability Act - S. 2973. We especially support the transparency and disclosure requirements, and the provisions de-linking PBM compensation from prices.
- Better Mental Health Care, Lower-Cost Drugs, and Extenders Act - S 3430. We think the required reports to Congress are of particular importance. We support the concept of the rebate pass-through provisions, but we need to see CBO scoring for this provision, and we are concerned about the impact on premiums.

The House Energy and Commerce Committee has also advanced legislation addressing PBM practices. We support provisions in the Lower Cost, More Transparency Act, H.R. 5378, that improve transparency and reporting requirements. We were also pleased to see the House Ways and Means Committee include reform delinking PBM compensation from prices in legislation it *advanced earlier this month* – H.R. 8261, the "Preserving Telehealth, Hospital, and Ambulance Access Act. In our view, however, none of the provisions in House legislation go far enough in reforming PBMs and ensuring they are putting patients and consumers first.

We are also following closely and supporting the Federal Trade Commission (FTC) investigation into PBMs as well. We look forward to the first interim report on that investigation expected this summer. We hope Congress uses the report to inform future legislation, and that Congress gives strong backing for the FTC to take action it may recommend.

Section V. The Inflation Reduction Act Strikes A Balance To Ensure Innovation We Need At Prices We Can Better Afford

It's important to note that the Inflation Reduction Act (IRA) is built to strike a balance to ensure the innovation we need at prices we can better afford. In the run-up to the enactment of the IRA, the drug industry kept telling us that the legislation would stifle investment and kill innovation and access to new drugs. No one cares more about innovation than patients. But if you pull back the curtain on this pharma fear-mongering and look at what has actually happened since the IRA enactment, the argument doesn't hold up. Here are eight reasons why.

The industry has plenty of money for innovation. In the wake of the Inflation Reduction Act passage, investors are upbeat. Drug company stocks are doing fine.[28] The industry is flush with cash and has great access to capital.[29] [30]

According to the Congressional Budget Office (CBO), despite Big Pharma's claims that the implementation of the Inflation Reduction Act would stifle innovation and significantly impact profit margins, there has been a consistent and continuous increase in venture capital investment in pharmaceutical companies, demonstrating stability and resilience within this sector as shown in Figure 1.[31]

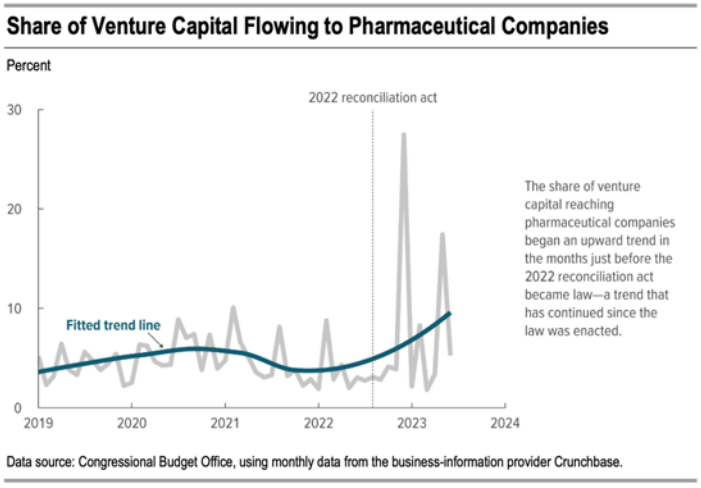
[28]Cheddar Berk, C., (2022, December). Health-care stocks are looking good for 2023 and not just because the sector is a 'safe haven.' *CNBC*. https://www.cnbc.com/2022/12/21/health-care-stocks-2023-big-pharma-still-favored-but-good-bets-in-biotech-are-out-there.html

[29]Cranmer, J. (2023, March). Market rebound on hold, but pharmas open for business, says J.P. Morgan's Gaito. *BioCentury*. https://www.biocentury.com/article/647325

[30] Chen, E. (2024, March). Pharma has over $500B in capital for deals. *STAT News*. https://www.statnews.com/2024/05/08/biotech-news-regeneron-eli-lilly-pfizer-duchenne-trial-deaf-gene-therapy-fda/

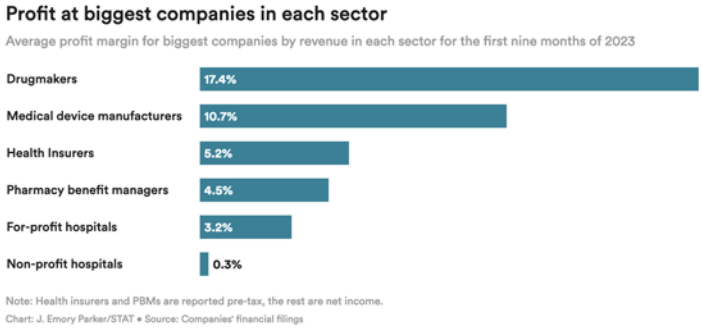
[31](2023, December). Re: Additional Information About Drug Price Negotiation and CBO's Simulation Model of Drug Development. *Congressional Budget Office*. https://www.cbo.gov/system/files/2023-12/59792-Letter.pdf

Figure 1.



Drug companies remain by far and away the most profitable sector of the healthcare industry–more than tripling the profit of Pharmacy Benefit Managers (PBMs) and insurers.[32]

Figure 2.



Since the passage of the Inflation Reduction Act:

[32] Bannow, T., Trang, B. (2024, January). Here's who's profiting the most in health care. *STAT News.* https://www.statnews.com/2024/01/02/heres-whos-profiting-the-most-in-health-care/

- Pfizer acquired biotech company Seagen for $43 billion.[33]
- Sanofi bought a diabetes product company for $2.9 billion.[34]
- Novartis spent $15 billion in a stock buyback.[35]
- Even in the face of the Inflation Reduction Act, drug companies reported *increased* investment in research and development (R&D). For example, in 2022 10-K filings, Johnson & Johnson reported an 11.8 percent increase in R&D spending in 2022, Merck reported an 11 percent increase in R&D spending, and Moderna reported a 65 percent increase in R&D spending and projected further increases in 2023.[36]
- "Bayer plans to invest $1 billion on research and development this year in an effort to double its sales in the United States within a decade."[37]
- Sanofi said that it would increase the number of Phase 3 studies it is conducting by 50 percent between 2023 and 2025 at a financial cost of about $700 million a year.[38]

<u>The Inflation Reduction Act *incentivizes* innovation by curbing drug companies' ability to drive profits by raising prices on old drugs at will.</u>

- To make more money, drug companies will have to develop high-value new drugs that can command high prices, instead of repurposing old products.
- The negotiation process includes the consideration of therapeutic advances and meeting unmet needs, which will reward more innovative drugs.
- The law maintains the key incentive for innovation that currently exists in the U.S. by allowing drugmakers to be compensated handsomely for investment and risk by setting their launch prices, maintaining the Food and Drug Administration (FDA)-awarded period of exclusivity, and exempting all medications from negotiated prices for a nine to 13 year period.

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[33] Dunleavy, K. (2023, December). Done deal: Pfizer completes $43B acquisition of Seagen, doubling its oncology pipeline. *Fierce Pharma.* https://www.fiercepharma.com/pharma/done-deal-pfizer-completes-43b-acquisition-seagen-doubling-its-oncology-pipeline

[34] Feuerstein, A., (2023, March). French pharma Sanofi buys maker of diabetes treatment for $2.9 billion. *STAT News.* https://www.statnews.com/2023/03/13/french-pharma-sanofi-buys-maker-of-diabetes-treatment-for-2-9-billion/

[35] Burger, L. (2023, March). Novartis initiates new trading line for share buybacks. *Reuters.* https://www.reuters.com/business/healthcare-pharmaceuticals/novartis-launches-new-share-buyback-up-10-its-stock-2023-03-13/

[36] (2022, April). Talking Points Based on Review of 2022 SEC 10K filings. *Patients For Affordable Drugs Now.* https://patientsforaffordabledrugsnow.org/wp-content/uploads/2023/04/TPs-10-K-0315202380.pdf

[37] Colrs, R. (2023, June). How drug pricing reforms are affecting Bayer's investments. *STAT News.* https://www.statnews.com/2023/06/20/drug-pricing-bayer/

[38] Herper, M. (2023, December). Sanofi says it has 12 blockbusters in its back pocket. Will investors believe it?. *STAT News.* https://www.statnews.com/2023/12/06/sanofi-says-it-has-12-blockbusters-in-its-back-pocket/

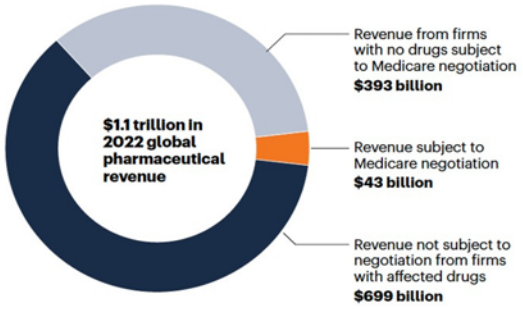
- The U.S. will continue to pay the highest drug prices and offer the largest pharmaceutical market in the world. Drug companies will continue to innovate in order to have access to such a lucrative market.

The Congressional Budget Office (CBO) says the Inflation Reduction Act will have a minimal to non-existent impact on new drug development.

- According to the CBO, the Inflation Reduction Act will decrease the number of new drugs over the next 30 years by only about 15 out of 1,300 expected – that's only a little over one percent.[39]
- Since only 10 to 15 percent of "new" drugs represent true therapeutic advancements, of the 15 new drugs foregone, only one or two might actually be true innovations.[40]
- Pharma cries poor every time policy reforms take even a small piece of change out of its pocket. But the reduction in drug industry revenue from the Inflation Reduction Act will be very small overall — estimated at less than one percent through 2032.[41] Figure 3 shows we are barely making a dent in the drug industry's global revenues with Medicare negotiation, which the industry is spending an enormous sum of money to prevent in the courts.[42]

[39](2022, July). Estimated Budgetary Effects of Subtitle I of Reconciliation Recommendations for Prescription Drug Legislation. *Congressional Budget Office*. https://www.cbo.gov/publication/58290
[40] Light, D., Lexchin, R. (2012, August) Pharmaceutical research and development: what do we get for all that money? *BMJ*. https://www.bmj.com/content/345/bmj.e4348
[41] Hopkins, J. (2023, January). A New U.S. Law Aims to Reduce Drug Prices. But First, It Might Raise Them. *The Wall Street Journal*. https://www.wsj.com/articles/inflation-reduction-drug-prices-11673628922
[42]Vogel, M., Kakani, P., Chandra, A., Conti, R., (2024, January) Medicare price negotiation and pharmaceutical innovation following the Inflation Reduction Act. *Nature*. https://www.nature.com/articles/s41587-023-02096-w

Figure 3.



Share of 2022 global pharmaceutical revenue subject to Medicare drug price negotiation. Forty-three billion dollars of the global pharmaceutical industry's $1,135 billion in revenues would have been subject to a negotiated price in 2022. The 31 companies that would have had a drug with a Medicare negotiated price in effect in 2022 had an additional $699 billion in global revenue not subject to negotiation. Another $393 billion in revenue was generated by companies with no drugs subject to negotiation.

- Far from the draconian price setting Big Pharma has complained about, AstraZeneca CEO Pascal Soriot told a Senate committee recently that initial steps in Medicare negotiation are positive: "So far, what we've seen is relatively encouraging."[43]
- Raymond James analyst Chris Meekins wrote: "As we have been saying since the Inflation Reduction Act first passed, we believe the sector-wide impact of the Inflation Reduction Act, including negotiation, on the pharmaceutical industry to be minimal."[44]

Taxpayers are the source of early high-risk, basic science that drives innovation — not industry.

- The National Institutes of Health (NIH) is the single largest source of biomedical research in the world. Its budget in 2023 was almost $48 billion.[45] The NIH contributed to

[43]Joseph, A. (2024, February). As Medicare drug pricing negotiations begin, AstraZeneca stays mum on government's offer. *STAT News*. https://www.statnews.com/2024/02/08/astrazeneca-medicare-drug-pricing/
[44]Owens, C. (2023, August). Medicare drug price negotiations could have limited impact at first. *Axios*. https://www.axios.com/2023/08/30/biden-medicare-drug-pricing-negotiations-impact
[45](2023, March). National Institutes of Health (NIH) Funding: FY1996-FY2023. *Congressional Research Service*. https://crsreports.congress.gov/product/pdf/R/R43341/45#:~:text=In%20total%2C%20the%20NIH%20FY2023,until%20the%20end%20of%20FY2025.

research associated with *all 356 new drugs approved by the FDA from 2010-2019*, totaling more than $230 billion.[46]

- The reason President Biden has established the Cancer Moonshot and the Advanced Research Projects Agency for Health (ARPA-H) with billions in funding to accelerate early, high-risk research is because Big Pharma won't take the risks on its own. Taxpayers must underwrite this early work to find bold new treatments and perhaps cures.

Lower drug prices help people access existing, innovative drugs they need right now, but can't afford.

- Innovation is worthless if people can't access it.
- CBO reports one of the ways the IRA saves money is by improving adherence to drug therapies which leads to better health because lower prices enable more people to buy and use their drugs as directed.[47]

Finally, Big Pharma consistently threatens that patients will lose access to newly developed drugs. It notes that more drugs are available — and are available faster — in the United States than in other wealthy countries. Pharma frequently cites a white paper from the White House 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."[48] 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.[49, 50] *After the IRA is fully implemented our country will 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.*[51]

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[46] Ledley, F., Clearly, E., Jackson, M. (2020, September). 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

[47](2023, February). How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act. *Congressional Budget Office*. Page 31. https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf

[48](2018, February). Reforming Biopharmaceutical Pricing at Home and Abroad. *The Council of Economic Advisers.* https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf

[49](2020, March). Global Medicine Spending and Usage Trends. *IQVIA.* https://www.iqvia.com/en/insights/the-iqvia-institute/reports/global-medicine-spending-and-usage-trends

[50] (2020). Association of Community Cancer Centers v. Alex M. Azar II. Civil Action No. CCB-20-3531. *PhRMA.* https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Complaint-on-MFN-Rule-Filed-2020-12-04.pdf

[51] 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

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 are altered by lowering prices under the IRA:

- Medicare must cover all drugs in six protected classes, which even the Pharmaceutical Research and Manufacturers of America (PhRMA) acknowledges ensures access to these drugs.[52, 53]
- Medicare must cover at least two drugs in each class of drugs.[54]

Medicaid must cover *every drug* offered by a manufacturer in the United States if the manufacturer agrees to give Medicaid a best-price guarantee.[55]

The pharmaceutical industry's threats to innovation and access don't hold up. The IRA restores balance to move us in the direction of fair prices and profits while still getting the innovation we need.

Section VI: Conclusion

Let's be clear: Big Pharma is not fighting for the interest of patients or because lowering its prices a bit will cripple innovation. It's fighting to restore and maintain its complete economic power over the American people to dictate prices of brand-name drugs–a power it has in no other nation on the planet. The head of the powerful trade association, PhRMA, affirmed that fact in a moment of candor when he said in an interview a couple of years ago that his industry is "particularly adept at … rolling the tanks, if you will, to push back against policy proposals *adverse to the industry's interests*."[56] The industry's multiple lawsuits to block Medicare negotiation that will touch only about four percent of its global revenue is further evidence this struggle is about keeping the U.S. market as the one place in the world where it can dictate prices at the expense of people's lives and livelihoods.

Of course, drug companies want to disguise that truth. Instead, they blame others and never offer policy solutions that involve lowering their prices. They seek to distract attention from their central role in making drugs unaffordable in America today.

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[52](2019, May). Medicare Advantage and Part D Drug Pricing Final Rule (CMS-4180-F). *Centers for Medicare & Medicaid Services.* https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f
[53] Powaleny, A. (2015, December). Medicare Part D's six protected classes. *PhRMA.* https://catalyst.phrma.org/medicare-part-d-six-protected-classes
[54] (2021, May). What Medicare Part D drug plans cover. *CMS.gov.* https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover
[55] (2019, May). Medicaid's Prescription Drug Benefit: Key Facts. *Kaiser Family Foundation.* https://www.kff.org/medicaid/fact-sheet/medicaids-prescription-drug-benefit-key-facts/
[56] Florko, N. (2021, April). PhRMA chief talks strategy — and he's surprisingly optimistic about drug pricing reform. *STAT News.* https://www.statnews.com/2021/04/13/phrma-chief-talks-strategy/

And they try to scare us by saying that if we don't bend to their will, we won't get the drugs we need for the future. They pose 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. You'll do whatever you have to do.

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

While we at Patients For Affordable Drugs NOW would have gone further in the Inflation Reduction Act, it clearly was built with the goal of striking that balance as a foundational principle. That point is driven home by a fact that is worthy of repeating: **The IRA does not change the key way our nation rewards investment and risk-taking for innovation–we continue to allow drug companies to set launch prices and maintain those prices for a minimum of nine to 13 years before potentially facing negotiated prices.**

This story from John in Baltimore captures so well the challenges patients face and the need to lower drug prices. Like me, he has multiple myeloma and must take very expensive drugs. He says: "I'm on a tightrope that is scarier than the disease itself. I did everything to protect myself and my family from financial disaster, but I feel as though after everything I've been hijacked by a drug company. I have no other options and they want to keep it that way."

I feel incredibly grateful to spend *my* retirement fighting so John can feel secure in his retirement, and not be held hostage by a drug company. I ask that you help John and millions of other Americans by moving forward with bipartisan patent and PBM reforms to make our system work better for the people it is supposed to serve.

Thank you.

WRITTEN TESTIMONY OF

Adam Mossoff

Professor of Law,
Antonin Scalia Law School
George Mason University

BEFORE THE

COMMITTEE ON THE JUDICIARY

United States Senate

"Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market"

MAY 21, 2024

Chairman Durbin, Ranking Member Graham, and Members of the Committee:

Thank you for this opportunity to speak with you today about the longstanding policy debate over drug prices in which inaccurate claims about the patent laws and other statutes, as well as unreliable data, is impeding the ability of Congress to engage in evidence-based policymaking.[1]

For at least half a century, the cost of medical care in the United States has long been debated in healthcare policy.[2] The causes of healthcare prices are complex and multi-dimensional, if only because the U.S. healthcare system is complex. The modern healthcare system comprises a myriad of legislative, administrative, and regulatory regimes enacted by the federal government and all fifty states, which are intertwined with equally complex commercial institutions built through private rights in property and contract.[3] In policy discussions about drug prices, though, some

[1] I am speaking on own behalf, and my testimony does not reflect the views of my employer or of any institution or organization with which I am affiliated.

[2] *See, e.g.*, *Consumer Group Decries Rise in Drug Prices*, L.A. TIMES, Mar. 16, 1995, at 1 ("Prices of the 20 top-selling prescription drugs are rising faster than inflation, despite drug company promises to slow the increases, a consumer group charged Wednesday."); *Uncertain Progress on Health Costs*, N.Y. TIMES, July 17, 1984, at B20 ("The Reagan Administration is declaring victory over 'the health care inflation monster' because medical costs are rising less feverishly. Any celebration, however, should wait until all the causes of the decline are better understood."); E. RICHARD BROWN, ROCKEFELLER MEDICINE MEN: MEDICINE AND CAPITALISM IN AMERICA 1 (1979) ("The crisis in today's health care system is deeply rooted in the interwoven history of modern medicine and corporate capitalism . . . The system's most obvious problems are the cost, inflation, and inaccessibility of medical care in the United States.").

[3] *See* Douglas A. Hastings, *Foreword: The Changing Face of Law and Medicine in the New Millennium*, 26 AM. J.L. & MED. 135, 135 (2000) ("For over 200 years, our healthcare system has been, in effect, a mixed public

activists, scholars and policymakers reduce this legal and institutional complexity to a single cause—patents.[4]

The patent system is now at the center of policy debates and academic discussions about drug prices. Academics and activists blame patents for "rising drug prices."[5] Legislators have introduced numerous bills addressing a wide range of legal and policy issues concerning drug patents, such as the number of patents, the quality of patents, and the scope of protection of patents, among others. Federal agencies, such as the Patent and Trademark Office (PTO), the Federal Trade Commission (FTC), and the Food and Drug Administration (FDA), have issued formal requests for information, engaged in studies and investigations, and hosted workshops in considering new regulations or regulatory guidelines for an equally wide range of issues concerning drug patents, such as adopting new requirements for patent applications. Lastly, lawsuits have been filed in courts, and the FTC has engaged in enforcement actions, asserting violations of the antitrust laws.

In written testimony for a single hearing before this committee, it is impossible to address all of these legal and policy activities in all three branches of the federal government. For the sake of brevity, my testimony here is limited to the misinterpretation of two statutes in the policy debates concerning the causes and solutions to allegedly high drug prices: the Bayh-Dole Act and 28 U.S.C. § 1498. For approximately two decades, professors and activists have mistakenly argued that both statutes authorize agencies to "lower drug prices by breaking patent barriers."[6] The National Institute of Standards and Technology (NIST), which is charged with implementing the Bayh-Dole Act, is now officially considering this argument. On December 7, 2023, NIST proposed new guidelines that would authorize federal agencies to exercise the "march in" power in § 203 of the Bayh-Dole Act in granting licenses unauthorized by a patent owner for the purpose of lowering prices in the marketplace.[7] Academics and activists have also long argued that § 1498 is an existing "tool" for the federal government to impose price controls on patented products and services,

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and private system, essentially built on a private chassis with a great deal of public funding, regulating and prodding. It also has been a profoundly federalist system, generating fifty-one health regulatory schemes.").

[4] *See, e.g.*, Sean Tu, *FDA Reexamination: Increased Communication Between the FDA and USPTO to Improve Patent Quality*, 60 HOUS. L. REV. 403, 406 (2022) ("Patients, doctors, and insurers have all felt the distress of rising drug prices . . . . Underlying much of these cost increases are the exclusive rights granted by patents.").

[5] *See id.*; *see also* I-MAK, *Drug Pricing Crisis* https://www.i-mak.org/health-equity/#pricing (accessed June 20, 2021) (stating that a "a root cause of the high cost of medicines is . . . unjust patent monopolies"); Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. & TECH. 275, 284 (2016) ("Drug prices in the United States are among the highest in the world . . . [T]hey result from . . . [o]ur patent system . . . [and its] grant of a monopoly [that] allows the manufacturer to charge any price[.] . . ."); Amy Kapczynski & Aaron S. Kesselheim, *'Government Patent Use': A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFFAIRS 791, 791 (2016) (claiming that "new medicines . . . are expensive not because they are expensive to manufacture but because they are protected by patents").

[6] *See* Letter to Senator Elizabeth Warren from Amy Kapczynski, Aaron S. Kesselheim, et al., at 8 (Apr. 20, 2022), https://tinyurl.com/yt62wt4t. Professor Kapczynski and Professor Kesselheim are the co-authors of this letter, which is based on their previously published academic articles, and thus this letter is identified as the "Kapczynski-Kesselheim Letter." *See also* Alfred B. Engelberg, Jerry Avorn, & Aaron Kesselheim, *A New Way to Contain Unaffordable Medication Costs – Exercising the Government's Existing Rights*, 386 N. ENGL. J. MED. 1104, 1104 (2022), https://www.nejm.org/doi/full/10.1056/NEJMp2117102 (stating that "existing laws" provide the government with the authority to lower drug prices and identifying § 1498 and the Bayh-Dole Act).

[7] *See* National Institute of Standards and Technology, Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. 85593 (Dec. 7, 2023).

including drugs.[8] Their arguments concerning § 1498 have not been implemented yet by any agency, but this price-control theory of § 1498 has been endorsed by Senators and House Members in letters to agencies and administration officials, urging them to take action.[9]

Neither the Bayh-Dole Act nor § 1498 are price-control statutes, and thus they do not authorize federal agencies to impose price controls on patents. This is clear by their plain legal text, as well as by their past interpretation by courts and agencies. The Bayh-Dole Act promotes the commercialization of patented inventions that may result from government funding of research, and § 1498 secures patent-owners in obtaining compensation for unauthorized uses of their property rights by the government. Neither law says anything about drug prices specifically or about reasonable prices generally. If the government used either law to impose price controls on patented drugs, this would conflict with the text and purpose of these statutes. It would also represent an unprecedented and fundamental change in U.S. patent law. From 1790 through the twentieth century, Congress rejected bills that would impose compulsory licensing on patents.[10] The effort to use the Bayh-Dole Act or § 1498 for similar purposes is fundamentally at odds with these statutes and threatens to undermine the U.S. patent system's historic success as a driver of U.S. global leadership in biopharmaceutical innovation.

In this written testimony, I will explain why neither the Bayh-Dole Act nor § 1498 can be used to break patents to impose price controls on prescription drugs. First, it sets forth the proven success of the patent system as a driver of innovation in healthcare, which is the necessary legal and empirical framework to evaluate the argument to "lower drug prices by breaking patent barriers."[11] This argument threatens to undermine the legal system that has saved lives and improved everyone's quality of life. It then describes the Bayh-Dole Act and § 1498, explaining how neither authorizes price controls on patented drugs. The policy argument that these laws are "tools" to impose price controls on prescription drugs contradicts the clear text and purpose of these statutes, violating the principle of evidence-based policymaking that is essential to good governance.

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[8] Kapczynski-Kesselheim Letter, *supra* note 6, at 1; *see also* Joseph Adamczyk, Adrienne Lewis, Shivani Morrison, and Christopher Morton, *§ 1498: A Guide to Government Patent Use, a Path to Licensing and Distributing Generic Drugs* (Jan. 2021), https://dx.doi.org/10.2139/ssrn.3882823 (proposing to use § 1498 to license generic drug companies to make and sell patented drugs at lower price than that charged by a patent owner); Brennan, Kapczynski, et al., *supra* note 5, at 279 (claiming that "a legal remedy that has been hiding in plain sight" in § 1498 to lower drug prices)

[9] *See, e.g.*, Letter to Secretary Gina Raimondo, Secretary Xavier Becerra, and Under Secretary Laurie E. Locascio from House Member Lloyd Doggett, Senator Elizabeth Warren, Senator Angus S. King, Jr., and 75 other House Members and Senators (Feb. 6, 2024), https://www.warren.senate.gov/imo/media/doc/Bayh-Dole%20Interagency%20Guidance%20Comment%20Letter%20FINAL%202.6.24.pdf; Letter to Secretary Xavier Becerra from Senator Bernard Sanders (June 7, 2023), https://www.sanders.senate.gov/wp-content/uploads/6.7.2023-Letter-from-Chairman-Sanders-to-Secretary-Becerra.pdf.

[10] *See, e.g.*, Bruce W. Bugbee, *Genesis of American Patent and Copyright Law* 143-44 (1967) (discussing the rejection of a Senate proposal for a compulsory licensing requirement in the bill that eventually became the Patent Act of 1790); Kali Murray, *Constitutional Patent Law: Principles and Institutions*, 93 Nebraska Law Review 901, 935-37 (2015) (discussing 1912 bill that imposed compulsory licensing on patent owners who are not manufacturing a patented invention, which received twenty-seven days of hearings, but was not enacted into law).

[11] Kapczynski-Kesselheim Letter, *supra* note 6, at 8.

The Patent System Spurs Innovation in Healthcare

The patent system has been a key driver of the U.S. innovation economy for over 200 years, as economists, historians, and legal scholars have repeatedly demonstrated.[12] The patent system was central to the successes of the Industrial Revolution in the nineteenth century, the pharmaceutical and computer revolutions in the twentieth century, and the biotech and mobile telecommunications revolutions in the twenty-first century.[13] Patent systems that secure reliable and effective property rights to inventors consistently and strongly correlate with successful innovation economies.[14]

Dr. Zorina Khan, an award-winning economist, has demonstrated that reliable and effective property rights in innovation—patents—were a key factor in thriving markets for technology in the United States in the nineteenth century.[15] Other economists have also identified features of these robust nineteenth-century innovation markets—such as an increase in "venture capital" investment in patent owners, the rise of a secondary market in the sale of patents as assets, and the embrace of specialization via licensing business models—as indicators of value-maximizing economic activity made possible by reliable and effective patents.[16] This remains true today: a twenty-first-century startup with a patent *more than doubles* its chances of securing venture capital financing compared to a startup without a patent, and this patent-based startup has statistically-significant increased chances of success in the marketplace as well.[17]

These general economic insights and historical facts are especially evident in the biopharmaceutical sector. Historically, the U.S. has been a global leader in first securing innovations in new drugs, diagnostics, and other biotech innovations in healthcare.[18] The U.S. is a global leader in biomedical innovation today. More than one-half of new drugs worldwide are invented in the U.S., improving the quality and duration of human life here and abroad.[19] For this

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[12] *See, e.g.*, ROBERT P. MERGES, AMERICAN PATENT LAW: A BUSINESS AND ECONOMIC HISTORY (2023); JONATHAN M. BARNETT, INNOVATORS, FIRMS, AND MARKETS: THE ORGANIZATIONAL LOGIC OF INTELLECTUAL PROPERTY (2021); DANIEL SPULBER, THE CASE FOR PATENTS (2021); B. ZORINA KHAN, INVENTING IDEAS: PATENTS, PRIZES, AND THE KNOWLEDGE ECONOMY (2020); Stephen Haber, *Innovation, Not Manna from Heaven* (Hoover Institution, Sep. 15, 2020); B. Zorina Khan, *Trolls and Other Patent Inventions: Economic History and the Patent Controversy in the Twenty-First Century*, 21 GEO. MASON L. REV. 825, 837-39 (2014); Naomi R. Lamoreaux, Kenneth L. Sokoloff & Dhanoos Sutthiphisal, *Patent Alchemy: The Market for Technology in US History*, 87 BUS. HIST. REV. 3 (Spring 2013); RONALD A. CASS & KEITH N. HYLTON, LAWS OF CREATION: PROPERTY RIGHTS IN THE WORLD OF IDEAS (2013).

[13] *See generally* MERGES, *supra* note 12; BARNETT, *supra* note 12; KHAN, *supra* note 12.

[14] *See, e.g.*, Stephen Haber, *Patents and the Wealth of Nations*, 23 GEO. MASON L. REV. 811 (2016); Jonathan M. Barnett, *Patent Tigers: The New Geography of Global Innovation*, 2 CRITERION J. INNOVATION 429 (2017).

[15] *See* B. ZORINA KHAN, THE DEMOCRATIZATION OF INVENTION: PATENTS AND COPYRIGHTS IN AMERICAN ECONOMIC DEVELOPMENT, 1790–1920, at 9-10 (2005) ("[P]atents and . . . intellectual property rights facilitated market exchange, a process that assigned value, helped to mobilize capital, and improved the allocation of resources. . . . Extensive markets in patent rights allowed inventors to extract returns from their activities through licensing and assigning or selling their rights.").

[16] *See, e.g.*, Naomi R. Lamoreaux, Kenneth L. Sokoloff & Dhanoos Sutthiphisal, *Patent Alchemy: The Market for Technology in US History*, 87 BUS. HIST. REV. 3, 4–5 (2013).

[17] *See* Joan Farre-Mensa, et al., *What Is a Patent Worth? Evidence from the U.S. Patent "Lottery,"* 75 J. Finance 639 (2019), https://doi.org/10.1111/jofi.12867.

[18] *See* Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine Is Undermining U.S. Leadership in Innovation*, 24 Geo. Mason L. Rev. 939, 942-44 (2017).

[19] *See* Ross C. DeVol, Armen Bedroussian & Benjamin Yeo, *The Global Biomedical Industry: Preserving U.S. Leadership* 5 (Sep. 2011), http://www.ncnano.org/CAMIExecSum.pdf.

reason, the U.S. patent system was long identified as the "gold standard" in securing reliable and effective property rights in the fruits of innovative labors—patents.[20]

Studies further demonstrate the fundamental role of patents in the pharmaceutical sector, as compared to other mechanisms for protecting intellectual property investments, such as trade secrets.[21] The economics of research and development (R&D) in the biopharmaceutical sector explain why reliable and effective patents serve this role. Total R&D expenditures underlying each new drug is estimated to be $2.6 billion, representing 10-15 years of research, testing, and development before the first patient is prescribed this drug as a treatment.[22] The likelihood that these vast investments in time and money will succeed is extremely low: a mere 12% of potential new drugs that reach clinical trials are approved by the Food & Drug Administration.[23]

The creation and distribution to patients of new healthcare treatments is made possible by massive investments in R&D and in their commercial development, production, and distribution. Annual private investment in the biopharmaceutical sector is approximately $129 billion (as of 2018).[24] This is almost *triple* the total amount of total public funding of $43 billion of R&D in healthcare innovations (as of 2018).[25] As a result, diagnoses that once were either death sentences or led to a greatly diminished quality of life—cancer, hepatitis, and diabetes—are now treatable and manageable medical conditions within a relatively normal lifespan.

For these reasons, empirical studies demonstrate that weak patent protection lowers investment in R&D in new drugs, delays the introduction of new medicines, and slows economic growth.[26] This result is unsurprising: healthcare innovators will not incur very large, risky investments unless they are secured in the fruits of their productive labors. Courts have long recognized that the promise of property rights in inventions serve the same function as property rights promised to a farmer who labors over a year to produce crops.[27] The economic and moral principles are the same.

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[20] Madigan & Mossoff, *supra* note 18, at 940-41.

[21] *See, e.g.*, Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or not)*, NAT'L BUREAU OF ECON. RSCH. (Feb. 2000) (NBER Working Paper No. 7552), http//www.nber.org/papers/w7552.pdf.

[22] *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016); *see also* PhRMA, *Research & Development Policy Framework*, https://www.phrma.org/en/Advocacy/Research-Development; Henry G. Grabowski, *Patents, Innovation and Access to New Pharms.*, 5 J. INT'L ECON. LAW 849 (2002).

[23] DiMasi, *supra*, note 22, at 25.

[24] *See* U.S. Investments in Medical and Health Research and Development 2013–2018, at 7 (Research America, 2019), https://www.researchamerica.org/wp-content/uploads/2022/09/InvestmentReport2019_Fnl.pdf. This is almost triple the amount of annual public funding of $43 billion of R&D in healthcare innovations. *Id.* at 8.

[25] *See id.*, at 8.

[26] *See* E. R. Berndt & I. M. Cockburn, *The Hidden Cost of Low Prices: Limited Access to New Drugs in India*, 33 HEALTH AFFAIRS 1567 (2014), https://doi.org/10.1377/hlthaff.2013.1307; PwC, *Vision 2025: Unlocking India's Potential for Leadership in Pharmaceutical Innovation*, at 8 (Oct. 2016), https://www.pwc.in/assets/pdfs/publications/2017/vision-2025-unlocking-indias-potential-for-leadership-in-pharmaceutical-innovation.pdf.

[27] *See* Davoll v. Brown, 7 F. Cas. 197, 199 (C.C.D. Mass. 1845) ("[W]e protect intellectual property, the labors of the mind, productions and interests as much a man's own, and as much the fruit of his honest industry, as the wheat he cultivates, or the flocks he rears."); *see also* Hovey v. Henry, 12 F. Cas. 603, 604 (C.C.D. Mass. 1846) ("An inventor holds a property in his invention by as good a title as the farmer holds his farm and flock.").

The U.S. has been a global leader in securing reliable and effective patent rights to innovators in the biopharmaceutical sector, which has prompted massive investments and successful development of new drugs that have led to longer lifespans and improved quality of life, as well as contributing to growth in the U.S. innovation economy. The principle of evidence-based policymaking establishes this legal and evidentiary framework by which policymaker must evaluate legislative or regulatory proposals to weaken or eliminate patent rights in new drugs. For example, those seeking to break patents to impose price controls on prescription drugs bear the evidentiary burden to prove why weakening this essential legal platform for the global innovation economy will not stifle innovation and ultimately harm patients.

They have not met this burden. Since professors and activists have been unable to meet their evidentiary and policy burden, they instead argue that Congress already made this controversial policy decision in two laws it enacted many decades ago—the Bayh-Dole Act and § 1498. These arguments are legally incorrect, as detailed below.

The Bayh-Dole Act Does Not Authorize Price Controls on Prescription Drugs

Congress enacted the Bayh-Dole Act in 1980 to provide an incentive for private parties to make the significant, risky investments in new product development, in creating manufacturing capabilities, and in setting up supply and distribution chains that bring new innovations to consumers. These are necessary investments in translating original discoveries into useful commercial products.[28] Before 1980, the government effectively claimed ownership in inventions resulting from government-funded research, offering nonexclusive licenses to anyone requesting one; this undermined the commercialization of these inventions given the absence of property rights that are the legal platform for contracts and other commercial activities.[29] The Bayh-Dole Act corrected this mistaken policy by reaffirming the longstanding rule in the U.S. patent system that innovators can obtain patents for their inventions, even if these inventions arising from some upstream government-funded research in the inventions. As property rights, patents facilitate licensing and other commercial activities in the marketplace.[30]

Section 203 in the Patent Act, as enacted in the Bayh-Dole Act, creates a limited exception to this core function of the Bayh-Dole Act by creating a "march in right" to further the Bayh-Dole Act's function in promoting commercialization of new inventions for which there was some federal funding in the upstream research process.[31] To ensure commercialization of inventions arising from research funded by government agencies, § 203 authorizes a federal agency that has funded research that resulted in a patented invention "to grant a nonexclusive, partially exclusive, or exclusive license" under four specified conditions.[32] A federal agency may grant these licenses "to a responsible applicant" without authorization from the patent owner in four delimited

[28] *See generally* BARNETT, *supra* note 12.

[29] *See, e.g.*, S. Rep. No. 480, 96th Cong., 1st Sess., at 2 (1979) (explaining that the government's policy of owning patents on inventions arising from government-funded research and offering nonexclusive licenses "has proven to be an ineffective policy" and that "the private sector simply needs more protection for the time and effort needed to develop and commercialize new products than is afforded by a nonexclusive license").

[30] *See id.*, at 28 ("It is essentially a waste of public money to have good inventions gathering dust on agencies' shelves because of unattractiveness of nonexclusive licenses.").

[31] *See* 35 U.S.C. § 203 (2011).

[32] § 203(a).

circumstances: (1) if "the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use," (2) "to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or licensee," (3) "requirements for public use specified by Federal regulations . . . are not reasonably satisfied by the contractor, assignee, or licensee," or (4) "a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement."[33]

For two decades, professors and activists have argued that § 203 authorizes agencies to march in for the purpose of lowering drug prices. NIST's proposed march-in guidelines implement these arguments in expressly providing that "reasonable price" is a criterion for an agency to issue unauthorized licenses, effectively imposing price controls on patented products or services produced by private companies and sold to private consumers in the marketplace.[34]

The statutory text of § 203 does not support the unprecedented consideration of "reasonable price" as a basis for authorizing the march-in power. As a preliminary matter, the four march-in conditions, which are set forth in § 203(a) in the disjunctive, constitute the only authorizations in the Bayh-Dole Act for a federal agency to exercise the march-in power. Notably, there is no mention of "reasonable price" or "price" in the four authorizing conditions for a federal agency to invoke the march-in power to issue licenses without approval from a patent owner.

Congress would have expressly enacted text conferring a price-control power in § 203 if it intended a "reasonable price" to trigger use of the march-in power under § 203. Congress has enacted numerous statutes that have authorized officials or agencies to impose price controls on transactions in the marketplace.[35] The Emergency Price Control Act of 1942 is one such example.[36] Similarly, rate-regulation statutes enacted by the states according to their police powers expressly authorize legislators or regulators to set "prices" or determine "rates."[37] Contrary to these price-control or rate-regulation statutes, § 203 is devoid of any archetypical pricing terms, such as "price," "prices charged by an assignee or licensee," "market price," or "reasonable price."

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[33] § 203(a)(1)-(4).

[34] *See* National Institute of Standards and Technology, Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. 85593, 85598 (Dec. 7, 2023) (stating that "march-in is warranted" and thus an agency may issue licenses without authorization by the patent owner if "the price or other terms at which the product is currently offered to the public are not reasonable").

[35] *See, e.g.*, Economic Stabilization Act of 1970, Pub. L. No. 91-379, § 202, 84 Stat. 799, 799-800 ("The President is authorized to issue such orders and regulations as he may deem appropriate to stabilize prices, rents, wages, and salaries at levels not less than those prevailing on May 25, 1970."); Housing and Rent Act of 1947, Pub. L. No. 129, 61 Stat. 193, 198 (imposing rent controls on existing structures set at levels permitted to be charged under the Economic Price Control Act of 1942).

[36] *See* Pub. L. No. 77-421, 56 Stat. 23 (1942).

[37] *See, e.g.*, Nebbia v. People of New York, 291 U.S. 502, 515 (1934) ("The Legislature of New York established by chapter 158 of the Laws of 1933, a Milk Control Board with power, among other things to 'fix minimum and maximum ... retail prices to be charged by ... stores to consumers for consumption off the premises where sold.'"); Stone v. Farmers' Loan & Trust Co., 116 U.S. 307, 308 (1886) (reviewing "the statute of Mississippi passed March 11, 1884, entitled 'An act to provide for the regulation of freight and passenger rates on railroads in this state, and to create a commission to supervise the same, and for other purposes'").

According to the "the ordinary meaning of the words used" in § 203 in the Bayh-Dole Act, the march-in power does not authorize licenses for the purpose of imposing price controls.[38]

Moreover, there is no catch-all clause in § 203 authorizing the march-in power for anything not already covered by the four specific march-in conditions. This is significant for at least two reasons. First, Congress knows how to create broadly framed and expansive authorizations for agency action, if this is its purpose. For example, Congress has expressly created broadly-framed authorizations of general administrative powers in other statutes, such as the well-known language in the Federal Communications Act of 1934 authorizing the Federal Communications Commission to grant radio transmission licenses according to whether the "public convenience, interest, or necessity will be served thereby."[39] Second, the canon of statutory construction of *expressio unius est exclusio alterius* establishes that, without a catch-all clause, the march-in power is delimited to only these four express exemptions from the longstanding rights of patent owners covered by the Bayh-Dole Act to freely assign or license their property in the marketplace.[40]

In sum, Congress chose not to create an open-ended grant of authority in § 203 by listing only four specific march-in conditions that strictly specify the narrow scope and application of the march-in power exemption in the Bayh-Dole Act. This comports with the primary function of the Bayh-Dole Act in promoting private commercialization of patented innovations in the marketplace. In its preamble provision, the Bayh-Dole Act expressly identifies its general policies and objectives.[41] It does *not* state that a function of this statute is to ensure that patented inventions should be available to consumers at reasonable prices in the marketplace.[42]

Recognizing this lack of express textual authorization to impose "reasonable price" mandates on patents covered by the Bayh-Dole Act, academics and activists who have argued for over two decades that this price-control power is inherent in the first march-in condition in § 203(a)(1). This condition states that a failure "to achieve practical application" of an invention can be a trigger for any agency to march in and issue licenses without authorization of the patent owner. The advocates for price controls argue that, since "high prices" can prevent the fully "practical application" of invention by preventing some consumers from being able to purchase it, then this provision authorizes an agency's march-in power to license this patented invention to lower the price in the

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[38] INS v. Phinpathya, 464 U.S. 183, 189 (1984) (stating that "in all cases involving statutory construction, our starting point must be the language employed by Congress, . . . and we assume that the legislative purpose is expressed by the ordinary meaning of the words used") (quotations and citations omitted).

[39] 47 U.S.C. § 307(a) ("The Commission, if public convenience, interest, or necessity will be served thereby, subject to the limitations of this Act, shall grant to any applicant therefor a station license provided for by this Act.").

[40] *See* Tennessee Valley Authority v. Hill, 437 U.S. 153, 188 (1976) ("In passing the Endangered Species Act of 1973, Congress was also aware of certain instances in which exceptions to the statute's broad sweep would be necessary. Thus, § 10, 16 U.S.C. § 1539 (1976 ed.), creates a number of limited 'hardship exemptions,' . . . . meaning that under the maxim *expressio unius est exclusio alterius*, we must presume that these were the only 'hardship cases' Congress intended to exempt."); *see also* 73 Am. Jur. 2d Statutes § 129 (2002) (describing the statutory canon of interpretation, *expressio unius est exclusio alterius*).

[41] *See* 35 U.S.C. § 200.

[42] *Id.* Here, the Bayh-Dole Act lists a series of statutory objectives, including "encourage maximum participation of small business firms in federally supported research and development efforts," "to promote the commercialization and public availability of inventions made in the United States by United States industry and labor," and "to promote the utilization of inventions arising from federally supported research or development," among others, but it does never lists or identifies lower "prices" or "reasonable prices" as a goal. 35 U.S.C. § 200.

marketplace.[43] The newly proposed NIST guidelines adopt this theory, stating that if "price or other terms . . . offered to the public are not reasonable," then this will "unreasonably limit availability of the invention to the public" as a trigger for this march-in power.[44]

This price-control theory of the march-in power is wrong as a matter of law. First, this argument and the proposed NIST guidelines ignore that the march-in power in § 203(a)(1) is limited to only the original federal "contractor or assignee," and thus it does not apply to the *licensee* that is selling the product or service in the marketplace. Unlike the three other march-in conditions, § 203(a)(1) applies only to when either the original university researcher who obtained a patent (contractor) or the university to whom the researcher transferred his or her patent (assignee) is not *licensing* the invention to firms and other market actors to manufacture and commercially distribute the invention in the marketplace. This limited application of § 203(a)(1) is confirmed by the express inclusion of "licensee" in the three other march-in conditions of § 203(a)(2)-(4) given the function of those march-in conditions in addressing failures by licensees to commercialize a patented invention, such as lacking manufacturing capability to produce the invention or breach of the license itself. In sum, all four march-in conditions in § 203 ultimately serve the Bayh-Dole Act's core function in promoting commercialization in the marketplace of patented inventions that resulted from research that was supported in some way by federal monies.

Second, the price-control theory of the march-in power violates the rule of statutory interpretation that a statutory provision is always construed in the context of the entire statutory regime in which that specific provision or phrase exists. This is closely related to the first point that the advocates for the price-control theory of the march-in power have invoked the "practical application" language in § 203(a)(1) without recognizing the express limitation of this trigger to actions only by the original inventor or immediate assignee. Here, the price-control theory advocates focus laser-like on the isolated phrase "practical application" in § 203(a)(1) and on a similarly isolated phrase in a lengthy definition of this term in § 201(f) that the invention should be "available to the public on reasonable terms."[45] These academics and activists thus derive an entire theory of unprecedented and vast regulatory power to control prices in the marketplace of patented products and services based on only two isolated phrases in two separate sections of the Bayh-Dole Act—"practical application" and "reasonable terms."

As a matter of statutory interpretation, this out-of-context isolation of brief phrases in statutory provisions commits the classic interpretative error of wooden textualism.[46] Courts always inquire

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[43] *See, e.g.*, Kapczynski- Kesselheim Letter, *supra* note 6, at 6-7; Fran Quigley & Jennifer Penman, *Better Late than Never: How the U.S. Government Can and Should Use Bayh-Dole March-In Rights to Respond to the Medicines Access Crisis*, 54 WILLAMETTE L. REV. 171 (2017); Peter S. Arno & Michael H Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TULANE L. REV. 631 (2001).

[44] National Institute of Standards and Technology, Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. at 85598.

[45] *See* 35 U.S.C. § 201(f) (defining "practical application" to mean "to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms").

[46] *See* Sackett v. Environmental Protection Agency, 143 S. Ct. 1322, 1340 (2023) ("construing statutory language is not merely an exercise in ascertaining 'the outer limits of a word's definitional possibilities'") (quoting

into "the specific context in which that language is used, and the broader context of the statute as a whole."[47] The Supreme Court has bluntly stated in far too many cases to cite or quote: "We do not . . . construe statutory phrases in isolation; we read statutes as a whole."[48] "Courts have a 'duty to construe statutes, not isolated provisions.'"[49] This is especially relevant in assessing a statutory argument that would authorize vast, unprecedented powers by federal agencies to engage in unauthorized licensing of patents that Congress has expressly rejected in other contexts.[50]

Congress stated its express intent in the Bayh-Dole Act: "It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development."[51] The march-in power is an *exemption* from the function of the Bayh-Dole Act to stimulate universities and other researchers receiving federal research funds to obtain patents to utilize licenses in commercializing their inventions. In fact, this exemption was included in the Bayh-Dole Act precisely because it advances this primary commercialization function of the statute: if a patented invention is not licensed or made available in the marketplace by its owner or licensees, then an agency is authorized to act to achieve this goal. Accordingly, § 203(a)(1)-(4) set forth four specific conditions in which the march-in power is justified, and these conditions identify situations in which inventions are not sold or commercialized in the marketplace.

Lastly, the absence of a legal basis in the Bayh-Dole Act for the price control theory of the march-in power in § 203, as adopted in the recently proposed NIST guidelines, is confirmed by Supreme Court precedent that agencies may not arrogate powers to themselves that are not specifically granted in statutes. An unprecedented agency power to impose price controls on all patented products or services produced and sold in the marketplace that were created from upstream research supported by some federal funding requires more than vague or generalized statutory terms like "effective steps to achieve practical application."[52] This is especially true given that

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FCC v. AT&T, 562 U.S. 397, 407 (2011)); *cf.* Antonin Scalia, *Common-Law Courts in a Civil Law System: The Role of the United States Federal Courts in Interpreting the Constitution and Law*, *in* A MATTER OF INTERPRETATION: FEDERAL COURTS AND THE LAW 23-24 (Amy Gutmann, ed., 1997) (critiquing out-of-context linguistic construction of statutory terms because a "good textualist is not a literalist").

[47] Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997).

[48] Samantar v. Yousuf, 560 U.S. 305, 319 (2010) (quoting United States v. Morton, 467 U.S. 822, 828, (1984)).

[49] Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 559 U.S. 280, 290 (2010) (quoting Gustafson v. Alloyd Co., 513 U.S. 561, 568 (1995)); *see also* Gonzales v. Oregon, 546 U.S. 243, 273 (2006) (stating that "statutes 'should not be read as a series of unrelated and isolated provisions.'") (quoting Gustafson v. Alloyd Co., 513 U.S. 561, 570, (1995)); Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000) ("It is a 'fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'") (quoting Davis v. Michigan Dept. of Treasury, 489 U.S. 803, 809 (1989)); Louisville & N.R. Co. v. Gaines, 3 F. 266, 276 (C.C.M.D. Tenn. 1880) ("Where the language [of a statute] is clear and explicit the court is bound . . . . It must be construed as a whole. The office of a good expositor, says My Lord Coke, 'is to make construction on all its parts together.'").

[50] *See supra* note 10, and accompanying text (discussing the rejection by Congress of efforts to adopt in the patent laws or amend the patent laws to authorize compulsory licensing by the U.S. government).

[51] 35 U.S.C. § 200.

[52] 35 U.S.C. § 203(a)(1).

Congress has consistently and repeatedly *rejected* bills that would impose compulsory licensing on U.S. patent owners, from the First Congress in 1790 up through the twentieth century.[53]

The Supreme Court has consistently instructed agencies that "Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions— it does not, one might say, hide elephants in mouseholes."[54] The Supreme Court has thus rejected other agencies' claims to regulatory authority under similarly vague and generalized terminology as the statutory phrase "practice application" in § 203(a)(1), the statutory justification of the price-control theory of the march-in power embraced by professors and activists and recently adopted by NIST in its proposed guidelines. In these many other legal cases, the Supreme Court has stated bluntly that "'Congress could not have intended to delegate' such a sweeping and consequential authority 'in so cryptic a fashion.'"[55] The Supreme Court again stated last year that it repeatedly "requires Congress to enact exceedingly clear language if it wishes to significantly alter . . . the power of the Government over private property."[56] The price-control theory, and its adoption by NIST in its proposed guidelines, lacks statutory authorization in § 203 in pursuing the policy goal of imposing price controls on the property rights in patents.

Agency Interpretations of § 203 Confirm It Does Not Authorize a Price-Control Power

The plain text of § 203 and its function within the Bayh-Dole Act as a whole explain why federal agencies—spanning bipartisan administrations over several decades—have repeatedly rejected numerous petitions to use the march-in power to impose price controls on drug patents. In 2016, the Congressional Research Service identified six petitions submitted to the NIH requesting it to exercise its march-in power solely for the purpose of lowering prices of patented drugs sold in the healthcare market.[57] The NIH denied all six petitions on the grounds that § 203, as confirmed by the NIH's prior interpretation of this statutory provision, did not permit the march-in power to be used for the purpose of lowering drug prices.[58] By 2019, four more petitions had been filed with the NIH by policy organizations and activists, each requesting again that the NIH invoke the march-in power for the sole purpose of lowering drug prices.[59] As with the prior six petitions

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[53] *See supra* note 10, and accompanying text (discussing the rejection by Congress of efforts to adopt in the patent laws or amend the patent laws to authorize compulsory licensing by the U.S. government).

[54] Whitman v. Am. Trucking Associations, 531 U.S. 457, 468 (2001).

[55] *See* West Virginia v. Environmental Protection Agency, 142 S. Ct. 2587, 2608 (2022) (quoting Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 159 (2000)). *See also* MCI Telecommunications Corp. v. American Tel. & Tel. Co., 512 U.S. 218, 231 (1994) ("It is highly unlikely that Congress would leave the determination of whether an industry will be entirely, or even substantially, rate-regulated to agency discretion—and even more unlikely that it would achieve that through such a subtle device as permission to 'modify' rate-filing requirements.").

[56] *Sackett*, 143 S. Ct. at 1341 (quoting United States Forest Service v. Cowpasture River Preservation Ass'n, 140 S. Ct. 1837, 1849-50 (2020)).

[57] *See* John R. Thomas, *March-In Rights Under the Bayh-Dole Act* 8-10 (Congressional Research Service, Aug. 22, 2016).

[58] *Id.*

[59] *See Return on Investment Initiative for Unleashing American Innovation* 29 (NIST Special Publication 1234, April 2019) (identifying 10 petitions to break patents through the march-in power in § 203 solely for the purpose of imposing price controls on drug patents).

reaching back to the 1990s, the NIH rejected these petitions on the statutory ground that "the use of march-in to control drug prices was not within the scope and intent of its authority."[60]

In 1997, for example, the NIH was petitioned to invoke the march-in power for the Isolex 300, a patented medical device used in organ transplant procedures.[61] The NIH rejected the petition for failing to meet the burden of proof that any of the four march-in conditions specified in § 203 had been triggered, authorizing the NIH to march in and license other companies to make and sell this medical device in the healthcare market. The NIH found that the Isolex 300 was being commercialized in the marketplace: the patent owner was actively licensing the patented device, seeking regulatory approval, and meeting research demands.[62] These facts precluded the triggering of the march-in power under the four authorizing conditions in § 203.

In rejecting this march-in petition, the NIH further explained why lowering prices on a medical device like the Isolex 300—imposing price controls on the healthcare market—was not justified by the plain text of § 203 and the function of the Bayh-Dole Act in promoting the commercialization of patented inventions. The NIH stated that, even if the petitioner proved that there would be greater accessibility and *lower prices* given additional licenses from the NIH invoking the march-in power, this rationale lacked authorization under § 203.[63] The NIH stated bluntly that the march-in power in § 203 did not exist for the purpose of "forced attempts to influence the marketplace."[64] It acknowledged the contradiction between the Bayh-Dole Act's primary function in promoting the commercialization of new innovations in the marketplace and adopting a march-in power for the purpose of imposing price controls, observing that "such actions may have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies."[65] This was not merely a freestanding policy assessment by the NIH of this petition; it derived this conclusion from the plain meaning of § 203 within the context of the Bayh-Dole Act and its commercialization function.

Another petition in 2004 again requested that the NIH invoke the march-in power in § 203 to license a patent specifically to lower the price for Norvir, a drug used to treat AIDS. Again, the NIH rejected the petition.[66] The NIH explained that "the extraordinary remedy of march-in is not an appropriate means of controlling prices," and that "[t]he issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively."[67] The NIH again rejected another march-in petition seeking to lower the price of Norvir in 2013, again stating that the imposition of price controls on drug patents was not a statutorily authorized march-in power in § 203 of the Bayh-Dole Act.[68] The NIH bluntly concluded: "As stated in previous march-in

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[60] *Id.*

[61] *See, e.g.*, NIH Office of the Director, *Determination in the Case of Petition of CellPro, Inc.* (Aug. 1, 1997), https://www.ott.nih.gov/sites/default/files/documents/policy/cellpro-marchin.pdf (rejecting petition in part to invoke march-in power given argument that company was too slow in bringing a medical device to market).

[62] *Id.*

[63] *Id.*

[64] *Id.*

[65] *Id.*

[66] *See* NIH Office of the Director, *In the Case of Norvir Manufactured by Abbott Laboratories, Inc.* (July 29, 2004), http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.

[67] Dr. Elias A. Zerhouni, Nat'l Institute of Health, *Determination in the Case of Norvir I*, at 5-6 (July 2, 2004).

[68] NIH Office of the Director, *In the Case of Norvir Manufactured by AbbVie* (Nov. 1, 2013), https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf.

considerations the general issue of drug pricing is appropriately addressed through legislative and other remedies, not through the use of the NIH's march-in authorities."[69] The frustration by NIH officials with the serial petitions seeking to impose price controls on drug patents via the march-in provision in the Bayh-Dole Act is palpable.

Lastly, on March 21, 2023, the NIH rejected a petition (filed again) for this agency to invoke the march-in power solely to lower the price of Xtandi, a cancer drug covered by patent.[70] In its latest rejection of the price-control theory of the Bayh-Dole Act, the NIH reiterated that the "purpose of the Bayh-Dole Act is to promote commercialization and public availability of government-funded inventions."[71] With this statutory framework and purpose in mind, the NIH expressly "found Xtandi to be widely available to the public on the market" and "[t]herefore, the patent owner, the University of California, does not fail the requirement of bringing Xtandi to practical application."[72] The NIH further pointed out that this decision about Xtandi is consistent with its prior multiple rejections of march-in petitions also seeking to lower drug prices.[73] It also recognized that the administrative processes and delays, especially in light of Xtandi's remaining patent term, led it to conclude that "NIH does not believe that use of the march-in authority would be an effective means of lowering the price of the drug."[74]

The NIH's multiple decisions over several decades in interpreting the scope of the march-in power granted to it under § 203 is significant evidence that the Bayh-Dole Act does not authorize an agency to consider "reasonable price" as a criterion for triggering the march-in power. Yet, NIST has now proposed new guidelines that would include "reasonable price" as a criterion for agencies like the NIH to use the march-in power under § 203. The eleven or more decisions ranging from the 1990s through 2023 in which the NIH has consistently rejected march-in petitions requesting it impose price controls on drug patents under § 203 constitute "the well-reasoned views of the agencies implementing a statute [that] 'constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance.'"[75]

The Bayh-Dole Act's Sponsors Stated Their Law Does Not Authorize Price Controls

The price-control theory of the march-in power was first announced in a law journal article by two professors published more than two decades after the enactment of the Bayh-Dole Act.[76] In 2001, Professors Peter Arno and Michael Davis claimed to have discovered a previously unrecognized mandate in the Bayh-Dole Act that "Congress's concern with march-in rights focused exclusively on . . . price control."[77] They supported their price-control theory that the exclusive focus of Congress was on price controls in adopting § 203 in the Bayh-Dole by identifying approximately

[69] *Id.*

[70] *See* Letter from Lawrence A. Tabak, Performing the Duties of the NIH Director, to Robert Sachs and Clare Love (Mar. 23, 2023), https://www.keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-12march2023.pdf (rejecting petition to impose price controls on Xtandi).

[71] *Id.* at 2.

[72] *Id.*

[73] *Id.*

[74] *Id.*

[75] *See* United States v. Mead Corp., 533 U.S. 218, 227 (2001) (quoting Bragdon v. Abbott, 524 U.S. 624, 642 (1998) (quoting Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)))

[76] *See* Arno & Davis, *supra* note 43.

[77] *Id.*, at 659.

seven references to "prices" in the entire legislative record of the Bayh-Dole Act.[78] This is a prime example of the famous statement by Judge Harold Leventhal that the use of legislative history can be "the equivalent of entering a crowded cocktail party and looking over the heads of the guests for one's friends."[79] For example, other scholars have found statements in the legislative history of the Bayh-Dole emphasizing the commercialization function of patents as the primary goal of this law—the "first-listed goal in the statute" according to two scholars.[80]

A year after their law journal article was published, Professors Arno and Davis published a *Washington Post* op-ed describing their new price-control theory of the Bayh-Dole Act,[81] and Senator Birch Bayh and Senator Robert Dole responded by rejecting their argument outright. Since Professor Arno and Davis's price-control theory of the Bayh-Dole Act and its march-in power had never been advanced before—Professors Arno and Davis explicitly recognize in their article's title that the price-control power was "unrecognized and unenforced"[82]—this was the first time that Senators Bayh and Dole addressed this issue. They explained in a letter to the editor in the *Washington Post* published two weeks after the op-ed by Arno and Davis:

> Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. . . . The [Arno and Davis] article also mischaracterizes the rights retained by the government under Bayh-Dole. The ability of the government to revoke a license granted under the act is not contingent on the pricing of the resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.[83]

This letter to the editor does not have the same legal status under the rules of statutory interpretation as does the text and official interpretation of a statute by courts and agencies, but Senators Bayh and Dole's analysis of their namesake law is entirely consistent with these rules of statutory interpretation. They come to the same conclusion as these legal rules, as explained in the prior section: the march-in power does not authorize price controls and any such argument that it does is unconnected to the text and function of the law enacted by Congress in 1980. The

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[78] *See id.*, at 656-67 (identifying a total of about seven statements in the entire legislative record to "price" or "pricing" of patented products as something that should be restricted or controlled). Professors Arno and Davis also conflate all references in the legislative record to "public interest" as necessarily denoting "price control," but this is an act of linguistic gymnastics that no court would accept in justifying a non-textual interpretation of a statute as authorizing price controls when such authorization is found nowhere in the specific text of the statute.

[79] Conroy v. Aniskoff, 113 S. Ct. 1562, 1567 (1993) (Scalia, J., concurring).

[80] *See* Ian Ayres & Lisa Larrimore Ouellette, *A Market Test for Bayh-Dole Patents*, 102 CORNELL L. REV. 271, 287 (2017) (observing that commercialization is the "first-listed goal in the statute" and supporting this point about the function of Bayh-Dole from quotes from the legislative history).

[81] *See* Peter Arno & Michael Davis, *Paying Twice for the Same Drugs*, Washington Post (March 27, 2002), https://www.washingtonpost.com/archive/opinions/2002/03/27/paying-twice-for-the-same-drugs/c031aa41-caaf-450d-a95f-c072f6998931/ (emphasis added).

[82] Arno & Davis, *supra* note 43.

[83] Birch Bayh and Robert Dole, *Our Law Helps Patients Get New Drugs Sooner*, Wash. Post (Apr. 11, 2002), https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/.

arguments by professors and activists for the price-control theory, and the newly proposed march-in guidelines by NIST, are all born of the price-control theory spawned by Professors Arno and Davis in 2001. This price-control theory is an unprecedented assertion of agency power to control prices in private market transactions without a legal basis in the Bayh-Dole Act.

Distorting Bayh-Dole to Impose Price Controls Would Still Not Achieve Any Alleged Benefits

Even if one assumes for the sake of argument that the text and function of the Bayh-Dole Act could permit an agency to break patents to lower drug prices, it will not achieve this benefit alleged by academics and activists. The Bayh-Dole Act applies only to a small subset of patents. It is applicable only to "subject inventions,"[84] which are defined narrowly in the statute as "any invention of the contractor [i.e., the party receiving government funding] conceived or first actually reduced to practice in the performance of work under a funding agreement."[85]

Few drug patents satisfy this statutory definition. A 2019 study found that, of the 1,151 patents in the Food and Drug Administration's (FDA's) *Approved Drug Products with Therapeutic Equivalence* (the "Orange Book") covering 197 top-selling drugs, only 30 patents included a disclosure that the patent was covered by the Bayh-Dole Act or was assigned to a government agency.[86] This is only 10.2% of these 197 approved drugs in the Orange Book,[87] and a mere 2.6% of the total patents covering FDA-approved drugs. These findings are consistent with an earlier 2011 study of the number of Bayh-Dole patents covering drugs.[88] The relatively small number of Bayh-Dole patents is unsurprising, since biopharmaceutical companies invest heavily in R&D without relying on any government funding.[89] If the federal government provides some funding late in the lengthy and multi-stage process of developing a new drug, this often does not trigger the Bayh-Dole Act.[90] Unless an invention was conceived or first reduced to practice while performing work under the federal funding agreement, the Bayh-Dole Act does not apply to the patent.

In addition, prescription drugs are often covered by more than one patent, just like many products from golf balls to smartphones. Since the march-in provision under the Bayh-Dole Act applies only to specific patents covered by the statute, rather than to all patents that may cover a final commercial product, a federal agency would have no march-in powers to exercise for a

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[84] 35 U.S.C. §§ 202(c)(4), § 203(a).

[85] *Id.* at § 201(e).

[86] *See* Genia Long, *Federal Government-Interest Patent Disclosures for Recent Top-Selling Drugs*, 22 J. MED. ECON. 1261, 1262, 1264 (2019). The Bayh-Dole Act requires any patent subject to the law must "include within the specification . . . a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention." 35 U.S.C. § 202(c)(6).

[87] Long, *supra* note 86, at 1265.

[88] *See* Bhaven N. Sampat & Frank R. Lichtenberg, *What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?* 30 HEALTH AFFAIRS 332 (2011) (finding that 9% of a sample of 379 drugs approved between 1988 and 2005 listed at least one patent in the Orange Book that either had a Bayh-Dole government interest statement or had a government agency as the first-named assignee).

[89] *See supra* note 24, and accompanying text (reporting average annual private investments of $129 billion).

[90] To take just two examples in which the Bayh-Dole Act would not cover a patent despite the use of federal funding at some point in the R&D process for a new drug: first, a federal agency provides a grant to a public university running multi-drug clinical trials on a disease, or, second, a federal agency provides a grant to a private drug innovator who is already in a phase 3 clinical trial.

prescription drug unless *all* of the patents covering that drug qualify as a "subject invention" within the meaning of the Bayh-Dole Act.[91] This is a very narrow slice of the universe of total prescription drugs. In the 2019 study, only *two* of the 197 drugs (1%) in the Orange Book were completely covered by patents that had Bayh-Dole Act disclosures or were assigned to a government entity.

Agency Uses of Patented Inventions under the Bayh-Dole Act is Not a Price-Control Power

Lastly, advocates for breaking patents to lower prices on prescription drugs argue that the federal contract provision in the Bayh-Dole Act provides another statutory basis for achieving this policy goal. But this is equally incorrect. The Bayh-Dole Act grants a federal agency "a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world."[92] Even professors and activists acknowledge that this provision has never been invoked by a federal agency to impose price controls on products or services.[93] Yet, they still contend that the "plain text and statutory purpose" of this provision permits it to be used for such purposes in the "production of drugs for use by government programs, such as Medicare and Medicaid" in which the government is a third-party payor for drugs manufactured by private companies and prescribed to private citizens.[94]

As with the failure to abide by the text and purpose of the march-in provision in § 203, this secondary argument for the price-control theory of the Bayh-Dole Act represents an unprecedented and unjustified extension of the Bayh-Dole Act. First, the statutory text in the federal contract provision of the Bayh-Dole Act does not refer to or expressly provide for licenses for manufacturing and selling drugs at lower prices when these drugs are paid for by Medicare and Medicaid. These federal assistance programs were in existence at the time the Bayh-Dole Act was enacted, and thus Congress would have acknowledged such a power for federal contracts under these programs if this was a function of this provision in the Bayh-Dole Act. It did not do so, either expressly or impliedly.[95]

Second, the statutory phrase "for or on behalf of the United States" in the federal contract provision is not an open-ended authorization for the government to create unauthorized licenses for private companies to make and sell patented inventions in the healthcare market to consumers. If it did confer this power, then it makes the march-in provision irrelevant, because any general purpose sought by the government, such as imposing price controls on prescription drugs in healthcare market transactions, could be achieved through the federal contract provision in the Bayh-Dole Act. There would be no need for Congress to enact the march-in power provision in § 203 because these specific, limited conditions would necessarily be encompassed within the unlimited grant of power in the federal contract provision. Again, it is a fundamental rule of statutory interpretation

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[91] *See* 35 U.S.C. § 202(c)(4).

[92] *Id.*

[93] *See* Kapczynski-Kesselheim Letter, *supra* note 6, at 5.

[94] *Id.*

[95] The Supreme Court has repeatedly rejected agency claims to new, unprecedented powers based in generalized statutory language like the federal contract provision in the Bayh-Dole Act. The Supreme Court has been clear that "'Congress could not have intended to delegate' such a sweeping and consequential authority 'in so cryptic a fashion.'" West Virginia v. Environmental Protection Agency, 142 S. Ct. 2587, 2608 (2022) (quoting Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 159 (2000)).

that a provision must be construed within the context of the entire statute and that any one provision must not be construed in a way that renders other provisions in the statute to be irrelevant.[96]

For these reasons, federal agencies have interpreted the meaning of the federal contract provision to permit direct use of an invention by the government for "government purposes," such as use of patented inventions for and by the military, rather than for purely commercial use by private companies and private citizens.[97] Similarly, the NIH has repeatedly declined petitions to create an unauthorized license under the federal contract provision for drugs.[98]

Section 1498 Does Not Authorize Agencies in the Executive Branch to "Break" Patents

A second law invoked by advocates for breaking patents to impose price controls on prescription does not have a name, and thus it's known only as § 1498.[99] As noted, Representative Doggett and Senators Warren and King urged the Biden Administration earlier this year to use § 1498 to impose price controls on drug patents.[100] A year ago, Senator Bernard Sanders wrote to Secretary Xavier Becerra that he can use § 1498 to "break the patent monopoly" and impose price controls on a new drug to treat Alzheimer's currently under review by the FDA.[101] Similarly, professors and activists have argued that § 1498 confers a generalized "patent use power" on agencies that they can invoke to break patents to lower prices on prescription drugs in the healthcare market.[102] Similar to the arguments to use various provisions of the Bayh-Dole Act to impose price controls on drug patents, these claim scontradict the text, function, and longstanding interpretation of § 1498. Section 1498 does not grant the government a freestanding power to infringe patents, let alone to "break" them to impose price controls.

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[96] *See, e.g.,* Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 559 U.S. 280, 290 (2010) ("Courts have a 'duty to construe statutes, not isolated provisions.'") (quoting Gustafson v. Alloyd Co., 513 U.S. 561, 568 (1995)); Gonzales v. Oregon, 546 U.S. 243, 273 (2006) (stating that "statutes 'should not be read as a series of unrelated and isolated provisions.'") (quoting Gustafson v. Alloyd Co., 513 U.S. 561, 570, (1995)).

[97] *See, e.g.*, Dep't of Defense, *Intellectual Property: Navigating Through Commercial Waters*, 2-2–2-3 (Apr. 30, 2001) ("[T]he general approach is that the contractor is permitted to retain title to the invention, and the Government receives a nonexclusive license to use that invention for Government purposes."); Nat'l Institute of Health, *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interest are Protected*, 5 (July 2001) ("By law, the funding agency retains residual interest in grant- and contract-supported inventions, such as a royalty-free, paid-up license to use the technology for government purposes."); 32 C.F.R. § 37.860(b) (Bayh-Dole license does not include the right to use or practice the invention for commercial purposes).

[98] *See* Dr. Francis Collins, Nat'l Institute of Health, *Determination in the Case of Xtandi*, 1 (Jun. 20, 2016) ("[W]e decline to . . . utilize the government's license in the patents."), https://www.techtransfer.nih.gov/sites/default/files/documents/policy/pdfs/Final_Response_Goldman_6.20.2016.pdf; Dr. Francis Collins, Nat'l Institute of Health, *Determination in the Case of Norvir II*, 5 (Nov. 1, 2013) (noting that "the NIH is a research institution not a drug manufacturer"), https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf.

[99] *See* 28 U.S.C. § 1498.

[100] *See* note 9, and accompanying text.

[101] *See* Letter from Senator Bernard Sanders to Xavier Becerra, Secretary of Commerce (June 7, 2023), https://www.sanders.senate.gov/wp-content/uploads/6.7.2023-Letter-from-Chairman-Sanders-to-Secretary-Becerra.pdf.

[102] Kapczynski-Kesselheim Letter, *supra* note 6, at 1-4.

Section 1498 is an eminent domain statute, authorizing a lawsuit to be filed in court for compensation when the government uses a patent without authorization.[103] It provides that "[w]henever ... a patent ... is used or manufactured by or for the United States without license of the owner," the patent owner may file a lawsuit "against the United States in the Court of Federal Claims for the recovery of his reasonable and entire compensation."[104] Congress first enacted this law in 1910 following some confusion in the courts at the turn of the twentieth century concerning the continuing protection afforded by nineteenth-century sfederal courts to patents as private property rights under the Takings Clause of the Fifth Amendment.[105] The Takings Clause states that "nor shall private property be taken for public use, without just compensation."[106] This explains the statutory requirement in § 1498 that manufacture or use of a patent must be "by or for the United States," which triggers the jurisdiction of a court to receive a lawsuit by a patent owner seeking "reasonable and entire compensation" for the governmental use of a patent.

The similar language in the federal contract provision of the Bayh-Dole Act that an agency has a license to a patent covered by this statute when the invention is used "for or on behalf of the United States" is evidence of the same meaning this language has in § 1498: both statutes apply when patented inventions are directly used by the federal government or made for the federal government pursuant to a government contract (in which case the contractor is immunized by the government). The classic scenarios in which § 1498 applies are the production and use of patented inventions for the U.S military, the U.S. Postal Service, and, in the modern era, U.S. agencies like the Veterans Health Administration of the U.S. Department of Veterans Affairs.[107] For this reason, courts have consistently and unequivocally interpreted § 1498 as an eminent domain statute that is applicable only to the manufacture or use of a patented invention by or for the federal government.[108]

Still, professors, activists, and policymakers advocating for the price-control theory of § 1498 maintain that § 1498 can authorize any use of a patented invention by any privatge person or company from which the federal government may receive some type of generalized "benefit."[109] Thus, they argue, § 1498 can be used to impose price controls via an agency authorizing a generic drug company to make and sell a patented drug. This would "benefit" the government by reducing

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[103] Such laws are required for all citizens seeking protection of their constitutional rights. For example, § 1498 serves the same function as 42 U.S.C. § 1984 and 42 U.S.C. § 1988, which authorize courts to receive complaints for claims that the federal or state governments violated someone's constitutional rights under the due process or equal protection provisions of the Fourteenth Amendment.

[104] 28 U.S.C. § 1498(a).

[105] *See* Adam Mossoff, *The False Promise of Breaking Patents to Lower Drug Prices*, 97 ST. JOHN'S L. REV. (forthcoming 2023), https://papers.ssrn.com/abstract=4348499; Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents under the Takings Clause*, 87 B.U. L. REV. 689, 701-11 (2007).

[106] U.S. CONST. amend. V.

[107] This is true reaching back to nineteenth-century court decisions applying the Takings Clause to unauthorized governmental uses of patents, and which Congress was explicitly codifying in enacting § 1498. *See* Mossoff, *The False Promise of Breaking Patents to Lower Drug Prices*, *supra* note 105, at 7-10 (describing cases).

[108] *See, e.g.*, Decca Ltd. v. United States, 544 F.2d 1070, 1082 (Ct. Cl. 1976) ("It is [the government's] taking of a license, without compensation, that is, under an eminent domain theory, the basis for a suit under § 1498."); Irving Air Chute Co. v. United States, 93 F. Supp. 633, 635 (Ct. Cl. 1950) (stating that § 1498 is "an eminent domain statute").

[109] *See* Kapczynski-Kesselheim Letter, *supra* note 6, at 3.

costs for federal programs like Medicare, whose beneficiaries are prescribed drugs produced by private companies and prescribed by private physicians.[110]

This is an unconstrained reading of § 1498 that contradicts its plain text. As already noted, Congress knows how to enact price-control statutes, such as the Emergency Price Control Act of 1942,[111] and § 1498 does not authorize price controls in private transactions in the marketplace. Nor does it provide that lawsuits must proceed against the government whenever the government broadly "benefits" from a product or service that it paid for through some agency program or law. Section 1498 states only that the government must pay "reasonable and entire compensation" when a patent is used "by or for the United States." This is statutory text that has deep roots in eminent domain law in which the government has used property rights like patents without authorization.[112] As an eminent domain statute, the plain text of § 1498 makes clear that it *protects* patent owners when their property rights are taken by or for the government. It is not an *authorization* to the government to use patents or to license others to use patents whenever the federal governments may "benefit" from this use in some way or other.

This is why courts have repeatedly rejected this argument advanced by professors, activists, and some policymakers when defendants have made this same argument in patent infringement cases.[113] In *Larson v. United States*,[114] for example, a patent owner sued a medical device company for patent infringement and the defendant argued that, since "the government reimbursed the cost [of the infringing medical device] through Medicare and other federal programs," the patent owner must proceed against the government in the Court of Federal Claims under § 1498.[115] The *Larson* court flatly rejected this argument, stating that "government reimbursement of medical care expenses did not constitute a use of a medical patent for government purposes," as required by the text of § 1498 in authorizing lawsuits against the federal government when a patent is used by or for the federal government.[116] Almost two decades later, another federal court affirmed the decision in *Larson*, stating that "[t]he fact that the government has an interest in the [healthcare] program generally, or funds or reimburses all or part of its costs, is too remote to make the government the program's beneficiary for the purposes underlying § 1498."[117]

These court decisions were reaffirmed last year in *Arbutus Biopharma Corp. v. Moderna*. In this case, Arbutus sued Moderna for patent infringement in its production and sale of its COVID-19 vaccine and Moderna filed a motion to dismiss, arguing that Arbutus could only sue the government under § 1498 given the federal government's advance purchase contracts for COVID-19 vaccine doses produced by Moderna. The court rejected Moderna's argument and permitted the

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[110] *Id.*

[111] *See supra* notes 35-37, and accompanying text (describing this and other price control statutes).

[112] *See, e.g.*, James v. Campbell, 104 U.S. 356, 358 (1881) (The "exclusive property in the patented invention ... cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land."). In 1952, Congress codified in the patent statutes that patents are property rights. *See* 35 U.S.C. § 261 ("patents shall have the attributes of personal property").

[113] *See* Hon. Judge Susan G. Braden & Joshua A. Kresh, *Section 1498(A) Is Not a Rx to Reduce Drug Prices*, 77 FOOD & DRUG L.J. 274, 282-86 (2022) (reviewing cases).

[114] Larson v. United States, 26 Cl. Ct. 365 (1992).

[115] Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis, 583 F.3d 1371, 1379 (Fed. Cir. 2009) (describing the defendant's argument in *Larson*).

[116] *Larson*, 26 Cl. Ct. at 369.

[117] *Advanced Software Design Corp.*, 583 F.3d at 1379 (quoting *Larson*, 26 Cl. Ct. at 369).

lawsuit to proceed against, holding that the government purchase contracts of vaccine doses manufactured by Moderna were for use by and for private citizens and not just government employees like military personnel or civil servants.[118] The court concluded that Moderna's "development and sale of the vaccines was for the benefit of the vaccine's recipients," who were private citizens, and it was not solely for the benefit of the federal government or its employees.[119]

In conclusion, § 1498 does not apply to private commercial activities in which private companies manufacture and sell products for use by private parties in the marketplace. By its express terms, as confirmed by its interpretation by multiple courts, § 1498 is an eminent domain statute that is limited to unauthorized uses of patented inventions by or for the federal government, such as use of patented inventions by the military or by federal agencies, such as the Veterans Administration. Contrary to the argument advanced by professors and activists in a letter to Congress in 2022, and repeated in the more recent letters by senators to administration officials, § 1498 does not apply to circumstances in which the federal government "facilitate[s] the purchase of low-cost generics by private entities," even if the private entities are "reimbursed by Medicare and Medicaid."[120] In fact, one of the sources of scholarship cited by the professors and activists in their 2022 letter acknowledges forthrightly that § 1498 would need to be "modified" in order "to apply to governmental payment for drugs prescribed for beneficiaries of such federal health programs as Medicare and Medicaid."[121]

Distorting § 1498 to Impose Price Controls Would Still Not Achieve Any Alleged Benefits

If one assumes for the sake of argument that the government could invoke § 1498 to authorize the manufacture and sale of generic versions of patented drugs, this would not achieve the policy goal of lowering healthcare prices. Given the plain text of § 1498, patent owners must receive "reasonable and entire compensation" for the unauthorized use of their patents,[122] which is the market value of the patent and any resulting license rate. This would impose an enormous cost on the U.S. Treasury, vitiating any benefits to the federal government from lower costs for healthcare services.

Section 1498 requires payment of "reasonable and entire compensation" to a patent owner, which is consistent with the requirement in Takings Clause cases and remedies law generally that a plaintiff be made whole, as if the violation of one's rights did not occur.[123] In the past 39 years, the U.S. Court of Appeals for the Federal Circuit has decided four § 1498 cases—a rate of about

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[118] Arbutus Biopharma Corp. v. Moderna, CV 22-252, 2022 WL 16635341 (D. Del. Nov. 2, 2022), *affirmed*, 2023 WL 2455979 (D. Del. Mar. 10, 2023).

[119] *Arbutus Biopharma Corp.*, 2022 WL 16635341, at *7.

[120] Kapczynski-Kesselheim Letter, *supra* note 6, at 3.

[121] MILTON SILVERMAN & PHILIP R. LEE, PILLS, PROFITS, AND POLITICS 187 (1974). This monograph is cited in the Kapczynski-Kesselheim Letter, *supra* note 6, at 2 n. 9.

[122] 28 U.S.C. § 1498(a).

[123] *See, e.g.*, Seaboard Air Line Ry. Co. v. United States, 261 U.S. 299, 304 (1923) (Under the Takings Clause, the property owner is entitled to "be put in as good [a] position pecuniarily as he would have been if his property had not been taken.") (citations omitted); Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1547 (Fed. Cir. 1995) (en banc) (In awarding damages, a court "simply asks, once infringement of a valid patent is found, what compensable injuries result from that infringement, i.e., how may the patentee be made whole.").

one per decade.[124] Consistent with the text and function of § 1498 as an eminent domain statute, none of these cases arose from an agency directing a private company to make a product that competed in the marketplace with another product sold by another private company. Thus, these cases are not precedent for determining what counts as "reasonable and entire compensation" in the proposed price-control scheme in which the government authorizes a generic drug company to make and sell a prescription drug at a lower price than the drug innovator and the patent owner is required to sue the government under § 1498.

If the government undertakes this unprecedented use of § 1498 in which the government authorizes a generic competitor in the marketplace to make and sell a drug at lower prices than the drug innovator, courts will likely apply the legal rules for patent infringement cases in which they award, according to the patent statute, "damages adequate to compensation for the infringement."[125] Courts have construed this statutory language to award a patent owner's *lost profits* when the patent owner is forced to compete against an infringing, commercial competitor.[126] In at least one earlier § 1498 case, the Court of Claims observed that lost profits may be available when a patent owner is unwilling to license a patent, which would include a drug innovator under the price-control scheme for § 1498.[127]

Thus, even under the price-control scheme of § 1498, the federal government would be required to pay the lost profits to the drug innovator as "reasonable and entire compensation" for the governmental authorized infringement by the generic drug company. This eliminates any alleged savings to the public fisc and thus eliminates any alleged "benefit" to the government. In fact, it vastly *expands* the federal government's financial liabilities in paying for medical care, as the federal government would now be paying for extensive numbers of drugs produced and sold in the private healthcare market. The government would incur additional costs through paying lost profits as compensation to drug innovators in innumerable § 1498 claims that were not occurring before.

The Price-Control Scheme of § 1498 Creates Legal Uncertainties and Additional Costs

The potential for significant, additional costs in the price-control theory of § 1498 also arises from other existing regulatory regimes in patent law that go unacknowledged by its proponents. Among several, the most apparent source of uncertainty and additional costs is the Hatch-Waxman Act.[128]

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[124] *See* FastShip LLC v. United States, 892 F.3d 1298, 1310 (Fed. Cir. 2018); Paymaster Techs., Inc. v. United States, 180 F. App'x 942, 944–45 (Fed. Cir. 2006); Hughes Aircraft Co. v. United States, 140 F.3d 1470 (Fed. Cir. 1998); Gargoyles, Inc. v. United States, 113 F.3d 1572, 1572 (Fed. Cir. 1997).

[125] *See* 35 U.S.C. § 284 (providing that "court shall award the claimant damages adequate to compensate for the infringement").

[126] *See, e.g.*, General Motors Corp. v. Devex Corp., 461 U.S. 648, 654-55 (1983) ("Congress sought to ensure [in § 284] that the patent owner would in fact receive full compensation for 'any damages' he suffered as a result of the infringement."); Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc) ("[T]he general rule for determining actual damages to a patentee that is itself producing the patented item is to determine the sales and profits lost to the patentee because of the infringement."); Del Mar Avionics, Inc. v. Quinton Instrument Co., 836 F.2d 1320, 1326 (Fed. Cir. 1987) ("The general rule for determining the actual damages to a patentee that is itself producing the patented item, is to determine the sales and profits lost to the patentee because of the infringement.").

[127] *See Decca Ltd.*, 640 F.2d at 1167.

[128] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 84-417, 98th Cong. (Sep. 24, 1984). This law is commonly known as the Hatch-Waxman Act.

Enacted in 1984, the Hatch-Waxman Act created a regulatory system in the FDA and a litigation regime in the courts to promote faster generic drug entry in the healthcare market while maintaining incentives for innovation.[129] Although the 2002 letter from professors and activists references the Hatch-Waxman Act in its footnotes,[130] they fail to address how the proposed price-control theory of § 1498 would necessarily and inescapably become intertwined with the Hatch-Waxman regime, raising costs and legal uncertainties. For the sake of brevity, this section will only briefly summarizes this serious threat of extensive legal and policy questions and disputes.

Under the Hatch-Waxman Act, a generic drug company seeking to market a generic version of a drug files a special application with the FDA requesting approval to market its drug, and the final approval date depends on the existing patent term of the drug patent, legal protections by other statutes, or both. The generic drug company can enter the market before patent expiration by challenging the validity of the patent or alleging noninfringement. There are legal requirements for notice to the innovator drug company, which typically leads to a patent infringement lawsuit in court.[131] If the generic drug applicant is successful in court, it may enter the healthcare market prior to the expiration of the patent term. If not, it cannot market its drug until the patent expires. The proponents of the price-control theory of § 1498 do not acknowledge how the proposed regulatory directives for a generic drug company to make and sell a patented drug would be affected by the existing Hatch-Waxman regime for generic drug companies. This legal uncertainty will lead to additional litigation and add significantly to the costs of doing business for generic drug companies and drug innovators alike. It will also significantly increase the administrative costs in the U.S. Court of Federal Claims.[132] Without a proper institutional and legal assessment of how the price-control theory of § 1498 would be implemented within existing institutions and laws governing drug patents, any attempt to do so by an agency would violate the fundamental requirement of good government that it engage only in evidence-based policymaking.

Conclusion

The price-control theories of the Bayh-Dole Act and § 1498 represent policy arguments superimposed on two statutes by professors and activists seeking a quick-and-easy path to lower drug prices. The theories rationalize unprecedented regulatory powers for imposing price controls on prescription drugs in the healthcare market without a statutory basis in either the Bayh-Dole Act or § 1498. In perhaps sensing their failure in fulfilling their burden of evidence-based policymaking in their argument to break patents as the primary solution to lower drug prices in a complex healthcare market, advocates bootstrap the necessary policy and economic arguments by asserting that Congress has already adopted a price-control policy over patents in these two federal statutes. These price-control schemes under both the Bayh-Dole Act and § 1498 contradict the text, function, and past interpretation of both of these statutes by courts and agencies. Neither the Bayh-Dole Act nor § 1498 is an existing "tool" for breaking patents to lower drug prices.

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[129] For a complete description of the Hatch-Waxman Act and its complex regulatory and litigation regime, *see* Thomas, *supra* note 57; *see also* Christopher M. Holman, *Government Involvement in Pharmaceutical Development Can Come Back to Haunt a Drug Company*, 40 BIOTECHNOLOGY L. REP. 4 (2021). For an in-depth review of the history, enactment, and political economy of the Hatch-Waxman Act, *see* Erika Lietzan, *The History and Political Economy of the Hatch-Waxman Amendments*, 49 SETON HALL L. REV. 53 (2018).

[130] *See* Kapczynski-Kesselheim Letter, *supra* note 6, at 3 n.16 & 5 n.29.

[131] *See* 21 U.S.C. § 355(j)(5)(B)(iii).

[132] *See* Braden & Kresh, *supra* note 113, at 293.

Statement of Arti K. Rai
Elvin R. Latty Distinguished Professor of Law, Duke Law School

Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market
Hearing Before the Senate Committee on the Judiciary
May 21, 2024

Chair Durbin, Ranking Member Graham, and members of the Senate Judiciary Committee. Thank you for the invitation to testify before you today on the topic of competition in prescription drug markets. I have worked on this topic for several decades, both as the Elvin R. Latty Distinguished Professor at Duke Law School and during my recent service within the Executive Branch.[1] My research on these questions, some of which is discussed below, is funded by non-profit foundations and government agencies only.

The drug competition question has many different aspects, and my statement will address only a few of the relevant issues. I will focus on the ways in which biopharmaceutical patents of questionable validity create substantial challenges for competition. I will also identify narrowly tailored solutions to address the problem of questionable grants.

To be clear, I believe that the incentives provided by properly granted patents are very important for drug discovery and development. The patent incentive is particularly critical for small molecule drugs. Under the Hatch-Waxman statute, which governs competitive entry for small molecules, exclusivity over clinical trial data generated by the originator company lasts only 5 years. In contrast, under the Biologics Price Competition and Innovation Act, data exclusivity for large molecules lasts 12 years.[2]

While appropriately granted patents serve an important incentive role, poor-quality patents raise prices for consumers without promoting innovation. Unfortunately, we have substantial evidence that poor-quality patents are impeding competition. In what follows, I will review some of this evidence and discuss three surgical interventions for improving quality, competition, and innovation.

These are, first, greater coordination between the USPTO and FDA; second, limiting assertion of patents that are obvious variations of patents that have been determined to be invalid; and third, ensuring the continued vitality of the Patent Trial and Appeals Board.

Improving Patent Quality Through Interagency Coordination

I will begin with measures that can be taken to improve patent quality through greater coordination and information flow between the USPTO and the FDA. These measures should not be controversial. In fact, Congress has been quite eager to secure this coordination.

A number of Senators, including members of this Committee, have expressed concerns about applicant submissions and statements to the FDA that are highly relevant to patent validity but that are nonetheless never brought to the attention of the USPTO. These submissions can take the form of statements made to the FDA that are flatly inconsistent with statements made to the USPTO. For example, an applicant may provide a variety of evidence to the FDA to support its argument that a particular product is only a trivial variation of an already marketed product and therefore does not require additional testing prior to approval. Meanwhile, at the USPTO, the same applicant withholds this evidence and instead states that the product is truly nonobvious and therefore deserving of a patent. This was the scenario in *Belcher v. Hospira*,[3] a 2021 case in which the behavior in question was so egregious that the Court of Appeals for

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[1] In 2021, I served as Senior Advisor to the Office of the General Counsel at the Department of Commerce. In that capacity, I worked on President Biden's July 9, 2021 Executive Order on "Promoting Competition in the American Economy." My full CV is available at www.law.duke.edu/fac/rai.

[2] Notably, despite this 12-year exclusivity, originator biologics manufacturers not only assert many more patents in litigation than small molecule originators, but the filing of biologics patents appears to be timed so that a large percentage of these patents issue around the time the 12-year exclusivity is due to expire. Victor L. Van de Wiele et al., *The Characteristics of Patents Impacting Availability of Biosimilars*, 40 NATURE BIOTECHNOLOGY 22, 24 (2022).

[3] 11 F.4th 1345 (Fed. Cir. 2021).

the Federal Circuit found that the Chief Science Officer for Belcher had committed the very serious patent law transgression of inequitable conduct and that the patent in question was therefore unenforceable.

Inequitable conduct is, however, very difficult to prove. Rightly so, as it seriously damages the reputation of an individual found guilty of such behavior. Findings of inequitable conduct require proof that an individual intended to mislead the USPTO with respect to information she knew to be material to patentability. The problem of incomplete information flow to the USPTO is, however, more systemic than occasional judicial findings of inequitable conduct would suggest.

For example, manufacturing process patents represent, by far, the largest category of patents asserted by originator biologics firms against would-be biosimilar competitors.[4] My co-author Nicholson Price and I have shown that over 70% of these assertions involved patents with a priority filing date of more than one year after the branded product in question had been approved for marketing by the FDA.[5] For such late-filed patents, longstanding Supreme Court case law makes it clear that the firm seeking the patent should make the USPTO aware of ways it is using manufacturing processes related to, or identical to, those it seeks to patent commercially, even if that commercial use is secret. The idea is straightforward – a firm that has been relying on secrecy for commercial advantage should not subsequently be able to extend its exclusivity further by securing a patent either on the same information or an obvious variation. The Supreme Court affirmed this line of case law as recently as the 2019 case of *Helsinn v. Teva*.[6]

In the case of originator biologics firms, the manufacturing process information that is secretly being used commercially is known to the FDA: FDA applicants must submit it as part of their approval process. However, the USPTO has not been aware of such prior commercial activity.

Responding to Congressional and White House interest in the question, the USPTO has recently issued guidance stating that applicants have a duty of disclosure and reasonable inquiry with respect to information disclosed to other agencies.[7] In fact, this guidance specifically instructs examiners that they can inquire about secret commercial use of manufacturing processes disclosed to the FDA.

The USPTO's guidance is certainly helpful. But placing the burden on examiners and applicants means that enforcement must generally occur primarily through doctrines like inequitable conduct. As noted earlier, inequitable conduct is very difficult to prove. Moreover, fault-finding in costly federal court litigation many years after the questionable patent has been issued is not the best approach to the information flow issue. The problem is a system-level problem, and it deserves a system-level solution.

The system-level solution is straightforward. The Executive Branch has the relevant information. It is simply siloed – an all-too familiar problem for government agencies. One reason information sometimes remains siloed is agencies' acute awareness of the need to maintain trade secrecy. This is where a Congressional push would be very useful. As Senator Durbin's proposed Patent Interagency Coordination and Improvement Act (co-sponsored by Senators Tillis, Grassley, Coons, and Welch) recognizes, information flow from the FDA to the USPTO can be managed in a manner that is perfectly consistent with trade secrecy.

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[4] S. Sean Tu, Rachel Goode, and William B. Feldman, *Biologics Patent Thickets and Terminal Disclaimers*, 331 JAMA 355 (2024).
[5] Arti K. Rai and W. Nicholson Price II, *An Administrative Fix for Manufacturing Process Patent Thickets*, 39 NATURE BIOTECHNOLOGY 20 (2021).
[6] 586 U.S. 123 (2019).
[7] USPTO, Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board, 87 Fed. Reg. 45764 (2022).

Under this proposed Act, or similar legislation, information about the manufacturing process for a given biologic that the FDA had on hand at the time of the originator biologic's approval for marketing could be made available in a trade-secret-protected fashion to the USPTO. The USPTO could then use the information to ensure that any subsequent manufacturing process patent granted to the originator was valid because it was novel and nonobvious over the prior commercial use. Additionally, potential biosimilar competitors could then be confident that any issued patent with a priority date later than one year after marketing had not been used to make the biologic at launch and thus did not need to be infringed to make a biosimilar.

As Senator Durbin's proposed legislation recognizes, interagency coordination could also involve assistance in the other direction – from the USPTO to the FDA. Specifically, the USPTO could assist the FDA in determining whether small molecule patents that originator firms proposed for listing on the Orange Book legitimately belong on the Orange Book. In work with Jorge Contreras, I have argued that this sort of *ex ante* procedure would be quite similar to what administrators of patent pools have utilized to address the problem of over-declaration of patents in the standard-setting arena.[8]

Terminal Disclaimers and Obviousness-Type Double Patenting

Another mechanism for substantially improving competition without deterring genuine innovation relates to terminal disclaimers. Unlike late-filed manufacturing process patents of the sort discussed in the prior section, groups of patents linked by terminal disclaimers don't result in additional patent term. However, such patents add to the overall thicket of patents with which a challenger must contend.

Terminal disclaimers are stipulations that the application on which a given applicant is seeking a patent will expire at the same time as an earlier patent owned by the applicant. Although terminal disclaimers can be filed for a number of different reasons, the reason that is most problematic for purposes of unduly thwarting biopharmaceutical competition arises when terminal disclaimers are used to overcome obviousness-type double patenting rejections. In this context, the patent examiner has determined that the follow-on application is obvious given the applicant's prior patent. Rather than fighting the rejection, the applicant chooses to file a terminal disclaimer.

Disclaimers filed to overcome obviousness-type double patenting rejections indicate an applicant's uncertainty about the patent application's strength over the prior patent. Under current Federal Circuit case law,[9] however, invalidation of the prior patent does not automatically invalidate the follow-on patent. As a consequence, challengers must invalidate patents linked by terminal disclaimers individually. That can be a very expensive undertaking.

Data on the number of terminal disclaimers involved in biologics patenting suggest the scope of the challenge. One study that examined biologics patents asserted in litigation against biosimilars between 2010 and April 2023 found that 48% of these patents contained terminal disclaimers.[10]

A USPTO notice of proposed rulemaking issued on May 10, 2024 attempts to address this issue.[11] It states that the agency is considering requiring a statement from patent applicants that file terminal disclaimers to overcome obviousness-type double patenting rejections that they will not seek to enforce

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[8] Jorge L. Contreras and Arti K. Rai, *Orange Book Over-Declaration of Pharmaceutical Patents: the Advantages of Ex Ante Over Ex Post Review*, HEALTH AFFAIRS FOREFRONT, December 13, 2023.
[9] Simple Air v. Google, 884 F.3d 1160 (Fed. Cir. 2018).
[10] S. Sean Tu, Rachel Goode, and William B. Feldman, *Biologics Patent Thickets and Terminal Disclaimers*, 331 JAMA 355 (2024).
[11] USPTO, Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting, 89 Fed. Reg. 40439 (2024).

patents encumbered by terminal disclaimers if the patents to which they are linked have been invalidated. I believe that the proposed rule is a good idea as a policy matter and is an appropriate exercise of the agency's rulemaking authority.

That said, the patent statute does not clearly define the scope of the agency's rulemaking authority over initial examination. Instead, the statute refers to rules that "govern the conduct of proceedings in the Office."[12] The Court of Appeals for the Federal Circuit has sometimes interpreted this language to hold that the agency's rulemaking authority over initial examination is narrowly "procedural."[13] For this reason, a finalized rule is vulnerable to litigation arguing that the rule exceeds the scope of the agency's rulemaking authority.

A very useful revision to the patent statute would expand the scope of the agency's rulemaking authority over initial examination. For example, a revision could conform the initial examination language to that used to describe the agency's rulemaking authority over the PTAB. In the PTAB context, the Supreme Court has held that the relevant statutory language, which references "governance"[14] generally, is not limited to very narrow matters. This sort of revision would allow the USPTO to adjust nimbly to ground-level realities, including gaming tactics, in a variety of different contexts.

Alternatively, Congress could simply revise the patent statute to state that patents encumbered by terminal disclaimers made to overcome obviousness-type double patenting rejections over a prior patent are unenforceable or invalid if the prior patent is held invalid.

Robust Review of Biopharmaceutical Patents at the Patent Trial and Appeals Board

Third, it is important to preserve robust review of biopharmaceutical patents at the Patent Trial and Appeals Board (PTAB). In the America Invents Act of 2011, Congress created the PTAB to serve as more efficient and accurate mechanism than district courts for correcting inevitable USPTO errors.

Particularly in the case of biologics, where large numbers of patents cover a single molecule, PTAB challenges have played an important role in addressing patents that block competition. According to one study that looked at use of the PTAB through June 2021, 102 biologics patents covering 34 FDA-approved molecules had been challenged at the PTAB.[15] This number was substantially greater than the 9 FDA-approved drugs that had, by June 2021, faced patent challenges in district courts. Because challenges at the PTAB do not have a standing requirement, competitors don't have to wait until they are ready to launch before challenging erroneously granted patents.

It's also important to note that the PTAB's highly professional judges, who are specifically required by statute to be trained in both science and law, carefully evaluate challenges. In the period through June 2021, the PTAB granted review on only 43 of the 102, or 43%, of the challenged patents.[16] Moreover, of those 43 patents, it found only 24 patents to be invalid on all challenged claims.

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[12] 35 U.S.C. 2(b)(2)(A).
[13] Cooper Technologies Co. v. Dudas, 536 F.3d 1330, 1335 (Fed. Cir. 2008).
[14] Cuozzo v. Lee, 579 U.S. 261 (2016).
[15] Victor T. Van de Wiele, Aaron S. Kesselheim, and S. Sean Tu, *Biologics Patent Challenges Under the America Invents Act*, 42 NATURE BIOTECHNOLOGY 374 (2024).
[16] *Id.*

Not surprisingly, studies have repeatedly shown that the PTAB's affirmance rate at the Federal Circuit exceeds that of district courts.[17] And in the case of biopharmaceutical patents in particular, the PTAB may, if anything, be too cautious. One study on small molecules found that while the PTAB's decisions are overwhelming affirmed by the Federal Circuit, it is more likely to be reversed on decisions finding *patentability* than decisions finding *unpatentability*.[18]

Robust expert review by the PTAB is a key pillar of a high-quality patent ecosystem and should be preserved.

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[17] Matthew G. Sipe, *Experts, Generalists, Laypeople – and The Federal Circuit*, 52 HARVARD J.L. & TECH. 576 (2019).

[18] Charles Duan, *On the Appeal of Drug Patent Challenges*, 72 AMERICAN UNIVERSITY LAW REVIEW 374 (2023).

TESTIMONY OF JOCELYN B. ULRICH, VICE PRESIDENT, POLICY AND RESEARCH PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

BEFORE THE SENATE JUDICIARY COMMITTEE

May 21, 2024

Chairman Durbin, Ranking Member Graham, and Members of the Committee, thank you for inviting me to participate in today's hearing. The robust competition that is created by the U.S. intellectual property (IP) framework 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 United States: over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone, more than any other industry.[1] This is also a vastly larger amount than the NIH spends on drug research and development, in FY 2020 the entire NIH budget was $43.3 billion,[2] only 8% of which was focused directly on drug development, while the biopharmaceutical industry as a whole invested $122 billion in research and development (R&D),[3] 100% of which was focused on drug development.

PhRMA appreciates the Committee's leadership in exploring opportunities to ensure affordable and accessible medications and examining competition in the prescription drug market. This market relies on a well-functioning, science-based regulatory system, strong and reliable intellectual property (IP) protections, and coverage and payment policies that encourage medical innovation to thrive. My testimony today will focus on two of those pillars, the IP system and coverage and payment policies.

As a starting point, America's IP framework should be credited for its distinct ability to balance the important goals of fostering innovation and promoting competition to control overall health care costs. Patents and other forms of IP protection are critical for the biopharmaceutical industry due to the lengthy, costly, and highly risky nature of biopharmaceutical R&D, which is necessary to bring innovative new medicines to patients. Fewer than 12% of the drug candidates that make it into clinical trials are eventually approved by the Food and Drug Administration (FDA). Estimates of total average capitalized pre-launch R&D costs range from $161 million to $4.54 billion (2019 US$), including one estimate that found it costs $2.6 billion to develop one medicine, including the costs of the many failures.[4,5]

By many measures, America's IP framework has been a resounding success, promoting incentives for innovation and patient access to needed medicines while leveraging our market-based system to drive competition and achieve cost containment. Since 2000, biopharmaceutical companies have launched more

than 750 new medicines in the U.S., resulting in significant progress against some of the most costly and challenging diseases.[6,7,8,9] Even though the period from 2009 and 2018 saw the introduction of many new treatments and cures, a Congressional Budget Office (CBO) examination of nationwide trends in medicine prices found that the average net price per prescription in Medicare Part D and Medicaid declined during that time period.[10]

These savings result from a unique system of cost containment: over time, new medicines help to improve patient outcomes and reduce overall health care costs while paving the way for lower-cost generics and biosimilars that bring long-term value to patients and the health care system.[11] As a result of the strong legal and regulatory frameworks that undergird this system, today 90% of prescriptions filled at the pharmacy counter are filled with generics and biosimilars, offsetting most of the health care spending on new brand drugs.[12] Going forward, net prices for brand medicines are projected to decline by up to 4 percent annually through 2028, and total prescription spending as a share of National Health Expenditures (NHE) is projected to remain constant at 14% through 2030, exactly the same share as it has been for the last decade.[13] Similar cost containment mechanisms do not exist for other health care services.[14]

Unfortunately, however, critics often rely on a misguided understanding of the vital role of IP to the biopharmaceutical research ecosystem to call for reforms that would put this carefully balanced system at risk over the long term. As such, it is more critical now than ever that we advance thoughtful policies that continue to incentivize urgently needed innovation while supporting a competitive marketplace.

For decades the competitive dynamics in the market for prescription medicines have worked successfully to balance innovation, patient access, and cost containment. But that balance is increasingly threatened by the misaligned financial incentives and conflicts of interest that characterize the pharmacy benefit manager (or PBM) market today. In recent years, the three largest PBMs have vertically integrated with health insurers, specialty and mail order pharmacies, and provider groups to form large health care conglomerates that are significantly impacting whether patients are able to benefit from biopharmaceutical innovation. These vertically integrated organizations have enormous influence over which medicines patients have access to, the circumstances under which those medicines are covered, and when and where they can be dispensed or administered to patients. A growing share of PBM compensation is now tied to the list price of medicines,[15] which experts note can distort the market by incentivizing PBMs to prefer medicines with higher list prices and large rebates over lower cost alternatives.[16] Rather than ensuring patients have rapid access to generics, biosimilars, and lower price therapies, we see PBMs denying or restricting coverage for these medicines.[17,18] Instead of using the rebates they negotiate with manufacturers to lower patient cost sharing, we see PBMs requiring patients to pay their deductibles and coinsurance based on a medicine's undiscounted list price. We discuss the ramifications of these practices later in the testimony.

PhRMA supports market-based solutions that will spur continued brand-to-brand, generic, and biosimilar competition while incentivizing medical advances to save and improve patient lives. In addition, we believe there are meaningful policy solutions that would solve the true barriers to patient access and affordability and improve competition that would not harm the IP system that underpins America's leadership in biopharmaceutical innovation. My comments provide context on the critical role of the biopharmaceutical industry in the U.S. economy, the existing statutory frameworks that increase access to generic and

biosimilar medicines while preserving incentives for innovation, the importance of the Bayh-Dole Act to the research ecosystem, the role of medicines in reducing spending on health care and improving patient outcomes, the impact of the Inflation Reduction Act (IRA) on competition, the impacts of vertical integration in the health care marketplace, and policy proposals to enhance competition.

Overview of How the Biopharmaceutical Industry Boosts the U.S. Economy

The biopharmaceutical industry is a major driver of innovation and economic growth both within the U.S. and globally. Through its research, production, and overall operations, the U.S. biopharmaceutical industry directly accounts for 1.6 percent of U.S. GDP (*i.e.*, its "value added"). Including the economic activity driven in other sectors of the economy the industry generates and supports more than $880 billion in value added within the economy, or 3.4 percent of U.S. GDP.[19]

The U.S. biopharmaceutical research sector leads the world in the development of new medicines with about 8,000 in development globally.[20] The sector generates high-quality jobs and powers economic output and exports for the U.S. economy, serving as "the foundation upon which one of the U.S.' most dynamic innovation and business ecosystems is built."[21] The U.S. biopharmaceutical sector directly employed more than one million workers in 2022, and with its substantial employment multiplier of 4.69, the industry supports more than 3.8 million additional jobs for a total employment impact of more than 4.9 million jobs supported across the U.S. economy.[22] The R&D intensive nature of the industry generates a productivity level of more than $402,000 per employee. In 2022 that was more than twice that of the average U.S. manufacturing worker, and more than three times the average U.S. worker. Furthermore, biopharmaceutical industry jobs are both high-wage and high-quality with average wages and benefits of more than $157,000 per worker, more than twice the average U.S. worker.[23]

Biopharmaceutical companies also support the broader life sciences ecosystem in the United States. The corporate venture capital funds of major biopharmaceutical companies "play an essential role in the sustainability of the biotech ecosystem, advancing the future of pharmaceutical innovation and biotech entrepreneurship."[24] All of this has a ripple effect throughout the U.S economy, in 2022 the biopharmaceutical industry exceeded $800 billion in direct output and supported an additional $850 billion in output through its supplies and other sectors of the economy for a total of more than $1.65 trillion.[25]

Overview of the Statutory Frameworks that Increase Competition while Preserving Incentives for Innovation

As noted by the 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."[26] 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.

The Hatch-Waxman Act 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. At the same time, generic companies did not have an abbreviated pathway for approval of generic copies of drugs approved after the 1962 amendments to the Federal Food, Drug, and Cosmetic Act after IP protections expired, and could not perform the studies need to support approval during the innovator patent term. 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,[27] overturning a Federal Circuit decision to the contrary,[28] and seek FDA approval to market products immediately upon patent expiration, or even prior to patent expiration if they challenge patents through the litigation framework created by the Hatch-Waxman Act. In addition, to protect the valuable clinical data generated by innovators during the drug development process, Congress also provided data protection for the innovator drug. Under the Hatch Waxman Act, with certain limited exceptions, generic companies must wait 5 years before filing abbreviated new drug applications for drugs including a new active moiety.

Given the nature of the framework created, patent litigation is an explicitly contemplated 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 attempt to market generic versions prior to expiration of listed patents. As a result, the effective patent life for small molecule medicines is about 13.0 years for drugs with sales greater than $250 million in 2008 dollars the year before generic entry, and 14.1 years overall.[29] This means that small molecule brand medicines face generic competition between 13-14 years after brand launch, even though the basic patent term is 20 years. Over the 40 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 as soon as possible under the statute—in the case of a new chemical entity, as early as 4 years after FDA approval.[30]

The BPCIA was enacted in 2010 and was intended to strike a balance between providing access to biosimilar medicines and preserving incentives for innovation of biological products. 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 created by the Hatch-Waxman Act and BPCIA litigation procedures differ, they both allow for, and naturally lead to, premarket patent litigation. Since Congress enacted the BPCIA in 2010, a robust biosimilars market has emerged in the U.S, with 38 biosimilars launched and competing on the market against 16 brand biologics, resulting in $23.6 billion in savings since the first biosimilar entry in 2015.[31,32]

An important provision of the Hatch-Waxman Act allows the basic term of one of the innovator's drug patents to be extended up to fourteen years from the approval date to ensure that research intensive companies will have the necessary incentives to conduct their R&D activities.[1] This partial patent term restoration is based on the effective patent life lost in FDA review and half of the time lost during clinical development, capped at 5 years, with the extended patent term not to exceed 14 years from FDA approval.[33] During the Congressional debate about the Hatch-Waxman Act it was noted that Congress had carefully considered the 14-year period: "[B]y providing up to fourteen years of market exclusivity, the Committee expects that research intensive companies will have the necessary incentive to increase their [R&D] activities."[34] This period of time to get a return on R&D investment was a pivotal feature of the Hatch-Waxman Act and was described at the time as the "heart of the compromise."[35]

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, resulting in $2.9 trillion in savings over the past ten years alone.[36]

Patents Also Support Critical Post-Approval Innovation

R&D doesn't stop the minute a medicine is first approved by FDA. R&D investment in medicines is an ongoing process that continues long past initial FDA approval, resulting in innovations that improve the lives of patients, including new uses, novel delivery mechanisms and new dosing schedules. These advances can involve significant R&D investments and lengthy and resource-intensive clinical trials, with no guarantees of success. Post-approval R&D can lead to new or improved treatment options for patients that may enable better health, quality of life, or reduce treatment burdens improving treatment adherence and health outcomes.

Patents are necessary to incentivize this important work and to ensure the full clinical benefit of medicines are realized. As a result, patents touch nearly every facet of biopharmaceutical production and use, from the active ingredient or component that produces its biological effect, to formulations of it, to new uses of it, to the way it is made; the result of this breadth of innovation is that most medicines are associated with many patents.

The types of patents covering biopharmaceuticals include:

- Active ingredient or component patents. These are the ingredients of the drug that have a physiological or pharmacological action.

[1] Note that patent term restoration also applies to biologic medicines.

- Drug product patents. These 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 use of health care services, such as hospitalizations. For example, long-acting injectable forms of oral treatments for schizophrenia have allowed for administration every two weeks or even as little as every 6 months. Long-acting forms have led to improved adherence and savings driven primarily by lower hospitalizations and outpatient care.[37,38]

- 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 medicines, such as by removing potential impurities that could impact the quality of the medicine. 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, new dosage forms 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.

The Importance of the Bayh-Dole Act to the Innovation Ecosystem

Strong and reliable IP protections are critical to fostering public-private partnerships and other forms of collaboration. Congress passed the Bayh-Dole Act in 1980 with bipartisan support to incentivize the private sector to transform discoveries resulting from government-funded early-stage research into useful products in any sector. By allowing grant recipients such as universities to retain the title to the patents covering their inventions and enabling them to license the patents and right to use those inventions to private sector partners, the Bayh-Dole Act facilitates the development of commercially available medical treatments. Prior to enactment of the Bayh-Dole Act, the government retained the patents on federally-funded inventions – and only 5% of those patents were ever licensed for use in the private sector.[39] Collaboration was further incentivized by The Federal Technology Transfer Act of 1986, which authorized Federal laboratories to enter into cooperative research and development agreements (CRADAs) with private businesses and other entities. These policies have proven critical to maximizing taxpayer benefit for government-funded research. Several studies have demonstrated that increases in NIH-funded basic research results in increased private R&D and innovation.[40] Analysis of industry R&D spending data found that in the decade following an increase in NIH funding, private R&D spending grew by about 8 times as much as the increase.[41] Another study found that each $10 million increase in NIH funding resulted in a generation of knowledge that catalyzed private sector investment with a net increase of 2.7 private sector patents per $10 million.[42]

While many medical breakthroughs begin in the research laboratories at the NIH or federally funded academic medical centers, technology transfer is what makes these discoveries available to improve public health through licensing and collaboration agreements with the private sector. According to the NIH Office of Technology Transfer, "technology transfer moves medical innovation from the benchtop through additional research and development, testing, regulatory approval, manufacturing, and finally to distribution as a medical product which will improve the health of everyone."[43] Partnership between the government and the private sector is critical because each plays a fundamentally different but complementary role in the biopharmaceutical research and development ecosystem. According to the Congressional Budget Office (CBO), "the complementary relationship between public and private R&D spending arises mainly because NIH funding focuses on basic research that leads to the discovery of new drugs and vaccines, whereas private spending focuses on applications of such research."[44] While NIH plays an important role in fostering basic research in genomics, molecular biology and other life sciences that have identified new disease mechanisms, these discoveries are far from fully developed therapies for patients.

The biopharmaceutical industry's unique role in the research ecosystem is to utilize its scientific and industrial expertise to take the necessary risks to build upon and further advance basic science research into safe and effective treatments that can be made available to patients. The federal government cannot research, develop and manufacture new treatments and vaccines without the resources, scientific expertise, R&D, manufacturing and technological platforms from private sector biopharmaceutical companies. A rich body of research describes the nature of the complementary roles of the public and private sectors in advancing medical treatments. In 2001, the NIH concluded in a study for Congress that the biopharmaceutical industry was responsible for the discovery and development of 91 percent (43 out of 47) of all the top-selling marketed drugs in 1999.[45] A 2010 analysis of 252 drugs approved between 1998 and 2007 found that 76 percent originated in industry vs. 24 percent in academia.[46] A 2014 study of the most transformational drugs

of the 25 prior years, as identified by over 200 physicians, found that the private sector was responsible for the vast majority of the work required to develop a therapy.[47] An analysis of the contribution of NIH funding to new drug approvals 2010 – 2016 found that although NIH funding contributed to published research associated with every one of the 210 new drugs approved by the FDA in those years, 90% of the NIH funding supported basic research related to the biological targets for drug action rather than the drugs themselves.[48] And an analysis of 23,230 NIH grants awarded in the year 2000 that were ultimately linked through the reported patent filings to 18 FDA-approved therapies showed that NIH funding totaled $0.670 billion, whereas private sector funding totaled $44.3 billion.[49] The research reflects that the disparate funding between the public and private sectors is a feature of allowing each sector to perform the role it does best in the ecosystem with federal funding: the public sector performs basic research to identify nascent concepts, and the private sector contributes the technical expertise and takes the significant, and necessary, financial risks to bring the initial research to fruition in the marketplace.

The NIH has certain rights and procedures when it seeks to license a patented invention for further development by the private sector. Companies that want to obtain a license to develop an NIH invention must complete an application, and if the applicant has requested an exclusive or partially exclusive license the NIH will publish a notice in the Federal Register, as required by law, and after review and evaluation of public comments will make a final determination regarding the license.[50] Private companies often prefer exclusive licenses that allow them to be the sole user of a patented invention for a specified period of time in order to provide a measure of certainty and predictability during the highly risky, lengthy, and costly drug development process which can cost an average of several billion dollars and take 10-15 years and with limited probabilities of success.[51] Manufacturers seek the certainty and predictability provided by IP protections to make the decades-long investments in new technologies, and in building and expanding upon state-of-the-art manufacturing facilities.

Though the Bayh-Dole Act allows the federal government to "march-in" under a narrow set of circumstances, "march-in" was never intended to serve as a mechanism for regulating the pricing of any products, including prescription medicines. The law's provisions provide the right for the government to "march in" under a narrow set of circumstances and force patent holders to grant a license to a "responsible applicant" able to utilize the technology to address an unmet need. In the nearly four decades that the Bayh-Dole Act has been in place, NIH, after careful review, has rejected each of the 7 march-in petitions based on pricing that have been submitted to the agency. In each case, NIH consistently concluded that the products subject to a march-in petition had reached practical application and health or safety needs were reasonably satisfied. Even in an instance where march-in was requested to respond to a manufacturing supply challenge, NIH concluded that the manufacturer was "working diligently to resolve its manufacturing difficulties"[52] and "no remedy that is available under the march-in provision would address the problems identified by the requestors."[53]

Policy proposals to place pricing restrictions on the private sector as a condition of partnering with the government have been tried before with disastrous results for patients and taxpayers. In 1989, the NIH imposed "reasonable pricing" conditions in all CRADAs between federal labs and outside parties to conduct research or development. The policy was revoked in 1995 after public meetings were held with companies, patient advocates and researchers after which the agency concluded that these pricing conditions

significantly chilled collaboration between the public and private sectors.[54] In his announcement of the decision, then Director of the NIH, Harold Varmus, M.D. said, "An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public," Dr. Varmus further said, "Eliminating the clause will promote research that can enhance the health of the American people."[55] After the removal of the clause, there was a subsequent rebound in CRADAs. [56]

In an Op-Ed to the Washington Post, the bill's authors Senators Birch Bayh and Bob Dole stated, "The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product."[57] Similar provisions cover the licensing of NIH inventions, which empower the NIH to terminate the license in whole or in part if the agency determines that the licensee is not executing its commitment to achieve practical application of the invention, the licensee if in breach of an agreement, termination is necessary to meet requirements for public use, or the licensee has been found by a court to have violated Federal antitrust laws in connection with its performance under the license agreement. Changing policy on these provisions to allow price to be considered as a factor for action on the part of NIH would chill the private sector's willingness to enter into contractual agreements and licenses with the agency.

Prescription Medicines Play a Key Role in Reducing Spending on Health Care and Improving Patient Outcomes

Prescription medicines are transforming the treatment of many diseases, resulting in decreased mortality rates, improved health outcomes and better quality of life for patients. For example, game-changing new medicines have played a key role in declining mortality across many forms of cancer. Due in part to many treatment advances, since peaking in the early 1990s, cancer death rates have declined by 33%.[58] Similarly, since the introduction of highly effective antiretroviral therapy in the mid-1990s and the many treatment advances that followed, the HIV/AIDS death rate has declined by 91% and patients with HIV today can hope to live close to normal life spans.[59] Across many diseases, biopharmaceutical innovation is ushering in the next generation of treatment advances for patients while also driving greater efficiency in health care. For example, personalized medicines are increasingly enabling the targeted delivery of the right medicine to the right patient at the right time—achieving better outcomes and avoiding unnecessary health care utilization.

Innovative medicines are a crucial part of the solution to our most pressing health care challenges, as they can dramatically reduce existing disease burden while helping to avoid other costly medical care by keeping patients healthy and out of the hospital. Importantly, unlike other parts of the health care system, new medicines also provide long-term value to society as they pave the way for low-cost generics and biosimilars, which improve health in perpetuity while keeping spending on prescription medicines a small and steady share of overall health care spending.[60] Meanwhile, the costs of hospitalizations, emergency room visits, and other medical procedures and services comprise a growing share of the nation's overall health care burden and threaten the future sustainability of our health care system.

Better disease management achieved through use of prescription medicines has long been credited with avoiding health complications and avoiding spending on other costly health care services such as emergency room visits, hospital stays, surgeries and long-term care. But new medicines can also dramatically reduce spending on existing disease burden and associated health care costs. These features make prescription medicines a central component of any strategy to improve health while reducing costs.

Improved adherence to prescribed treatment regimens is one of the primary mechanisms by which prescription medicines have demonstrated these cost-saving or "offsetting" benefits. A large body of evidence demonstrates that better use of medicines can reduce other sources of health care spending across a broad range of chronic conditions. For example, one study by CMS and CVS researchers found that every $1 spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes, or high cholesterol generated $3 to $10 in savings on emergency room visits and inpatient hospitalizations.[61,62] In the Medicare program, savings associated with improved adherence to treatment regimens to address chronic conditions is also well documented:

- Medicare saved $2.3 billion due to improved adherence to congestive heart failure medications as a result of seniors and people with disabilities gaining Medicare Part D prescription drug coverage. Further improvements in adherence could potentially save Medicare another $1.9 billion annually, generating upwards of $22.4 billion in federal savings over 10 years.[63]
- Among Part D beneficiaries with diabetes, adherence to therapy reduced total Medicare spending by $4,000 and fully offset the cost of medications for select therapeutic areas over 2 years.[64]
- Another study found that if Medicare beneficiaries who were nonadherent to high blood pressure medications became adherent, Medicare could save $13.7 billion annually, with over 100,000 emergency department visits and over 7 million inpatient hospital days averted.[65]

Evidence of medication adherence driving medical cost savings is similarly apparent in the Medicaid program. Among Medicaid patients with congestive heart failure, hypertension, high cholesterol, diabetes, asthma/chronic obstructive pulmonary disease, depression and schizophrenia/bipolar disorder, improvements in adherence could produce $8 billion in savings annually.[66] Similarly, Medicaid patients with schizophrenia who were adherent to their antipsychotic treatments had, on average, $20,787 lower health care costs than non-adherent patients over the course of a year.[67] And if 80% of the children enrolled in Medicaid achieved high adherence to asthma treatment in just 14 states, Medicaid could achieve $57.5 million in savings in one year.[68]

Beyond common chronic illnesses, a growing body of evidence demonstrates savings from use of medicines to treat complex chronic health conditions. For example, research shows that better adherence to medicines to treat Parkinson's disease, Crohn's disease, cystic fibrosis, multiple sclerosis and advanced melanoma leads to lower health care spending.[69,70,71,72,73]

Notably, the cost-saving benefits of prescription medicines are specifically supported by research showing that use of medicines curbs overall Medicare spending growth. One study found that roughly half of the marked slowdown in Medicare spending growth over the past decade or more is attributable to fewer acute

events among patients with cardiovascular disease. Moreover, about half of the reduction in cardiovascular deaths is due to greater use of cardiovascular medications capable of reducing hospitalizations for heart disease and stroke. The authors underscore the role that improved use of therapies can play in reducing acute events and medical spending over time.[74]

Given the immense disease burden across a range of health conditions in the United States, the opportunity to improve health and drive savings through better medication adherence in the years ahead is substantial. Consider chronic illness: 6 in 10 Americans have one or more chronic conditions, and 42% have 2 or more.[75] The cost of treating chronically ill patients accounts for 90% of the nearly $4 trillion spent on health care in the United States each year.[76,77] The number of individuals with 3 or more chronic conditions is projected to nearly double by 2030, greatly increasing the economic burden of chronic disease.[78] But it is estimated that just half of medications for chronic diseases are taken as prescribed.[79]

Moreover, in communities of color, evidence suggests that lower medication adherence is a key driver of health inequities across insurance coverage types and patients with a wide range of diseases, such as high blood pressure, hepatitis C and many more.[80,81,82] The downstream consequences of medication nonadherence include increased health care costs,[83] poor health outcomes,[84,85] and increased risk of mortality.[86] Therefore, the longstanding disparate outcomes faced by patients of color and other underserved communities represent enormous potential to reduce health care costs through improved adherence, while also driving towards a more equitable health care system.

The IRA Threatens the Future Innovation That Will Make Our Health Care System More Sustainable

Unfortunately, as a result of the price-setting policies imposed by the Inflation Reduction Act (IRA), the biopharmaceutical innovation most likely to drive down other health care costs will unfortunately be discouraged. In fact, these policies are expected to reduce the number of medicines developed in the future, some of which could reduce or eliminate the need for hospitalizations, surgeries, or other costly medical care. Accounting for this negative impact on patient health, one study from economists at the University of Chicago estimating the impact of certain price setting policies on biopharmaceutical innovation, found they would increase overall health care spending by $50.8 billion over a 20-year period.[87]

Specifically, the IRA allows the government to set prices for eligible medicines in Medicare. Small molecules—those that typically come in pill or capsule form—may be selected just 7 years after FDA approval, and biologics can be selected at 11 years—with the government-set price going into effect for both types of medicines 2 years later. As a result, these medicines would face price setting earlier than they would otherwise face generic or biosimilar competition. Shortening the timeframe by which manufacturers can earn potential revenues on medicines is expected to impact the future development of treatments.[88]

The timelines for price setting in the IRA also fails to recognize that after initial FDA approval, additional clinical studies—often those involving clinical trials—are conducted to understand the benefits of medicines in other diseases, treatment populations or in combination with other therapies. As a result, biopharmaceutical companies are now forced to make difficult decisions about whether it is feasible to invest in post-approval R&D that could lead to important new uses for already approved medicines. In disease areas

that rely heavily on this form of R&D to drive treatment advances for patients, the impact of these disincentives may be devastating.[89]

Additionally, CMS' inappropriate approach to defining qualifying drugs by active ingredient or moiety rather than by marketing application treatment under the new price setting framework further discourages the development of new dosage forms and formulations. To illustrate this point, while CMS was permitted to select 10 drugs for the first price-setting year, CMS' definition of drugs that qualify for price-setting enabled it to sweep in a broad range of dosage forms and formulations—including those that were submitted under entirely different drug applications. These actions send a clear signal discouraging drug manufacturers from developing new or improved dosage forms and formulations which offer to ease treatment burdens or improve outcomes for patients.

Moreover, by affording small molecule medicines a shorter timeframe on the market relative to other medicines before price-setting may occur, the "pill penalty" especially jeopardizes the development of these critical treatments and the post-approval R&D that is necessary to realize their full therapeutic potential. In disease areas such as cancer, where the majority of medicines approved are small molecules and post-approval R&D has been indispensable in driving progress for patients, the impact of price setting is expected to be substantial.[90] In fact, research shows more than 60% of small molecule cancer medicines approved a decade ago received additional indications in later years, and nearly half of those occurred 7 or more years after initial approval.[91]

One of the reasons small molecules play such an important role in the treatment of cancer is their unique ability to reach therapeutic targets inside cells. Similarly, the ability for small molecule medicines to cross the blood-brain-barrier also make them critical in the treatment of diseases with therapeutic targets inside the brain—including illnesses impacting the central nervous system, mental health conditions, neurodegenerative diseases, and many more.[92]

Beyond the reliance of small molecules in the treatment of many illnesses, they also provide great flexibility and convenience to patients, reducing barriers to treatment adherence—particularly as they are often available in oral dosage forms, which may be easily stored at home and self-administered. These features in turn reduce the burden of transportation challenges, caregiver costs, lost wages and other hurdles that have played a role in driving treatment non-adherence and longstanding health inequities.[93] Unfortunately, the IRA risks leaving many patients who rely on these valuable treatments behind.

In addition to the impacts on innovation, the IRA disrupts both the Hatch-Waxman and the BPCIA frameworks by substituting government price setting for future competition from generics and biosimilars. That is because, as the law has no floor price, it allows the government to impose such low prices on an innovator product that biosimilar and generic manufacturers may not be able to compete in the market, discouraging them from bringing products to market in the first place. This risk is heightened by the fact that generic and biosimilar manufacturers will not be able to predict with any certainty whether the branded reference product they are seeking to compete against will be selected for price setting under the IRA at the time when they need to make their investment and development decisions.

Specifically, with regard to small molecule drugs, the IRA undermines existing incentives for generic competition established in the Hatch-Waxman Act of 1984 by implementing price-setting far earlier than current timelines for generic competition. Currently the average effective patent life for small molecule drugs before generics enter the market is 13 to 14 years.[94] But under the IRA, the government may impose a set price for small molecule medicines 9 years after FDA approval, far earlier than current timelines. This timeline may be further exacerbated by CMS's inappropriate approach to defining qualifying drugs by active ingredient or moiety rather than by marketing application. That means potential generics must now weigh the economic viability of entering the market to compete against a brand product with a low government-set price. But generics rely on the ability to offer sharply lower prices to attract market share from brand competitors. In fact, generics often enter the market immediately upon patent expiration and are often adopted rapidly as a result of this successful dynamic. Today, 90% of prescriptions filled at the pharmacy are filled with generic or biosimilar medicines and many capture as much as 90% of the market within 3 months of entry.[95] But with limited ability to offer a sharply lowered price to attract market share from the price-set brand, the IRA imposes restraints on generic competition and upends incentives that currently drive market entry.

With regard to biologic medicines, the IRA will also strongly discourage biosimilar development as the new framework imposed by the IRA is at odds with the timelines created under BPCIA. The IRA allows for biologics to be selected for price-setting at year 11, with the government-set price going into effect 2 years later, unless the biologic has a biosimilar available. But under the BPCIA, a biosimilar cannot be approved until 12 years after the first licensure of a reference biologic. Seemingly to mitigate against this tension, a special rule was established in the law, which allows for potential biosimilar manufacturers to request a "pause" in the price setting process if there's a "high likelihood" for biosimilar entry within the requisite timeframe. However, the biosimilar pause leaves too much uncertainty as to whether or not drugs with legitimate biosimilar competition will be able to be exempted from price setting. This reality makes the decision to invest in biosimilar development extremely risky and potentially financially infeasible moving forward. Biosimilar manufacturers face long development timelines and significant costs due to the complexities of biologics manufacturing. In fact, biosimilar development can take 7-8 years and $100-$250 million in investment.[96] As a result, the prospect of entering a market to compete against a low government price-set product is likely to serve as a significant disincentive for biosimilar manufacturers.

The negative impact on the future of generic and biosimilar competition is already apparent with selection of CMS' initial list of drugs for 2026.[97] In fact, the majority of medicines on CMS' initial drug selection list for price setting already face pending generic and biosimilar competition.[98] However, due to the provisions in the IRA and CMS' flawed interpretation, if the pending generic and biosimilar products are unable to reach the market by August 1, 2024, they will be forced to compete against price-controlled products, reducing the chances of success in the marketplace. The disruption to longstanding legal and regulatory frameworks comes with considerable risk, potentially jeopardizing future competition and savings driven by generics and biosimilars in the years ahead. These savings totaled $408 billion last year alone, including $130 billion to Medicare.[99]

Impacts of Vertical Integration on Competition in the Health Care Marketplace

The PBM industry is dominated by three large companies with opaque business practices

PBMs act as intermediaries on behalf of payers to control coverage and reimbursement arrangements for prescription medicines. Situated between the biopharmaceutical companies that research, develop and manufacture innovative medicines and the patients likely to benefit from those treatments, PBMs play a central role in determining which medicines patients will have access to and at what cost for hundreds of millions of Americans.

After nearly two decades of horizontal consolidation, the PBM industry is now dominated by three large companies: CVS Caremark, Express Scripts, and OptumRx.[100] The combined share of these three largest PBMs has grown significantly, from 48 percent of prescription drug claims in 2010 to 80 percent in 2023.[101,102] Today, just six companies control 94 percent of prescription drug claims[103] and patients residing in more than three quarters of states are subject to highly concentrated "PBM markets" as defined by Department of Justice (DOJ) and Federal Trade Commission (FTC) Horizontal Merger Guidelines.[104] In many instances, smaller PBMs contract or partner with larger PBMs to leverage their infrastructure, with the larger entities acting as rebate aggregators in the commercial market for the smaller entities.[105,106] Such arrangements further contribute to the overall concentration of negotiating power.[107]

In recent years, the three largest PBMs have vertically integrated with health insurers, specialty and mail order pharmacies, and provider groups to form large health care conglomerates. These vertically integrated organizations have enormous influence over which medicines patients have access to, the circumstances under which those medicines are covered, and when and where they can be dispensed or administered to patients. The three largest PBMs have become key drivers of revenues and profits for their respective vertically integrated organizations.[108] Express Scripts generated more than 70 percent of its parent company's total revenues, and OptumRx and CVS Caremark were responsible for approximately one third of their affiliated insurance companies' total revenue in 2023.[109]

Extensive consolidation and vertical integration throughout the health care delivery system, including PBMs, insurers, hospitals, providers, and their affiliates, can have wide reaching effects on (1) patients' out-of-pocket costs, (2) patients' access, choice, and quality of care, (3) broader health system costs, and (4) market dynamics.

Consolidation and Vertical Integration in the Health Care System Impact Patient Access and Costs

Government agencies, economists, and other experts have noted that PBMs' fee models based on list prices can incentivize PBMs to favor medicines with higher list prices to maximize their revenues.[110,111] These dynamics demonstrate that having a generic or biosimilar version of a branded medicine available on the market is no longer sufficient for driving the expected cost savings to patients or the health care system. According to a Senate Finance Committee report, "PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price—and PBMs may retain at least a portion of what they negotiate."[112] Industry analysts have noted that these market dynamics have prompted some manufacturers to introduce two identical versions of a product – one with a higher list price and large rebates and a version with a lower list price, giving payers the option of which to cover.[113] This dynamic is especially acute when biosimilar and generic manufacturers are seeking to introduce lower list price versions of branded medicines. The three large PBMs appear to favor the versions with large rebates and have in some cases blocked access to the lower list priced options by

excluding them from their formularies.[114,115] The Health and Human Services (HHS) Office of Inspector General (OIG) has indicated that PBMs may have incentives to penalize manufacturers for reducing list prices, including removing medicines from the formulary or placing them on a less-preferred cost sharing tier, both of which may result in higher costs for patients.[116] In a recent survey, more than two thirds of biopharmaceutical company respondents indicated that they perceived list-price based fees charged by PBMs as a barrier to lowering list prices.[117]

Covering higher list price products with large rebates may financially benefit the PBM and health plan but can leave patients paying significantly more out of pocket due to benefit designs and pharmacy network arrangements established by PBMs and their vertically integrated affiliates. PBMs and health plans typically require patients with deductibles and coinsurance – who pay a percentage of the cost of their medicine rather than a fixed copayment – to pay based on the undiscounted list price. Benefit designs that incorporate high deductibles and coinsurance expose patients to high out-of-pocket costs, even though PBMs and health plans are often receiving a significant discount. This can result in patients paying more for their medicines than their health plan. For example, among drugs with high rebates, Part D beneficiary cost sharing can exceed plans' net costs.[118] The Government Accountability Organization (GAO) found that for 79 of the top 100 highly rebated medicines in Medicare Part D, the total costs to beneficiaries exceeded the total net costs to plan sponsors by nearly 400 percent ($21 billion vs. $5.3 billion).[119]

In addition, slow uptake of lower cost generic and biosimilar alternatives is directly related to the ability of PBMs and their affiliated specialty pharmacies to prefer medicines with higher list prices, which can increase costs for patients.[120] For example, newly available biosimilars for a leading biologic to treat autoimmune conditions initially struggled to gain market share due to significant access restrictions imposed by the big three PBMs. Despite estimates that substituting the biosimilar would lower employer costs by 58 percent and patient costs by 68 percent, early uptake was largely concentrated among patients covered by smaller PBMs and health plans.[121] According to a recent report from IQVIA, PBMs and PBM-owned specialty pharmacies have strong financial incentives to encourage uptake of the versions that are most profitable for them. IQVIA estimates that compared to utilization of the brand name biologic, a full transition to biosimilars for this autoimmune product would reduce PBM and affiliated specialty pharmacy profits by 84 percent and 78 percent, respectively.[122]

Likely in an effort to mitigate this potential loss of profit, two of the three largest PBMs, CVS Health and Express Scripts, launched their own version of this autoimmune biosimilar in April 2024.[123, 124] CVS Health will co-market a biosimilar through Ireland-based Cordavis,[125] a wholly owned subsidiary, and Express Scripts' biosimilar will be co-branded by Cayman Islands-based private-label distributor, Quallent Pharmaceuticals.[126,127] These arrangements allow CVS and ESI to profit off of their referral stream. It does not appear that CVS provides any meaningful manufacturing services related to their co-branded product other than a captive referral stream. These arrangements will allow CVS and Express Scripts to profit three separate times as the medicine makes its way through the supply chain: once when the biosimilar is commercialized by their affiliate, again when the product is placed on formulary, and a third time when the prescription is filled at a pharmacy they own. This profit potential creates a clear incentive for PBMs to favor coverage of the biosimilar they have a financial stake in and to pad their own bottom lines by steering

patients to fill those prescriptions at PBM-owned pharmacies. This co-ownership structure also allows the PBMs to keep remuneration from the drug, and to keep those remuneration flows related to the drugs secret.

Having access to lower list-priced medicines could reduce out-of-pocket costs for some patients by hundreds or thousands of dollars per prescription,[128] yet PBMs often exclude generics, biosimilars, and lower list priced versions of products from their formularies.[129] One study found the availability of lower list price versions of medicines to treat high cholesterol and hepatitis C was associated with a 14 percent to 60 percent reduction in out-of-pocket costs for commercially insured patients, with the largest savings observed for patients with coinsurance.[130] PBM decisions to deny or restrict coverage for generic drugs can also undermine market forces meant to drive investment in generic manufacturing, which can create or exacerbate generic drug shortages.[131,132]

PBMs often bill their health plan clients more than what they pay to the pharmacy for medicines and keep the difference, a practice known as spread pricing. An investigation by the *Wall Street Journal* (WSJ) revealed another way that vertically integrated PBMs profit from spread pricing: by marking up the cost of low-cost generic drugs and reimbursing their vertically integrated pharmacies significantly more than their pharmacies' acquisition cost. The WSJ investigation revealed that generic drugs dispensed by PBM-affiliated pharmacies can cost thousands of dollars more than the very same generic drugs dispensed at independent pharmacies because of this practice. Across a selection of generic drugs analyzed by the WSJ, the prices that CVS Health and Cigna/ Express Scripts charged to plan sponsors were 24 and 27 times higher, respectively, than the prices charged by the generic manufacturers themselves. For one generic cancer drug, CVS Health and Cigna/ Express Scripts reimbursed their own specialty pharmacies between $6,600 and $7,000 per prescription, while the same generic drug cost just $54 at a non-affiliated pharmacy.[133] The potential to earn high profits on otherwise low-cost generic drugs further incentivizes vertically integrated PBMs to steer patients to their own specialty and mail order pharmacies.

Generic drugs are a central part of the cost-containment mechanism built into the prescription medicine lifecycle. Once a brand medicine's patent protection ends and generics launch, it is not unusual for the cost of treatment to decline by upwards of 90 percent.[134] Marking up the prices of generic drugs eliminates this important source of cost savings in the health care system. It can also result in significantly higher out-of-pocket costs for patients, particularly those with coinsurance or deductibles. In the case of the aforementioned generic cancer drug, a CVS Health patient with 25 percent coinsurance would be responsible for paying $1,750 out of pocket if they filled their prescription at CVS Health's vertically integrated specialty pharmacy vs. $13.50 at an independent pharmacy. According to one health policy expert, "Someone in the middle of that transaction is making a lot of money, and they're doing it at the detriment of the consumers."[135]

Researchers estimate that misaligned PBM incentives result in U.S. consumers overpaying for generic drugs by as much as 20 percent.[136] Consequently, in 2021, 70 percent of Medicare Part D spending on 45 high-utilization generic drugs went to intermediaries' gross profit, rather than to the generic manufacturers who produced the drug.[137] These dynamics, whereby intermediaries leverage their vertically integrated relationships to absorb would-be generic manufacturer margins, have contributed to the instability in the

generics market leading to drug shortages, further throwing off the balance established under Hatch-Waxman.[138, 139]

Hospitals and the 340B program increasingly impact patient access and affordability

Unfortunately, health plans, PBMs, large hospital systems, and others in the supply chain continue to find ways to benefit from spending on medicines to bolster their own profitability, which often negatively impacts patient access and affordability. For example, hospitals have rapidly consolidated over the past decade, buying up physician practices and merging with other hospitals. Today, nearly 90% of U.S. metropolitan areas have "highly concentrated" hospital markets.[140] As a result, these hospital systems can leverage their size and lack of market competition to mark up the cost of medicines by an average of 500% from what they paid to acquire the medicine.[141] According to a study in JAMA, leading hospitals for cancer treatment mark up the cost of common cancer medicines for commercially insured patients by as much as 634%.[142] Another study found that hospital outpatient departments markup physician-administered drugs by 76% compared to physician offices.[143] These trends are not only impacting patient costs, and access to treatments, but also costs for the broader health system.

Given trends towards hospital consolidation, it is not surprising that hospital spending, which represents the largest share of health spending in the U.S., continues to grow. Hospitals account for nearly a third of every dollar spent on health care,[144] while retail and non-retail prescription medicine spending represent just 14%.[145] Additionally, hospital spending increased 4.5 times more than retail prescription drug spending between 2016 and 2021.[146] According to CMS, hospital spending is on track to expand by around 6% per year, through at least 2031.[147]

A central driver of hospital consolidation and increasing costs is the 340B drug pricing program. Congress created the 340B program in 1992 to provide access to discounts on outpatient medicines for certain health care safety-net providers treating large numbers of uninsured or otherwise vulnerable patients. [148] To achieve that goal, hospitals and clinics that meet certain eligibility criteria receive steep discounts on outpatient medicines from manufacturers. The average discount on 340B medicines is nearly 60%,[149] and in some cases, the discounts bring the price of a medicine down to just a penny.

The 340B program of today is unrecognizable in both character and size when compared to the targeted program Congress originally created, with more hospital conglomerates and for-profit companies using these discounts for themselves, leaving vulnerable patients behind.[150] For example, large hospital systems that generate significant profits on 340B discounted medicines may use these profits to expand care in wealthier areas while underinvesting in hospital locations in lower income areas, which often serve patients of color.[151] To make matters worse, experts note the program creates financial incentives to further consolidate and shift the administration of medicines to more costly hospital outpatient settings—which again increases costs for patients, employers, health plans and the entire health care system.[152,153]

Purchasing dynamics associated with the 340B program also create misaligned incentives to prescribe more expensive medicines, further driving up costs for patients and payers. While eligible hospitals receive large discounts on 340B medicines, they may still be reimbursed by payers at the same rates as non-340B

providers, creating financial incentives for 340B hospitals to prescribe more and/or more expensive medicines to capture a greater "spread."[154,155] According to Harvard researchers, "the most insidious effect of 340B...is the incentive it gives clinics to prescribe high-cost medications, even when effective and far cheaper options exist."[156] To this point, there is also evidence demonstrating the 340B program incentivizes use of more expensive medicines in the Medicare program when a lower-cost biosimilar may be available.[157]

As a result of these trends, several reports and studies have found higher drug spending at 340B facilities for Medicare and commercially insured patients compared to non-340B sites of care.[158,159] Additionally, MedPAC has noted that, although 340B hospitals are able to purchase outpatient medicines at a steep discount, beneficiary cost sharing in Medicare Part B is based off the default payment rate (typically, average sales price plus 6%), which leaves seniors paying higher out-of-pocket costs than they would face if Medicare paid less for 340B-discounted medicines.[160]

For-profit pharmacies, often affiliated with large PBMs, also profit from the 340B program. However, evidence shows the 340B discounts received by these pharmacies are rarely shared with patients.[161] At this point, it seems patients are the only ones not benefiting from the billions of dollars in discounts manufacturers provide each year to fund the 340B program.

Policy Proposals to Enhance 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 are critical for supporting affordable care. Prior to the passage of the IRA, the natural evolution of medicines was that, after an innovator undertook the time-consuming, uncertain, and expensive development process and obtained FDA approval, it would enjoy an appropriate period of IP protections, including both data protection and patent protections, following which generic or biosimilar versions, as appropriate, could be approved. Indeed, this is the very cycle that Hatch-Waxman and BPCIA were intended to encourage. The IRA is already significantly disrupting this cycle, reducing the incentives for the introduction of innovative therapies and disrupting the competition that results when there are multiple alternatives in a given therapeutic class. Furthermore, the increasing impact of vertical integration is hindering the ability of patients to access lower cost alternatives to brand medicines once they are available.

There are several areas where competition could be enhanced without reducing incentives for innovation, which are described below:

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 the process, innovator companies are required to submit information on patents claiming the drug substance, drug product, and methods of using the drug to FDA (known as "listing") for publication 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 a lawsuit 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 issues prior to marketing of the generic product. Hatch-Waxman also provided an incentive to generics to challenge patents under the Hatch-Waxman process in the form of 180-day generic exclusivity for the first generic to file a paragraph IV certification against later filed generic applicants.

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" standard, which is a legal standard involving 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. 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.

Advance 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.

Ensure the Patent System Continues to Provide Certainty to Investors and Innovators

As noted above, the IP system is a fundamental incentive to innovate. When making long-term decisions about investments in R&D, companies look for certainty, including with respect to the availability of IP protections that would protect the investments. PhRMA is pleased to see the Committee engaging on ways to ensure that the U.S. patent system continues to incentivize innovation and provide certainty to investors and innovators across sectors including with respect to providing clarity for patent owners on patent subject matter eligibility and Patent Trial and Appeal Board proceedings.

Ensure That Agencies Treat Information Shared Amongst Them with Proper Confidentiality Considerations

There have been discussions and legislation proposed about requiring enhanced collaboration between the USPTO and FDA. Data have not been presented suggesting there is a systemic issue warranting such legislation. There are also fundamental differences in how the agencies treat information provided to them, as the USPTO generally publishes information it receives after a period of time and FDA protects the highly sensitive trade secret information it requires about products. Any requirement to share such information with the USPTO would need to address fully confidentiality considerations.

Break the Link Between PBM Compensation and the Price of Medicines

To the extent that PBMs provide services to stakeholders in the pharmaceutical supply chain, they should be entitled to compensation based on the value of those services. However, PBM compensation should not be tied to the price of a medicine. PhRMA supports efforts in the both the House and the Senate to "delink" PBM compensation from the price of a medicine in both the commercial and Part D markets and instead limit PBM compensation to bona fide service fees based on the fair market value of services appropriately rendered for a manufacturer.[162] Multiple bills that would accomplish this goal are currently under consideration by Congress, including the Modernizing and Ensuring PBM Accountability Act (S.2973) and the Delinking Revenue from Unfair Gouging Act (DRUG) Act (H.R. 6283).[163,164,165,166] The Congressional Budget Office (CBO) has projected that delinking in both the Part D and commercial market would reduce federal spending.[167,168]

Rebate Pass Through at the Point-of-Sale

Requiring PBMs and health plans to share the savings they receive on medicines directly with patients at the pharmacy counter in the commercial market and Medicare Part D would lower patient out-of-pocket costs and help realign payer incentives. Patients who take brand medicines with large rebates could see sizable reductions in out-of-pocket costs if the rebates were passed on to them at the pharmacy counter.[169] Actuaries estimate that sharing negotiated rebates directly with patients at the point-of-sale would have a negligible impact on premiums.[170] The substantial savings for patients at the pharmacy counter would outweigh those premium increases and provide patients with increased access and affordability for often lifesaving medicines.

PBM Transparency

Lack of transparency and the complexity of PBM arrangements can make it difficult for plan sponsors to assess PBM performance on their behalf. Requiring PBMs (and their affiliates) to report aggregate information on prescription drug utilization, costs, rebates, and fees, as well as conflicts of interest would provide information necessary for employers and plan sponsors to properly evaluate whether PBMs are effectively managing the pharmaceutical benefit and would help ensure accountability to PBM customers.[171] According to CBO, proposed federal legislation that would require PBMs to disclose detailed aggregate information on prescription medicine spending and utilization to plan sponsors could enable employers and plan sponsors to better evaluate PBM contract provisions and obtain more favorable contracting terms, as well as increase competition among PBMs.[172,173,174] Improved transparency into PBMs' business model, including existing conflicts of interest, would provide valuable information to federal and state policymakers, employers, and patients.

Protect Patient Assistance

Policymakers should ensure that patient assistance benefits patients by closing policy loopholes that allow PBMs, their affiliates, and other vendors to utilize accumulator adjustment programs (AAPs), copay maximizers, and alternative funding programs to capture money intended for patients. The bipartisan Help Ensure Lower Patient (HELP) Copays Act would require commercial health plans to count patient assistance towards deductibles, coinsurance, copayments and out-of-pocket limits. This patient-centered reform would protect patients' choices about how they pay their cost-sharing obligations, effectively prohibiting the use of AAPs in all non-grandfathered commercial health plans and mitigating copay maximizers. The bill builds on action taken by 19 states, DC, and Puerto Rico that have already passed AAP bans in their state-regulated markets.[175]

Address the "Pill Penalty"

Rectify the disparate treatment of small molecule medicines under the IRA by aligning the price stetting timeline for small molecule medicines with those applicable to other drugs under the IRA's Medicare Drug Price Negotiation Program.

Fix the "Special Rule" for Biosimilars in the IRA

Ensure that biosimilar products that are seeking to come to market have adequate certainty and predictability under the "Special Rule" process to allow the necessary time to launch. Improvements should include making the pause automatic in certain circumstances, making the pause two years long, and providing a more appropriate timeframe for product launch.

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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 research and development of new medicines, and negatively impact patient access to innovative therapies and cures. 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 pragmatic solutions. 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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[1] PhRMA, 2023 PhRMA Annual Membership Survey, 2023, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/PhRMA_membership-survey_single-page_70523_es_digital.pdf.
[2] PhRMA analysis of NIH grant data.
[3] Research!America, U.S. Investments in Medical and Health Research and Development 2016 – 2020. January 2022.
[4] Schlander, M., Hernandez-Villafuerte, K., Cheng, CY. et al. How Much Does It Cost to Research and Develop a New Drug? A Systematic Review and Assessment. *PharmacoEconomics* 39, 1243–1269, 2021. https://doi.org/10.1007/s40273-021-01065-y
[5] JA DiMasi, Grabowski, RW Hansen. Innovation in the pharmaceutical industry: New estimates of R&D costs. *J Health Econ*. 2016;47:20-33. https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub.
[6] US Food and Drug Administration. Summary of NDA Approvals & Receipts, 1938 to the Present. https://www.fda.gov/about-fda/histories-fda-regulated-products/summary-nda-approvals-receipts-1938-present.
[7] US Food and Drug Administration. New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products 2012 – 2014. http://wayback.archive-it.org/7993/20161022052126/http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm.
[8] US Food and Drug Administration: Novel Drug Approvals for 2022. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022.
[9] US Food and Drug Administration. New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products 2015 – 2021. https://www.fda.gov/drugs/development-approval-process-drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products.
[10] Congressional Budget Office. Prescription Drugs: Spending, Use, and Prices. January 2022. https://www.cbo.gov/publication/57772.
[11] IQVIA. The Use of Medicines in the U.S. 2024: Spending and Usage Trends and Outlook to 2028. April 2024. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2024/the-use-of-medicines-in-the-us-2024-usage-and-spending-trends-and-outlook-to-2028.pdf.
[12] Association for Accessible Medicines, The U.S. Generic & Biosimilar Medicines Savings Report, September 2023.
[13] Altarum Institute. Projections of the Non-Retail Prescription Drug Share of National Health Expenditures. July 2022. https://drugchannelsinstitute.com/files/Projections-of-Non-Retail-Drug-Share-of-NHE-2022.pdf.
[14] For example, the price of a medicine commonly used to prevent cardiovascular disease dropped 95% between 2007 and 2017, while the average charge for a surgical procedure to treat it increased 94% over the same period. PhRMA analysis of Healthcare Cost and Utilization Project (HCUP). National (Nationwide) Inpatient Sample (NIS) database. 2007, 2017. Accessed July 2020. https://www.ahrq.gov/research/data/hcup/index.html.
[15] Percher E. Trends in Profitability and Compensation of PBMs and PBM Contracting Entities. Nephron Research. September 2023.
[16] 84 Fed. Reg. at 2341.
[17] Association for Accessible Medicines. The U.S. Generic & Biosimilar Medicines Savings Report. September 2023. https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf .
[18] Biosimilars Council, Humira Biosimilar Landscape: Still Waiting, January 2024. https://biosimilarscouncil.org/resource/humira-biosimilar-landscape-still-waiting.
[19] TEConomy Partners, LLC. The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. May 2024. Report prepared for PhRMA. https://www.teconomypartners.com/wp-content/uploads/2024/05/The-Econ-Impact-of-U.S.-Biopharma-Industry-2024-Report.pdf
[20] Adis R&D Insight Database.
[21] Battelle Technology Partnership Practice, The Economic Impact of the Biopharmaceutical Industry, July 2013.
[22] TEConomy Partners, LLC. The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. May 2024. Report prepared for PhRMA. https://www.teconomypartners.com/wp-content/uploads/2024/05/The-Econ-Impact-of-U.S.-Biopharma-Industry-2024-Report.pdf
[23] *Ibid.*
[24] von Krogh, G, et al., "The Changing Face of Corporate Venturing in Biotechnology," Nature Biotechnology 30, no. 10 (2012): 911-15.

[25] TEConomy Partners, LLC. The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. May 2024. Report prepared for PhRMA. https://www.teconomypartners.com/wp-content/uploads/2024/05/The-Econ-Impact-of-U.S.-Biopharma-Industry-2024-Report.pdf
[26] Patent and Trademark Office Director Andrei Iancu, 2018, Public Remarks, "The State of Care: Innovation and Access," July 2018.
[27] See 35 U.S.C. 271(e)(1).
[28] Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984)
[29] Grabowski H et al. Continuing trends in U.S. brand-name and generic drug competition. J Med Economics 2021;24(1):908-917.
[30] *Ibid*.
[31] Cencora. US Biosimilars Landscape, Updated as of March 2024. https://www.amerisourcebergen.com/-/media/assets/cencora-biosimilars-usmarketlandscape-11mar24.pdf.
[32] Association for Accessible Medicines. 2023 U.S. Generic and Biosimilar Medicines Savings Report, September 2023. https://accessiblemeds.org/resources/reports/2023-savings-report
[33] 35 U.S.C. § 156(c)(3). See H.R. Rep. No. 98-857, at 17 (1984); 130 Cong. Rec. 23,058 (1984) (statement of Rep. Synar) ("The average effective patent life of a pioneer drug is reduced by 7 years because of FDA review"); id. at 23,059 (statement of Rep. Kastenmeier) (noting that "the effective market life of [innovators'] patented inventions was being eroded by excessively long periods of regulatory review").
[34] H.R. Rep. No. 98-857, at 41 (1984).
[35] 130 Cong. Rec. 23,060 (statement of Rep. Kastenmeier).
[36] Association for Accessible Medicines, The U.S. Generic & Biosimilar Medicines Savings Report, September 2023.
[37] Zachary S. Predmore, et al., Improving Antipsychotic Adherence Among Patients With Schizophrenia: Savings for States, 66 Psychiatric Services in Advance 343 (2015).
[38] Rimal Bera, et al., Hospitalization Resource Utilization and Costs Among Medicaid Insured Patients With Schizophrenia With Different Treatment Durations of Long-Acting Injectable Antipsychotic Therapy, 34 *Journal of Clinical Psychopharmacology,* 30, 2014.
[39] Government Accountability Office (GAO). Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions, 2009. Available at: www.gao.gov/products/GAO-09-742.
[40] Wendy H. Schacht, *Federal R&D, Drug Discovery, and Pricing: Insights From the NIH-University-Industry Relationship*, Report RL32324 (Congressional Research Service), November 30, 2012.
[41] PhRMA. 2023 PhRMA Annual Membership Survey, July 2023. https://phrma.org/resource-center/Topics/Research-and-Development/2023-PhRMA-Annual-Membership-Survey.
[42] See Pierre Azoulay and others, "Public R&D Investments and Private-Sector Patenting: Evidence From NIH Funding Rules," *Review of Economic Studies*, vol. 86, no. 1 (January 2019), pp. 117–15. Available at: https://academic.oup.com/restud/article/86/1/117/5038510?login=true.
[43] The National Institutes of Health (NIH), The NIH and Its Role in Technology Transfer, https://www.techtransfer.nih.gov/nih-and-its-role-technology-transfer. NIH, The NIH and Its Role in Technology Transfer, https://www.techtransfer.nih.gov/nih-and-its-role-technology-transfer.
[44] The Congressional Budget Office, Research and Development in the Pharmaceutical Industry, April 2021. https://www.cbo.gov/publication/57126.
[45] Department of Health and Human Services (DHHS), NIH. (2001). Report to the United States Congress, NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected. July 2001.
[46] Kneller, R., The Importance of New Companies for Drug Discovery: Origins of a Decade of New Drugs. *Nature Reviews/Drug Discovery*, 9, 867-82, 2010.
[47] Chakravarthy R, Cotter K, DiMasi J, et al. Public- and private-sector contributions to the research and development of the most transformational drugs in the past 25 years: from theory to therapy. Ther Innov Regul Sci. 2016;50(6):759-768.
[48] Galkina Cleary, E., Beierlein, J. M., Khanuja, N. S., McNamee, L. M., & Ledley, F. D. (2018). Contribution of NIH funding to new drug approvals 2010-2016. Proceedings of the National Academy of Sciences of the United States of America, 115(10), 2329–2334. https://doi.org/10.1073/pnas.1715368115.
[49] D. Schulthess et al, The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals, September 2023, https://vitaltransformation.com/2022/09/the-relative-contributions-of-nih-and-private-sector-funding-to-the-approval-of-new-biopharmaceuticals/.
[50] NIH, Licensing Overview, https://www.techtransfer.nih.gov/licensing.
[51] JA DiMasi, Grabowski, RW Hansen. Innovation in the pharmaceutical industry: New estimates of R&D costs. *J Health Econ*. 2016;47:20-33.
[52] Thomas, J. March-In Rights Under the Bayh-Dole Act. CRS, 2016. Available at: https://fas.org/sgp/crs/misc/R44597.pdf.

[53] NIH. NIH Office of the Director: Determination in the Case of Fabrazyme Manufactured by Genzyme Corporation, 2010. Available at: https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf.
[54] NIH. Reports of the NIH Panels on Cooperative Research and Development Agreements: Perspectives, Outlook, and Policy Development, December 1994. Available from: https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH_%20CRADA_Report_on_Reasonable-Pricing_Clause_1994.pdf
[55] Press Release, NIH News, April 11, 1995. Available from: https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf.
[56] https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf
[57] Bayh, B. and Dole, R. Our Law Helps Patients Get New Drugs Sooner. *Washington Post* op-ed, 2011. Available at: https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?itid=sr_1.
[58] Siegel, RL, Miller, KD, Wagle, NS, Jemal, A. Cancer statistics, 2023. *CA Cancer J Clin*. 2023; 73(1): 17-48. doi:10.3322/caac.21763.
[59] CDC, NCHS, Deaths: Final Data for 2007. Vol. 58, #19, May 2010. https://www.cdc.gov/nchs/data/nvsr/nvsr58/nvsr58_19.pdf; CDC, NCHS, Deaths: final data for 2019. Natl Vital Stat Rep. 2021;70(8):1-87. Accessed July 2022. https://www.cdc.gov/nchs/data/nvsr/nvsr70/nvsr70-08-508.pdf.
[60] Altarum Institute. Projections of the Non-Retail Prescription Drug Share of National Health Expenditures. July 2022. https://drugchannelsinstitute.com/files/Projections-of-Non-Retail-Drug-Share-of-NHE-2022.pdf.
[61] MC Roebuck et al. Medication Adherence Leads To Lower Health Care Use And Costs Despite Increased Drug Spending. Health Aff 30 no. 1 (2011): 91-9.
[62] Urick, B. Y., et al. (2023). Estimating Medical Cost Offsets from Continuous Adherence Improvement Using Commercially Insured Members' Real-World Data. In AMCP Conference. https://www.primetherapeutics.com/wp-content/uploads/2023/02/4085-C_-AMCP_SP23_AdherenceImprovement_POSTER.pdf.
[63] TM Dall et al. The Economic Impact of Medicare Part D Coverage on Congestive Heart Failure. AJMC, 2013;19:S97-S100
[64] Stuart, B. C., Dai, M., Xu, J., E Loh, F. H., & S Dougherty, J. (2015). Does good medication adherence really save payers money?. Medical care, 53(6), 517-523.
[65] Lloyd, JT., et al. How much does medication nonadherence cost the medicare fee-for-service program? Medical care 57.3 (2019): 218-224.
[66] MC Roebuck, et al. Impact of Medication Adherence on Health Services Utilization in Medicaid. Medical care 56.3 (2018): 266-273
[67] Pilon, D. P., C.; Lafeuille, M.; Zhdanava, M.; Lin, D.; Cote-Sergent, A.; Rossi, C.; Lefebvre, P.; Joshi, K (2021). Economic burden in Medicaid beneficiaries with recently relapsed schizophrenia or with uncontrolled symptoms of schizophrenia not adherent to antipsychotics. In Journal of Managed Care and Specialty Pharmacy (Vol. 27, pp. 904-914).
[68] G Rust, et al. Potential Savings from Increasing Adherence to Inhaled Corticosteroid Therapy in Medicaid-Enrolled Children. AJMC 2015 March 21(3):173-180
[69] YJ Wei, et al. Antiparkinson Drug Adherence and Its Association with Health Care Utilization and Economic Outcomes in a Medicare Part D Population. Value in Health 2014 17(2), 196-204.
[70] BG Feagan, et al. Healthcare Costs for Crohn's Disease Patients Treated with Infliximab: A propensity Weighted Comparison of the Effects of Treatment Adherence. J Med Econ. 2014;17(12):872-80.
[71] AL Quittner et al., Pulmonary Medication Adherence and Health-Care Use in Cystic Fibrosis. CHEST Journal 2014, 146(1), 142-151.
[72] Zhou, J. W., E.; Hira, N. (2022). Adherence to Cystic Fibrosis Transmembrane Regulator Modulator Therapies, Hospitalizations, and Medical Costs in Patients with Cystic Fibrosis Using Marketscan Commercial Claims and Encounters Database. In ISPOR Conference.
[73] K Gupte-Singh, et al. Adherence to Cancer Therapies and the Impact on Healthcare Costs among Patients with Advanced melanoma in the USA. Proceedings of the 22nd Annual International Meeting International Society of Pharmacoeconomics and Outcomes Research; 2017 May.
[74] DM Cutler, K Ghosh, KL Messer, TE, Raghunathan, ST Stewart, and AB Rosen, Explaining the Slowdown in Medical Spending Growth Among the Elderly, Health Affairs, February 2019.
[75] Buttorff C, Ruder T, Bauman M. Multiple Chronic Conditions in the United States. Rand Corporation, 2017.
[76] Centers for Disease Control and Prevention. Health and economic costs of chronic diseases. Published June 6, 2022. Accessed July 6, 2022. https://www.cdc.gov/chronicdisease/about/costs/index.htm
[77] Buttorff C, Ruder T, Bauman M. Multiple Chronic Conditions in the United States. Rand Corporation, 2017; National Health Expenditure Data: Historical. Center for Medicare & Medicaid Services. December 15, 2021.
[78] Partnership to Fight Chronic Disease (PFCD). What is the Impact of Chronic Disease on America?

[79] M Viswanathan et al. Interventions to Improve Adherence to Self-Administered Medications for Chronic Diseases in the United States: A Systemic Review. Ann of Internal Med, Dec 2012.
[80] Mehta KM, Yin M, Resendez C, Yaffe K. Ethnic differences in acetylcholinesterase inhibitor use for Alzheimer disease. Neurology. 2005 Jul 12;65(1):159-62. doi: 10.1212/01.wnl.0000167545.38161.48. PMID: 16009909; PMCID: PMC2830864.
[81] Lauffenburger JC, Robinson JG, Oramasionwu C, Fang G. Racial/ethnic and gender gaps in the use of and adherence to evidence-based preventive therapies among elderly Medicare part D beneficiaries after acute myocardial infarction. Circulation. 2014; 129:754–763.
[82] Schmittdiel JA, Steiner JF, Adams AS, et al. Diabetes care and outcomes for American Indians and Alaska natives in commercial integrated delivery systems: a Surveillance, PREvention, and ManagEment of Diabetes Mellitus (SUPREME-DM) Study. BMJ Open Diabetes Res Care. 2014;2(1):e000043. Published 2014 Nov 17. doi:10.1136/bmjdrc-2014-000043
[83] Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. Impact of medication adherence on hospitalization risk and healthcare cost. Med Care. 2005 Jun;43(6):521-30. doi: 10.1097/01.mlr.0000163641.86870.af. PMID: 15908846.
[84] Bansilal S, Castellano JM, Garrido E, Wei HG, Freeman A, Spettell C, Garcia-Alonso F, Lizano I, Arnold RJ, Rajda J, Steinberg G, Fuster V. Assessing the Impact of Medication Adherence on Long-Term Cardiovascular Outcomes. J Am Coll Cardiol. 2016 Aug 23;68(8):789-801. doi: 10.1016/j.jacc.2016.06.005. PMID: 27539170.
[85] Choudhry NK, Glynn RJ, Avorn J, Lee JL, Brennan TA, Reisman L, Toscano M, Levin R, Matlin OS, Antman EM, Shrank WH. Untangling the relationship between medication adherence and post-myocardial infarction outcomes: medication adherence and clinical outcomes. Am Heart J. 2014 Jan;167(1):51-58.e5. doi: 10.1016/j.ahj.2013.09.014. Epub 2013 Oct 17. PMID: 24332142.
[86] Khunti K, Seidu S, Kunutsor S, Davies M. Association Between Adherence to Pharmacotherapy and Outcomes in Type 2 Diabetes: A Meta-analysis. Diabetes Care. 2017 Nov;40(11):1588-1596. doi: 10.2337/dc16-1925. Epub 2017 Aug 11. PMID: 28801474.
[87] TJ Philipson, G Di Cera, Issue Brief: The Impact of Biopharmaceutical Innovation on Health Care Spending. https://ecchc.economics.uchicago.edu/2022/08/03/the-impact-of-biopharmaceutical-innovation-on-health-care-spending.
[88]TJ Philipson, Y Ling, R Chang, The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act, October 2023, https://ecchc.economics.uchicago.edu/files/2023/10/Small-Molecule-Paper-Final-Oct-5-2023.pdf.
[89] TJ Philipson, Y Ling, R Chang, The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act, October 2023, https://ecchc.economics.uchicago.edu/files/2023/10/Small-Molecule-Paper-Final-Oct-5-2023.pdf.
[90] PhRMA, Emerging Value in Oncology, How Ongoing Research Expands the Benefits of Oncology Medicines, July 2023. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/PhRMA_Emerging-Value-Report/PhRMA_Emerging-Value-Report_FIN-web_July2023_v2.pdf.
[91] Partnership for Health Analytic Research, Implications of the Inflation Reduction Act Price Setting Provisions on Post-approval Indications for Small Molecule Medicines, June 2023. https://www.pharllc.com/publication/implications-of-the-ira-price-setting-provisions-on-post-approval-indications-for-small-molecule-medicines.
[92] PhRMA, Small Molecule Medicines: Why They're Vital for Patients, 2023. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/S-U/Pharma_Small-Molecule_White_Paper_factsheet_042623_v5.pdf.
[93] PhRMA, Small Molecule Medicines: Why They're Vital for Patients, 2023. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/S-U/Pharma_Small-Molecule_White_Paper_factsheet_042623_v5.pdf.
[94] Grabowski H, Long G, Mortimer R, Bilginsoy M. Continuing trends in U.S. brand-name and generic drug competition. J Med Econ. 2021 Jan-Dec;24(1):908-917.
[95] AAM, The U.S. Generic & Biosimilar Medicines Savings Report, September 2023. https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf
[96] Blackstone EA, Joseph PF. The economics of biosimilars. Am Health Drug Benefits. 2013 Sep;6(8):469-78.
[97] HHS, HHS Selects the First Drugs for Medicare Drug Price Negotiation, September 2023. https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html.
[98] Analysis based on publicly available information at FDA Orange Book and Purple Book and press sources. Additional generic applications may be pending with FDA beyond the 3 noted.
[99] AAM, The U.S. Generic & Biosimilar Medicines Savings Report, September 2023. https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.
[100] Herman B. FTC may probe pharmacy benefit managers. Axios, February 2022. https://www.axios.com/ftc-study-pharmacy-benefit-managers-drug-prices-3078116f-382a-4b05-ac62-da5bc1d1b892.html.
[101] Top 50 PBM Companies and Market Share by Annual Prescription Volume (Second Quarter 2010). *Drug Benefit News*, April 2010.
[102] Fein A. The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. *Drug Channels Institute,* March 2024.

[103] *Ibid.*
[104] Guardado J. Competition in Commercial PBM Markets and Vertical Integration of Health Insurers with PBMs: 2023 Update. American Medical Association, 2023. https://www.ama-assn.org/system/files/prp-pbm-shares-hhi.pdf.
[105] Fein A. The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. *Drug Channels Institute,* March 2024.
[106] Levitt JE, Lee DY. Cautionary tale: Plan sponsors losing manufacturer rebate dollars to PBMs through rebate aggregators. BenefitsPRO. April 2021. https://www.benefitspro.com/2021/04/15/cautionary-tale-plan-sponsors-losing-manufacturer-rebate-dollars-to-pbms-through-rebate-aggregators.
[107] PBM Accountability Project. Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers, December 2021. https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true.
[108] Potter W. Big Insurance Earnings Report Analysis 2023, April 2024. https://wendellpotter.substack.com/p/big-insurance-2023-revenues-reached.
[109] *Ibid.*
[110] 84 Fed. Reg. at 2341.; Medicare Payment Advisory Commission. Report to the Congress: Medicare Payment Policy. Chapter 13: The Medicare Prescription Drug Program (Part D): Status Report, March 2021. https://www.medpac.gov/document/chapter-13-the-medicare-prescription-drug-program-part-d-status-report-march-2021-report.
[111] Sood N, Ribero R, Van Nuys K. The Association Between Drug Rebates and List Prices. USC Schaeffer White Paper, February 2020. https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices.
[112] Senate Finance Committee. Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug. 2021. https://www.finance.senate.gov/imo/media/doc/Insulin%20Exhibit%20List.pdf .
[113] Kansteiner F. Viatris launched 2 version of its interchangeable insulin biosimilar. Why? Fierce Pharma, November 2021. https://www.fiercepharma.com/pharma/viatris-launches-two-versions-its-interchangeable-biosimilar-semglee-bid-to-tackle-pricing.
[114] Fein AJ. Four Crucial Questions About the Humira Biosimilar Price War. Drug Channels Institute, July 2023. https://www.drugchannels.net/2023/07/four-crucial-questions-about-humira.html.
[115] Fein AJ. The Big Three PBMs' 2023 Formulary Exclusions: Observations on Insulin, Humira, and Biosimilars. Drug Channels Institute, January 2023. https://www.drugchannels.net/2023/01/the-big-three-pbms-2023-formulary.html.
[116] Health and Human Services Office of Inspector General. Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. 84 Fed. Reg. 2340 (November 20, 2020). https://www.federalregister.gov/documents/2020/11/30/2020-25841/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals.
[117] Percher E. Trends in Profitability and Compensation of PBMs and PBM Contracting Entities. Nephron Research. September 2023. https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities.
[118] Hayes T, Schmidt R, Suzuki S. Assessing Postsale Rebates for Prescription Drugs in Medicare Part D. MedPAC, 2023. https://www.medpac.gov/wp-content/uploads/2022/07/Tab-F-DIR-data-April-2023-SEC.pdf.
[119] Government Accountability Office. Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending, September 2023. https://www.gao.gov/products/gao-23-105270.
[120] IQVIA. Adalimumab Biosimilar Tracking. Biosimilar Council, April 2024. https://biosimilarscouncil.org/wp-content/uploads/2024/04/04022024_IQVIA-Humira-Tracking-Executive-Summary.pdf.
[121] *Ibid.*
[122] *Ibid.*
[123] David Wainer. "Coming to a CVS Near You: A Store Brand Monoclonal Antibody," *Wall Street Journal*. April 29, 2024. https://www.wsj.com/health/pharma/cvs-biosimilar-drugs-production-08227182.
[124] Fein AJ. "What's Behind CVS Health's Novel Vertical Integration Strategy for Humira Biosimilars." Drug Channels. September 6, 2023. https://www.drugchannels.net/2023/09/whats-behind-cvs-healths-novel-vertical.html.
[125] Fein AJ. "What's Behind CVS Health's Novel Vertical Integration Strategy for Humira Biosimilars." Drug Channels. September 6, 2023. https://www.drugchannels.net/2023/09/whats-behind-cvs-healths-novel-vertical.html.
[126] David Wainer. "Coming to a CVS Near You: A Store Brand Monoclonal Antibody," *Wall Street Journal*. April 29, 2024. https://www.wsj.com/health/pharma/cvs-biosimilar-drugs-production-08227182.
[127] Fein AJ. "What's Behind CVS Health's Novel Vertical Integration Strategy for Humira Biosimilars." Drug Channels. September 6, 2023. https://www.drugchannels.net/2023/09/whats-behind-cvs-healths-novel-vertical.html.
[128] Xcenda. Skyrocketing Growth in PBM Formulary Exclusions Raises Concerns About Patient Access. September 2020. https://www.xcenda.com/insights/skyrocketing-growth-in-pbm-formulary-exclusions-raises-concerns-about-patient-access.
[129] *Ibid.*

[130] Wong WB, Seetasith A, Hung A, Zullig LL. Impact of list price changes on out-of-pocket costs and adherence in four high-rebate specialty drugs. PLoS One. 2023 Jan 19;18(1):e0280570. doi: 10.1371/journal.pone.0280570.
[131] GAO. Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability, February 2014. https://www.gao.gov/assets/d14194.pdf.
[132] FDA. Drug Shortages: Root Causes and Potential Solutions, February 2020. https://www.fda.gov/media/131130/download.
[133] Walker J. Generic Drugs Should Be Cheap, but Insurers Are Charging Thousands of Dollars for Them. *Wall Street Journal*, September 2023. https://www.wsj.com/health/healthcare/generic-drugs-should-be-cheap-but-insurers-are-charging-thousands-of-dollars-for-them-ef13d055.
[134] Conrad R, Lutter R. Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. US Food and Drug Administration, December 2019. https://www.fda.gov/media/133509/download.
[135] Walker J. Generic Drugs Should Be Cheap, but Insurers Are Charging Thousands of Dollars for Them. Wall Street Journal, September 2023. https://www.wsj.com/health/healthcare/generic-drugs-should-be-cheap-but-insurers-are-charging-thousands-of-dollars-for-them-ef13d055.
[136] Trish E, Van Nuys K, Popovian R. U.S. Consumers Overpay for Generic Drugs. *USC Schaeffer*, May 2022. https://healthpolicy.usc.edu/research/u-s-consumers-overpay-for-generic-drugs/.
[137] Mattingly TJ 2nd, Ben-Umeh KC, Bai G, Anderson GF. Pharmacy Benefit Manager Pricing and Spread Pricing for High-Utilization Generic Drugs. *JAMA Health Forum*. 2023 Oct 6;4(10):e233660. doi: 10.1001/jamahealthforum.2023.3660.
[138] GAO. Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability, February 2014. https://www.gao.gov/assets/d14194.pdf.
[139] FDA. Drug Shortages: Root Causes and Potential Solutions, February 2020. https://www.fda.gov/media/131130/download.
[140] Highly concentrated as defined by the Department of Justice and Federal Trade Commission Horizontal Merger Guidelines. https://www.justice.gov/atr/horizontal-merger-guidelines-08192010; https://www.finance.senate.gov/imo/media/doc/20230605_sfc_testimony.pdf.
[141] Moran, Hospital Charges and Reimbursement for Medicines: 2023 Update Analysis of Markups Relative to Acquisition Costs. August 2023. https://themorancompany.com/wp-content/uploads/2023/08/PhRMA-Hospital-Charges-Report-August-2023.pdf.
[142] Xiao R, Ross JS, Gross CP, et al. Hospital-Administered Cancer Therapy Prices for Patients With Private Health Insurance. *JAMA Intern Med.* 2022;182(6):603–611. doi:10.1001/jamainternmed.2022.1022. https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2791386.
[143] EBRI, Cost Differences for Physician-Administered Outpatient Drugs by Site of Treatment: State and Metropolitan Statistical Areas Variation, May 25, 2023. https://www.ebri.org/docs/default-source/fast-facts-(public)/ff-469-costdifferences-25may23.pdf?sfvrsn=3ff8392f_2.
[144] CMS. National Health Expenditure Historical Data. Released Dec 2022.
[145] Altarum. "Projections of the Non-retail Prescription Drug Share of National Health Expenditures." July 2022
[146] CMS. National Health Expenditure Historical Data. Released Dec 2022.
[147] CMS. National Health Expenditures Projections 2022 – 2031. Released Jun 2023. https://www.cms.gov/files/document/nhe-projections-forecast-summary.pdf.
[148] See 42 U.S.C. § 256b (the "340B statute").
[149] Brownlee A, Watson J. "The Pharmaceutical Supply Chain, 2013-2020." Berkeley Research Group, January 2022. https://ecommunications.thinkbrg.com/44/2328/uploads/brg-pharmaceutical-supply-chain-2022.pdf?intIaContactId=IXKabwLWBtOm%2fz%2fpgW%2btPQ%3d%3d&intExternalSystemId=1.
[150] A Fein, The 340B Program Climbed to $44 Billion in 2021—With Hospitals Grabbing Most of the Money, August 2022
[151] K Thomas, J Silver-Greenberg, How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits, New York Times, September 2022.
[152] S. Desai and J.M. McWilliams, "Consequences of the 340B Drug Pricing Program," N Engl J Med 2018.
[153] Gaynor, M "Antitrust Applied: Hospital Consolidation Concerns and Solutions Statement before the Committee on the Judiciary Subcommittee on Competition Policy, Antitrust, and Consumer Rights U.S. Senate" May 2021.
[154] Conti, Rena M., and Peter B. Bach., Cost Consequences of the 340B Drug Discount Program, Journal of the American Medical Association, May 15, 2013, https://jamanetwork.com/journals/jama/article-abstract/1680369.
[155] Desai, Sunita, and J. Michael McWilliams, Consequences of the 340B Drug Pricing Program, New England Journal of Medicine, Feb. 8, 2018,
[156] Marcus JL, et al., Perverse Incentives — HIV Prevention and the 340B Drug Pricing Program, New England Journal of Medicine, Jun 2, 2022, https://www.nejm.org/doi/full/10.1056/NEJMp2200601.
[157] Bond, Amelia M., Emma B. Dean, and Sunita M. Desai, The Role Of Financial Incentives In Biosimilar Uptake In Medicare: Evidence From The 340B Program, Health Affairs May 1, 2023, https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.00812.

[158] GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, Jun. 2015, https://www.gao.gov/products/gao-15-442.
[159] Hunter MT, et al., Analysis of 2020 Commercial Outpatient Drug Spend at 340B Participating Hospitals, Milliman, Sept. 2022, https://www.milliman.com/-/media/milliman/pdfs/2022-articles/9-13-22_phrma-340b-commercial-analysis.ashx.
[160] MedPAC, Report to Congress: Medicare and the Health Care Delivery System, Jun. 2015, https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-chapter-3-part-b-drug-payment-policy-issues-june-2015-report-pdf.
[161] IQVIA White Paper. Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies? October 2022
[162] United States, Congress, Senate Finance. Business meeting to consider an original bill entitled, "Modernizing and Ensuring PBM Accountability (MEPA) Act". Congress.gov, https://www.congress.gov/event/118th-congress/senate-event/334680?s=1&r=29. 118th Congress, Senate Committee Meeting, 26 Jul. 2023.
[163] United States, Congress, House. Protecting Patients Against PBM Abuses Act. Congress.gov, https://www.congress.gov/bill/118th-congress/house-bill/2880. 118th Congress, House Resolution 2880, Introduced 26 April 2023.
[164] United States, Congress, Senate. Modernizing and Ensuring PBM Accountability Act. Congress.gov, https://www.congress.gov/bill/118th-congress/senate-bill/2973. 118th Congress, Senate Bill 2973, Introduced 28 Sep. 2023.
[165] United States, Congress, Senate. DRUG Act. Congress.gov, https://www.congress.gov/bill/118th-congress/senate-bill/1542. 118th Congress, Senate Bill 1542, Introduced 10 May 2023.
[166] United States, Congress, House. DRUG Act. Congress.gov, https://www.congress.gov/bill/118th-congress/house-bill/6283. 118th Congress, House Resolution 6283, Introduced 08 Nov. 2023.
[167] Congressional Budget Office. Health Care Legislation As ordered reported by the House Committee on Energy and Commerce on December 6, 2023. March 2024. https://www.cbo.gov/system/files/2024-03/hr4881.pdf.
[168] Wanneh G. Senate Finance Passes Extra Policies To Build On MEPA PBM Bill. Inside Health Policy, November 2023. https://insidehealthpolicy.com/daily-news/senate-finance-passes-extra-policies-build-mepa-pbm-bill.
[169] Department of Health and Human Services Office of Inspector General. Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. Final Rule. November 30, 2020. https://www.federalregister.gov/documents/2020/11/30/2020-25841/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals.
[170] Milliman. Measuring the Impact of Point of Sale Rebates on the Commercial Health Insurance Market, July 2021. https://www.milliman.com/en/insight/measuring-the-impact-of-point-of-sale-rebates-on-the-commercial-health-insurance-market.
[171] Advisory Council on Employee Welfare and Pension Plan Benefits. Report to the Honorable Thomas E. Perez, United States Secretary of Labor: PBM Compensation And Fee Disclosure. 2014. https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure.pdf.
[172] Congressional Budget Office. Cost Estimate: Estimated Direct Spending and Revenue Effects of H.R. 5378, the Lower Costs, More Transparency Act. December 8, 2023. https://www.cbo.gov/system/files/2023-12/hr5378-DS-and-Revs_12-2023.pdf.
[173] Congressional Budget Office. Cost Estimate: S.1895, Lower Health Care Costs Act. July 16, 2019. https://www.cbo.gov/system/files/2019-07/s1895_0.pdf.
[174] CBO has continued to recognize savings from PBM transparency proposals. For example, see: https://www.cbo.gov/system/files/2022-06/hr7666.pdf.
[175] Avalere. Cort Ruling Will Limit Accumulators. October 2023. https://avalere.com/insights/court-ruling-will-limit-accumulators.

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Senate Judiciary Committee Hearing "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market, May 21, 2024

Senator Grassley's Written Questions for Dr. Feldman

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RESPONSES

1. Do you believe there is anti-competitive conduct occurring in the PBM marketplace that leads to higher drug costs for consumers? Please explain.

I believe that anticompetitive conduct is occurring in the PBM industry. The magnitude of the problem remains difficult to discern given the secrecy of PBM payment structures, but several practices raise concern. One is the preference for drugs with high rebates. Brand-name pharmaceutical firms set list prices and then negotiate with payers and their PBMs for confidential discounts that lower net prices. Because some PBM compensation is based on the magnitude of negotiated discounts rather than flat fees, PBMs may have incentives to favor high-priced drugs (with high rebates) on formularies over lower priced drugs. This can ultimately raise healthcare costs and increase patient cost-sharing since out-of-pocket costs are frequently tied to pre-rebate list prices.

A second problem in the PBM industry is "spread pricing"—where PBMs charge payers more than they reimburse pharmacies and retain the difference. One recent study found that spread pricing increased costs for generic drugs in Medicaid by $208 million in 2017-2018 in Ohio.[1] The 3 largest PBMs now control 79% of the US market and are vertically integrated with insurers and pharmacies, giving them substantial leverage to extract revenue from the pharmaceutical supply chain.[2]

Legislation aimed at reducing anticompetitive PBM behavior could help lower pharmaceutical costs, even if the size of the effect may be less than other interventions focused directly on pharmaceutical firms. I applaud the investigations now under way into PBMs led by the Federal Trade Commission,[3] the Department of Justice,[4] the Department of Health and Human Services Office of the Inspector General,[5] and others. A deeper understanding of PBM behavior is vital as lawmakers and regulators continue the important work of developing solutions to strengthen our pharmaceutical system.

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[1] Ohio Auditor of State. Auditor's report: pharmacy benefit managers take fees of 31% on generic drugs worth $208M in one-year period. August 16, 2018. Available from: https://ohioauditor.gov/news/pressreleases/Details/5042. Accessed June 10, 2024.
[2] Fiedler M, Adler L, Frank RG. A brief look at debates about pharmacy benefit managers. Available online from: https://www.brookings.edu/articles/a-brief-look-at-current-debates-about-pharmacy-benefit-managers/. Accessed June 10, 2024.
[3] Federal Trade Commission, FTC Deepens Inquiry into Prescription Drug Middlemen. May 17, 2023. Available online from: https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-deepens-inquiry-prescription-drug-middlemen. Accessed June 10, 2024.
[4] Matthews AW, Michaels D. US Opens UnitedHealth Antitrust Probe. Wall Street Journal. February 27, 2024. Available online from: https://www.wsj.com/health/healthcare/u-s-launches-antitrust-investigation-of-healthcare-giant-unitedhealth-ff5a00d2. Accessed June 10, 2024.
[5] US Department of Health and Human Services. Effects of Vertical Integration on Medicare Part D. Available online from: https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000843.asp. Accessed June 10, 2024.

2. Senator Cantwell and I have a bill, the Pharmacy Benefit Manager Transparency Act, to prevent unfair, anti-competitive practices by PBMs and to bring about greater transparency. Do you believe that this bill would help address competition concerns and lower the price of drugs for patients?

I think that this bill could help improve competition and lower prescription drug costs. The bill would eliminate spread pricing and certain retroactive fees charged to pharmacies unless PBMs passed 100% of negotiated rebates through to payers and disclosed an array of costs in the pharmaceutical supply chain. The bill would also require disclosures by PBMs to the Federal Trade Commission (FTC) and would give the FTC further enforcement authority to address anticompetitive PBM behavior. The Congressional Budget Office projected that the bill would save $740 million over 10 years.[6]

Whether these efforts would reduce out-of-pocket costs for patients is less clear. Because out-of-pocket costs are often tied to pre-rebate list prices, eliminating spread pricing and/or requiring 100% rebate pass-through to payers may not necessarily reduce these costs in the absence of further reform.[7] Still, I believe that the legislation represents a valuable step forward. There is no silver bullet to address every problem in the pharmaceutical system at once. I applaud the recent approach taken by the Senate Judiciary Committee targeting a variety of anticompetitive practices in the pharmaceutical supply chain—from PBM spread pricing to pay-for-delay settlements, sham citizen petitions, and patent thickets. This multipronged approach is precisely the sort of action we need to address high prescription drug prices. I would only encourage the Committee to continue and expand upon these efforts.

3. Chairman Durbin and I have attempted to pass our bill, the Drug Price Transparency for Consumers (DTC) Act, to require drug companies to list the price of a drug in their ads to empower consumers. The Trump Administration attempted to require it through rule-making, but Big Pharma opposed it. Why do you think Big Pharma opposes this policy?

I suspect that the pharmaceutical industry opposes this bill, because they prefer that patients not be told (or reminded) about the high prices of prescription drugs in the US. Median launch prices on new drugs are now well over $100,000 per year.[8] If disclosures were required, every advertisement about a prescription drug would also serve as a reminder about the dysfunction of the pharmaceutical industry. As it stands, companies spend large sums on these advertisements—with disproportionate amounts spent on drugs with lower therapeutic

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[6] Senator Chuck Grassley. PBM Transparency Act Saves $740 Million: CBO. Available from: https://www.grassley.senate.gov/news/news-releases/pbm-transparency-act-saves-740-million-cbo. Accessed June 10, 2024.
[7] Cai C, Rome BN. Reforming Pharmacy Benefit Managers - A Review of Bipartisan Legislation. N Engl J Med. 2023 Nov 2;389(18):1640-1643.
[8] Rome BN, Egilman AC, Kesselheim AS. Trends in Prescription Drug Launch Prices, 2008-2021. *JAMA*. 2022;327(21):2145-2147.

value[9]—and patients (and often physicians) may have little idea about the high prices charged by pharmaceutical firms.

The Pharmaceutical Research and Manufacturers of America (PhRMA) has argued that such disclosures would be confusing for patients and could dissuade use of medically recommended therapies.[10] The potential source of confusion stems from differences between list prices (wholesale acquisition costs), net prices (after application of confidential rebates), and out-of-pocket costs; list prices are often substantially higher than payer-negotiated net prices, and, for those with insurance, out-of-pocket costs may be a small fraction of list prices. However, I am confident that pharmaceutical firms could make the appropriate disclaimers in their advertisements when disclosing list prices. In addition, they could always choose to forgo advertisements if they felt that the requirements were too onerous.

[9] DiStefano MJ, Markell JM, Doherty CC, Alexander GC, Anderson GF. Association Between Drug Characteristics and Manufacturer Spending on Direct-to-Consumer Advertising. *JAMA*. 2023;329(5):386–392. Patel NG, Hwang TJ, Woloshin S, Kesselheim AS. Therapeutic Value of Drugs Frequently Marketed Using Direct-to-Consumer Television Advertising, 2015 to 2021. *JAMA Netw Open*. 2023;6(1):e2250991.

[10] Pharmaceutical Research and Manufacturers of America, "PhRMA Responds to HHS DTC Rule, Launches Website Providing Patients with Cost Information." Available online at https://phrma.org/resource-center/Topics/Access-to-Medicines/PhRMA-Responds-to-HHS-DTC-Rule-Launches-Website-Providing-Patients-with-Cost-Information. Accessed June 10, 2024.

Senate Judiciary Committee Hearing "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market, May 21, 2024

Senator Grassley's Written Questions for Mr. Mitchell

1. Do you believe there is anti-competitive conduct occurring in the PBM marketplace that leads to higher drug costs for consumers? Please explain.

Yes. 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. We need to increase transparency and curb anticompetitive practices by PBMs.

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 the Big Three PBMs–Cigna, Optum Rx, and CVS Health–in control of 80 percent of the $633 billion in U.S. spending on drugs, that is more than half a trillion dollars flowing through just those three entities annually. Vertical integration also unites all three major PBMs with insurers which only increases their market power. Opaque practices with that kind of money involved are a bad way to run a railroad. It's time for transparency to ensure PBMs are operating in the best interests of patients and consumers.

It's not just about transparency either. 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."

Let's be clear: These rebate 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 which has been built to benefit those who profit from it at the expense of those it is supposed to serve.

P4ADNOW supports reforming the practices of PBMs, including transparency requirements in order to 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 managers. In our ideal world, PBMs would have a fiduciary responsibility to patients and all beneficiaries, and all reforms would put patients at the center. While none of the PBM bills go as far as we would like, each takes important steps in the right direction and would make meaningful and important progress in the regulation and oversight of PBMs. We support key provisions of bills that have cleared the Finance Committee on unanimous or near-unanimous bipartisan votes:

- Modernizing and Ensuring PBM Accountability Act - S. 2973. We especially support the transparency and disclosure requirements, and the provisions de-linking PBM compensation from prices.
- Better Mental Health Care, Lower-Cost Drugs, and Extenders Act - S 3430. We think the required reports to Congress are of particular importance. We support the concept of the rebate pass-through provisions, but we need to see CBO scoring for this provision, and we are concerned about the impact on premiums.

The House Energy and Commerce Committee has also advanced legislation addressing PBM practices. We support provisions in the Lower Cost, More Transparency Act, H.R. 5378, that improve transparency and reporting requirements. We were also pleased to see the House Ways and Means Committee include reform delinking PBM compensation from prices in legislation it *advanced earlier this month* – H.R. 8261, the "Preserving Telehealth, Hospital, and Ambulance Access Act. In our view, however, none of the provisions in House legislation go far enough in reforming PBMs and ensuring they are putting patients and consumers first.

We are also following closely and supporting the Federal Trade Commission (FTC) investigation into PBMs as well. We look forward to the first interim report on that investigation expected this summer. We hope Congress uses the report to inform future legislation, and that Congress gives strong backing for the FTC to take action it may recommend.

2. Senator Cantwell and I have a bill, the Pharmacy Benefit Manager Transparency Act, to prevent unfair, anti-competitive practices by PBMs and to bring about greater transparency. Do you believe that this bill would help address competition concerns and lower the price of drugs for patients?

I believe S. 127 would address competition concerns and could help lower the prices of drugs for patients, but it would do the most good for pharmacies which have been subjected to unfair practices by PBMs. We would like to see additional reforms to ensure PBM practices and business models will directly benefit patients and consumers, first and foremost.

3. Chairman Durbin and I have attempted to pass our bill, the Drug Price Transparency for Consumers (DTC) Act, to require drug companies to list the price of a drug in their ads to empower consumers. The Trump Administration attempted to require it through rule-making, but Big Pharma opposed it. Why do you think Big Pharma opposes this policy?

Drug companies don't want to draw attention to the high prices of drugs which will remind people each time they see an ad how outrageous drug prices are in the U.S. Drug companies argue that list prices will mislead people "because no one pays list." To the contrary, list price is extremely important and highly relevant to U.S. patients and consumers—roughly 67 percent of whom pay for some or all of the cost of their drugs based on list price. That includes people on Medicare, many people with high deductible plans, and those without insurance. The "no one pays list" argument that drug companies continue to use is a red herring.

Senate Judiciary Committee Hearing "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market, May 21, 2024

Senator Grassley's Written Questions for Professor Mossoff

1. The Biden Administration is considering changing march-in rights policy under the Bayh-Dole Act as a way to reduce the price of prescription drugs. Professor Rai testified that she believed this was a "careful" approach and would provide a "gentle nudge" to deal with high prescription drugs costs. Do you agree with Professor Rai? What's your opinion on the Administration's proposed changes with respect to march-in rights?

The march-in guidelines announced by the National Institute of Standards and Technology on December 7, 2023 are neither "careful" nor a "gentle nudge." It represents an unprecedented claim to regulatory powers by administrative agencies to impose price controls on all patented products and services in the marketplace according whenever an agency official deems there is an "unreasonable price" (undefined in the proposed guidelines.) I direct you to pages 6-17 of my written testimony that sets forth the statutory analysis of the proposed guidelines lack any statutory authorization in the Bayh-Dole Act, contradict the express function of the Bayh-Dole Act, and will ultimately be ineffective and not lower drug prices.[1]

2. In Dr. Feldman's written and oral testimony, he suggests that the Committee consider several policies dealing with orange book listings, re-examination, litigation, generic approval standards, and incentives for patent challenges. Do you agree with these 5 specific proposals to address the high cost of drugs? Why or why not?

I do not agree with Dr. Feldman's proposals, for at least two reasons. First, his proposals violate the principle of good governance that Congress should follow in adopting evidence-based policymaking. The essential governing principle of evidence-based policymaking should guide the Congress in considering whether to adopt any legislation generally and patent laws specifically given the key role of the U.S. patent system as a driver of economic growth and innovation in healthcare, as I explained in my written testimony.[2] In this regard, Dr. Feldman's proposals would create new significant legal and regulatory burdens for patent applications and for patent owners in the biopharmaceutical sector. These innovators innovations have vastly improved the quality and length of life of all Americans. This is the baseline or framework by which to assess any

[1] *See* Adam Mossoff, Written Testimony, Senate Judiciary Committee Hearing on "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market" 6-17 (May 21, 2024), https://www.judiciary.senate.gov/download/2024-05-21-testimony-mossoff.

[2] *See id.*, at 4-6.

proposed legal or regulatory restrictions on drug innovators in receiving and using their property rights in their inventions. If there is a true need for real reform, it is easy to meet this evidentiary burden: mandates should be adopted only on the basis of rigorous studies and verifiable evidence that these new legal rules ameliorate proven systemic inefficiencies or other problems in the patent system. But Dr. Feldman's proposals do not meet this burden. His proposed new legal and regulatory restrictions for patent applications and for existing patent owners are not justified by empirical data or studies that justify the increased costs to innovators that would be created by his proposals—costs that undermine and frustrate the function of the patent system as a spur for invention and economic growth in the U.S. and in flourishing societies worldwide.

Given the absence of proper empirical support, Dr. Feldman's proposals would be ineffectual, unjustified, or will cause additional and unnecessary harms to innovators through increased costs and uncertainty that reduce investments and slow the pace of innovation in new drugs. At best, some of Dr. Feldman's proposed new laws or regulations already exist. If they do not exist, these new regulatory powers or restrictions on patent owners would impose additional costs and uncertainty on innovators, leading to higher drug prices given increased costs of regulatory compliance. All of these problems result from the fact that the bills and proposals are based on rhetorical assumptions that are not supported by evidence or rigorous statistical studies. Dr. Feldman's proposals continue to make the same mistaken assumption as I-MAK and other activists that the complex mix of laws, regulations, and public and private institutions that are determinants of drug prices should be ignored by Congress, the FDA, and the PTO. Instead, Dr. Feldman simplistically reduces these multidimensional causes of drug prices to a single cause: patents.

Orange Book Listings: The Interagency Patent Coordination and Improvement Act of 2023 (S.79) supported by Dr. Feldman and the additional authority he proposes for the Food and Drug Administration (FDA) to obtain additional information from the Patent and Trademark Office (PTO) is both unnecessary and harmful to the efficient operations of the PTO and FDA. Both the FDA and the PTO already have existing extensive legal authority to share information and consult with each other. Patent examiners work to ensure that they have the resources and information pertinent to perform their duties in examining patent applications, and they have the authority under Rule 105 to obtain all pertinent information.[3] Rule 105 authorizes examiners to access sources of information on inconsistent statements or prior art that are not otherwise publicly available. The Court of Appeals for the Federal Circuit has construed Rule 105 broadly that it authorizes an examiner to obtain "such information as may be reasonably necessary to properly examine" a patent application, and that this authority is bounded only by requests for information by an examiner that are "arbitrary and capricious."[4]

S.79 and the additional powers proposed by Dr. Feldman further beg the question why Congress is directing only a single agency—the FDA—to aid the work of examiners in obtaining pertinent information relevant to a patent application. Other agencies have similarly pertinent technical information on inventions that equally fall within their regulatory oversight functions, and innovators also apply for patents on these inventions. This would include, but is not be limited to, the machines, processes, chemical molecules, etc. that fall within the regulatory oversight and

[3] *See* 37 C.F.R. § 1.105.

[4] Star Fruits S.N.C. v. United States, 393 F.3d 1277 (Fed. Cir. 2005).

approval regimes run by the Federal Aviation Administration (FAA), Environmental Protection Agency (EPA), Securities and Exchange Commission (SEC), Nuclear Regulatory Commission (NRC), U.S. Department of Agriculture (USDA), U.S. Department of Transportation (USDOT), and many others. The same generalized concerns about systemic abuse by individuals making contradictory statements between agencies are just as salient for all of the inventions that are subject to regulatory controls of the myriad of these other agencies within the administrative state. This is particularly important given the absence any legitimate and reliable evidence of systemic abuse of the sort alleged by Dr. Feldman, I-MAK, and others that drug innovators are making false or contradictory statements of fact under the relevant laws and regulations of the FDA and PTO.

More importantly, the Senate Judiciary Committee should remain committed to the principle of *technology neutrality* that has long been a key factor in the historical success of the U.S. patent system as a driver of the U.S. innovation economy. As I explained in my Heritage Report, *For Biomedical Innovation, Congress Should Follow the Maxim "First, Do No Harm,"*:

> From the Patent Act of 1790 enacted by the First Congress through the most recent Patent Act of 1952, the U.S. patent system has applied the same legal rules and processes to all inventions. This is the principle of *technology neutrality*. It is the patent version of the basic idea that the right to property is secured equally to all owners regardless of who they are and what they own.
>
> The Interagency Patent Coordination and Improvement Act turns this vital legal and economic principle on its head: It will create new administrative agencies and officials, as well as new regulatory rules and processes, for reviewing patent applications for biomedical innovations such as a new cure for cancer. Patent applications for inventions in 6G, the Internet of Things, or even a new jet engine will not be subject to these new administrative processes and procedures.
>
> Patent legislation should not target specific technologies, whether drugs, mobile tech, or combustion engines, by creating special legal rules and administrative institutions in the patent system. This by itself is sufficient reason to oppose the Interagency Patent Coordination and Improvement Act. At best, it portends innumerable unintended consequences for the patent system, threatening to undermine its core function: the promotion and dissemination of new innovations. At worst, it creates new administrative processes that will ultimately prove to be destructive of this innovation system.[5]

Re-examination: As with the prior proposal, what appears superficially to be a moderate or commonsensical proposal about reexamination is belied by the evidence. The proposal to make reexaminations mandatory for all Orange Book listings reflects the well-known fallacy in economics known as the *nirvana fallacy*. This fallacy assumes a current problem and its associated costs can be solved by a new regulation that would be cost free—a nirvana world in which new public institutions, regulations, and processes are cost free as compared to the costs of the current

[5] Adam Mossoff, *For Biomedical Innovation, Congress Should Follow the Maxim "First, Do No Harm"* (Heritage Report, Nov. 14, 2022), https://www.heritage.org/government-regulation/report/biomedical-innovation-congress-should-follow-the-maxim-first-do-no.

private or public institutions creating the inefficiencies or other policy failings. In this case, Dr. Feldman's proposal is a double fallacy: he asserts that there are costs—what he obliquely calls "stakes"—of "invalid patents" in healthcare, and he necessarily assumes that his proposed reexamination mandate would address these "stakes" without creating additional costs or new costs for innovators. In fact, he refers to his mandatory proposal as only creating "routine reexamination," but reexaminations, let alone reexaminations, are neither routine nor cost free. This systemic mandate for all patents in the Orange Book would create extensive new costs at the PTO and for drug innovators. As a result, his purported goal of lowering drug prices will not be achieved given the unforeseen negative effects on millions invested in legitimate inventions in the further development of new innovative versions of existing products, such as new technologically complex auto-injectors. These are valid innovations, despite aspirations to the contrary by I-MAK and Dr. Feldman, just as automobile companies invest millions to develop updated versions of cars with computer-based self-driving capabilities or high-tech companies like Qualcomm and InterDigital develop invest millions to invent new versions of mobile telecommunications technologies—from 2G to 5G.

Litigation: Proposals to limit or otherwise impose new restrictions on an innovator seeking protection of its valid property rights against infringers represent the same nirvana fallacy. Paetnt bills in the past, such as the Innovation Act, that would have imposed additional limitations and restrictions on patent owners filing lawsuits, and these bills rightly failed in Congress given the ill effects their proposals would have on individual inventors, universities, and startups—core drivers of innovation who rely on patents to recoup R&D and commercialize their inventions in the marketplace. Arbitrary proposals such as restricting a patent owner to sue for infringement for only one drug patent in a family will have similar ill effects on innovators. Multiple patents exist on single consumer products—from golf balls to smartphones to drugs—and it is an arbitrary and capricious restriction to establish a single-patent rule for infringement. Lastly, and perhaps most importantly, Dr. Feldman's proposal would likely violate the Due Process and Takings Clauses of the Constitution, because it eliminates the ability of the owners of valid property rights to sue in Article III court when these property rights are infringed. This is tantamount to prohibiting an owner of multiple parcels of real estate that are being repeatedly trespassed from suing for protection from and renumeration for the violation of all the power-owner's rights. This eviscerates the right to exclude that the Supreme Court has consistently recognized as the essence of a property right, and has thus rightly recognized as a per se trigger for an unconstitutional taking when this right to exclude is eliminated by a law or regulation.[6]

Generic approval standards: I am not an expert on the FDA approval process for generics, and thus I defer to healthcare law experts and drug innovators on this proposal by Dr. Feldman. With that said, the governing principle of evidence-based policymaking still applies to this proposal, as does the nirvana fallacy. There must be evidence, based in reliable and verified data and analyzed according to transparent, rigorous, and replicable methods of analysis accepted by empirical researchers, that establishes that there is an inefficiency or other cost that will be (1) resolved by the proposed regulation, and (2) the inescapable and necessary costs in the proposal will not be greater than the existing costs of this proven problem. As doctors are wont to say: The cure cannot be worse than the disease. Policy-driven rhetoric, policy-based evidence-making of the sort now

[6] *See* Cedar Point Nursery v. Hassid, 141 S. Ct. 2063 (2021).

confirmed in I-MAK's numbers of patents and market exclusivity periods, or simple, bald-faced assertions of a problem are insufficient. These should be soundly rejected by the Committee.

Incentives for patent challenges: Again, I am not sufficiently versed in the empirical studies of Hatch-Waxman procedures to comment on whether these proposals are justified by the evidence. With that said, I can state that experience has shown that any systemic changes to the complex regulatory regime created by the Hatch-Waxman Act should be approached with extreme caution given the intricate institutional balance achieved by the Hatch-Waxman Act and its complicated legal and regulatory mechanisms. Off-hand proposals to alter its rules and institutional mechanisms can represent an ignorance of how regulatory and legal institutions function in the real world—the essence of someone committing the nirvana fallacy. Alternatively, such proposals can also represent a deliberate disregard for the need for evidence of systemic costs and inefficiencies as a necessary justification for new legal and regulatory restrictions that restrict or limit existing property rights within complex public and private institutions.

3. Do you agree with the various proposals to address issues with terminal disclaimers and obviousness-type double patenting? Please explain.

Senator Welch has proposed S.3583, which addresses the alleged problem of "patent thickets" by rendering unenforceable all but one patent joined by a terminal disclaimer. This bill is similar to Dr. Feldman's third policy proposal on litigation, as discussed above. S.3583 would apply to only patents covering a drug or biological product. This bill is bad policy and bad law.

First, reiterating a key point in my answer to your first question, patent law and policy should remain committed to the principle of technology neutrality. This principle of technology neutrality has been a key factor in the success of the U.S. patent system as a property rights system in driving economic growth and innovation. Thus, Congress should not craft special legal rules for specific types of patents in specific sectors of the innovation economy. This is not only good policy proven by more than two centuries of the historically unprecedented success of the U.S. patent system, it is also now an obligation for the U.S. in the modern era under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

In this regard, terminal disclaimer practice is not a specific practice among patent lawyers working only in the life sciences and biopharmaceutical sector. This is a general patent law practice. Yet, S.3583 creates a new litigation restriction based on this general patent law practice for a single type of patent covering a specific set of technologies—pharmaceutical innovations. It breaches the principle of technology neutrality in the basic patent laws by officially creating a new legal restrictions for one technology that is different from the legal rules for all other technologies. According to the principle of evidence-based policymaking, there is no justification for doing so, especially given the evidence that the equally important principle in U.S. patent law of technology neutrality has been key factor in its success in establishing the U.S. as a global technology leader.

Second, there is no legal justification for rendering a patent unenforceable that has been successfully prosecuted and has not been subject to challenge either in court or in an administrative proceeding at the Patent Trial and Appeal Board. Congress made the express decision that a patent

otherwise subject to obviousness double patenting can be valid provided this patent does not provide the patent owner with any extra patent term. In doing so, Congress sought to ensure that innovators had the incentive to engage in further research and development of new inventions based on new uses and other features of a prior invention, learning more about this prior invention and its characteristics and claiming those discoveries so long as their rightfully obtained patent protections for the fruits of their prior inventive labors are not extended in time. This law, and its underlying policy justification, are valid. There is no empirical evidence of systemic abuses requiring Congress to make a systemic alternation to the patent system.

If Congress is concerned about this issue, it could consider alternative mechanisms to encourage and protect this form of follow-on experimentation that do not require the innovator to seek additional patents. In some countries, for example, a patent-owner can extend the patent examination process and add claims to a single patent as similar experimentation reveals new inventions. That is not currently available in the U.S., but it is an example of an alternative approach that Congress could and should explore if it is serious about acting in this area.

What Congress must avoid is rendering unenforceable otherwise valid patents, granted by the PTO, and not invalidated by any competent legal institution following due process and the norms of the rule of law expected of any property owner under U.S. law.

Questions from Senator Tillis for Adam Mossoff Witness for the Senate Committee on the Judiciary Hearing "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market"

1. Could you please explain what issues you see with I-MAK's methodology and how their data may not be reliable for policy makers to rely upon?

The principal problem with I-MAK's numbers of patents for specific drugs and similarly reported total years of exclusivity of specific drugs is that I-MAK's numbers are unverified and unreliable. There is evidence that I-MAK created these numbers of patents and exclusivity periods to advance its preexisting policy position as an advocacy organization that "a root cause of the high cost of medicines is an outdated patent system" that creates "unjust patent monopolies."[1] For instance, I-MAK does not merely count patents and publish white papers stating these numbers (I-MAK calls its policy white papers "reports" to give them a fake patina of empirical objectivity). I-MAK actively engages in legal actions seeking to invalidate drug patents; it was the first advocacy organization that challenged a drug patent at the Patent Trial and Appeal Board.[2] Given its policy view that drug prices result from "patent monopolies," I-MAK publishes white papers with stylized tables and charts with eye-popping numbers representing total patents or total exclusivity periods for specific drugs. I-MAK does not disclose in its white papers its statistical methodology or the specific patents it has counted to reach these numbers. Congress and policymakers should not rely on I-MAK's white papers (ersatz "reports") because of the growing evidence that there are serious problems with the veracity of the numbers presented in I-MAK's white papers.

In 2022, I published the results of a "spot check" of some of I-MAK's numbers of patent numbers on some top-selling drugs.[3] I compared I-MAK's numbers of patents to the total numbers of patents listed in the Orange Book for the same drugs. As I explained at the time, the Orange Book provides

[1] *Drug Pricing Crisis*, https://www.i-mak.org/health-equity/#pricing (accessed June 20, 2021).

[2] *See First-Ever U.S. Patent Challenges Dispute Gilead's Monopoly on Hepatitis C Drugs that Blocks Millions from Treatment* (New York: I-MAK, Oct. 25, 2017), https://www.i-mak.org/2017/10/25/first-ever-us-patent-challenges-gilead-hepatitis-c/.

[3] *See* Adam Mossoff, *Unreliable Data Have Infected the Policy Debates Over Drug Patents* (Jan. 19, 2022), https://www.hudson.org/technology/unreliable-data-have-infected-the-policy-debates-over-drug-patents.

an important comparative baseline for evaluating I-MAK's numbers of patents. First, the Orange Book is the official, public listing of patents covering drugs that would be infringed by a generic drug company if it made, used, or sold a drug without authorization. The Orange Book, maintained by the Food and Drug Administration (FDA), has been called "the gold standard reference for generic drug substitution."[4] Second, the Orange Book serves a key role in the Hatch-Waxman regime,[5] which is relevant given that the accusations of "patent thickets" and "evergreening" by I-MAK and others that generic drug companies are allegedly unable to produce drugs in competition with drug innovators, undermining the effective implementation of this law. For this reason, the Orange Book is the best source for an official, public listing of the relevant patents that cover a (small molecule) drug, especially from the perspective of a generic seeking to make and sell this drug in competition with a drug innovator.

Since I published my 2022 essay, the Orange Book has become the subject of critiques by I-MAK, the Federal Trade Commission (FTC) and others for either listing too many patents or failing to list all the relevant patents. On the one hand, I-MAK accuses drug innovators of *failing to list all relevant patents* in the Orange Book, claiming in its white papers and letters to officials that it has found numbers of patents covering drugs that are larger by orders of magnitude than the total patents listed for these same drugs in the Orange Book. These accusations have driven policy efforts for greater collaboration between the FDA and the Patent and Trademark Office (PTO); these efforts have been driven by the (unproven) accusations that drug innovators are obtaining patents they somehow should not have obtained given vague accusations of discrepancies between filings in the FDA and the PTO, as evidenced in part by more patents existing than those listed in the Orange Book. On the other hand, the FTC is now accusing drug innovators of *listing too many patents*, including what the FTC deems to be junk patents that should not have been issued by the PTO. In its letters to the FDA, though, the FTC offers no legal analysis or evidence why the patents it identifies are invalid. Nonetheless, drug innovators are now caught in contradictory accusations—they are either listing *too few patents* in the Orange Book according to I-MAK or are listing *too many patents* according to the FTC. The laws of logic dictate that both I-MAK's and the FTC's claims cannot both be true at the same time. Your question asks about only I-MAK's unreliable numbers and so my answer is limited to I-MAK's policy argument and the numbers of patents it has created to support it, but the development in the debates over drug prices and drug patents of contradictory claims about strategic behavior by drug innovators underscores how much this debate is driven by rhetoric and arguments without any basis in evidence or logic.

My spot check between I-MAK's numbers of drug patents and the number of patents in the Orange Book revealed significant concerns about the reliability and accuracy of I-MAK's drug patent numbers.

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[4] Jennifer Gershman, *4 Interesting Facts About the Orange Book*, PHARMACY TIMES (Mar. 13, 2018), https://www.pharmacytimes.com/view/4-interesting-facts-about-the-orange-book.

[5] *See* U.S. Food and Drug Administration, *Orange Book Preface*, https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface (last accessed Jan. 31, 2023) ("On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (Hatch-Waxman Amendments). The Hatch-Waxman Amendments require FDA to, among other things, make publicly available, with monthly supplements, a list of approved drug products. The Orange Book and its monthly Cumulative Supplements satisfy this requirement.").

In its 2018 *Overpatented, Overpriced* white paper, for example, I-MAK asserts in a chart that Lyrica has 68 patents covering it. In contrast, the Orange Book lists only 4 patents covering Lyrica; in actuality, there are 3 patents, as one of the 4 patents is a reissue patent. Also, in contrast to I-MAK, the Orange Book lists the actual patents, not just a simple number of total patents covering the drug as I-MAK does in its 2018 white paper. This discrepancy in the numbers of patents for Lyrica is shockingly large—I-MAK asserts 68 patents cover Lyrica and the FDA identifies only 3 patents covering Lyrica.[6] This is a difference by *orders of magnitude* between the official, public listing of patents and I-MAK's numbers of drug patents. This is not merely a rounding error in whatever (undisclosed) algorithm I-MAK used to reach its conclusion of 68 patents on Lyrica.

Similar discrepancies by orders of magnitude are found in I-MAK's claims about the total patents covering Xarelto. I-MAK states in 2018 *Overpatented, Overpriced* that 30 issued patents cover Xarelto with an additional 49 pending patent applications covering this same drug. In its *America's Bestselling Drugs of 2019* white paper the following year, I-MAK increased the number of issued patents covering Xarelto to 32 and increased the number of pending patent applications to 51. I-MAK has provided no explanation for the basis for the higher numbers between 2018 and 2019.

As with Lyrica, there is a vast discrepancy between I-MAK's numbers and the listing of relevant patents covering Xarelto in the Orange Book. Whereas I-MAK identifies 32 total patents covering Xarelto, the Orange Book identified only 6 patents covering Xarelto and its uses by patients.[7]

A third and final example of vast differences between I-MAK's numbers of drug patents and the patents listed in the Orange Book is found in I-MAK's claims about the total patents covering Eliquis. In its 2018 *Overpatented, Overpriced* white paper, I-MAK states that 27 issued patents and another 48 patent applications cover Eliquis. In its *America's Bestselling Drugs of 2019* white paper issued the following year, I-MAK increases these numbers for Eliquis, asserting that 31 issued patents cover the drug and there were now 49 total patent applications. Similar to Lyrica and Xarelto, there is a large contrast with the Orange Book listing of patents for Eliquis. The Orange Book identifies 3 patents covering Eliquis and its uses, not the 27 patents or 31 patents claimed by I-MAK in 2018 and 2019, respectively.

These unverified, vast discrepancies between the Orange Book listings and I-MAK's number of drug patents raise serious questions about the unreliability and veracity of I-MAK claims. These concerns are even more pressing given that I-MAK is an advocacy organization that believes that "a root cause of the high cost of medicines is an outdated patent system" that creates "unjust patent monopolies."[8] Thus, I-MAK uses its numbers of drug patents in its advocacy work, and promotes others to use them as well, to convince Congress and officials to create new laws and policies that impose new restrictions and costs on drug innovators. This is being done on the basis of unverified numbers of patents and on an undisclosed statistical methodology for reaching these numbers.

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[6] Even if one includes the additional patents listed in the Orange Book for Lyrica CR, this adds only 3 patents. Thus, this would bring the total number of patents covering both Lyrica and Lyrica CR to 6 patents.

[7] The Orange Book currently lists only 4 patents for Xarelto.

[8] I-MAK, "Drug Pricing Crisis," https://www.i-mak.org/health-equity/#pricing (accessed June 20, 2021).

Lastly, it bears emphasizing that my essay is not the only published source of information identifying serious concerns about the unreliability and veracity of I-MAK's patent numbers. Such concerns were confirmed at the Joint PTO-FDA Public Listening Session on Collaboration Initiatives held at the PTO on January 19, 2023. At the Listening Session, Corey Salsberg, Vice President and Global Head Intellectual Property Affairs for Novartis, explained that Novartis had expended significant time and resources to reverse engineer I-MAK's claim in its 2017 white paper that a Novartis drug, Gleevec, was covered by "a total of 73 patents."[9] Mr. Salsberg stated that "the real number of issued US patents on Gleevec was five, with another one to four possibly covering some of the ways of making it, but only if those methods were (optionally) used. At least in our case, I-MAK appears to have reached its inflated figures by including *44 abandoned patent applications* that never issued as patents, as well as a variety of patents that don't cover our drug."[10]

Although I-MAK now claims to have published its datasets on its website and it offers generalized statements of its methods that essentially state that it carefully counts patents, I-MAK has never explicitly or directly explained the contradictions I identified in my 2022 essay between its numbers of patents in its previous white papers (which are still relied on by academics and commentators) and the patent numbers found in the Orange Book and in court opinions. I-MAK has also never responded to Mr. Salsberg's analysis of how I-MAK's patent numbers on Gleevec confirmed that I-MAK was counting *44 abandoned patent applications* in I-MAK's assertion that 73 total issued patents covered the drug Gleevec. It has neither rebutted Mr. Salsberg's analysis, nor has it corrected its 2017 white paper. In sum, I-MAK's numbers continue to be unverified and fundamentally unreliable given unexplained contradictions and evidence of manipulation of the underlying data to advance its policy advocacy position that "unjust patent monopolies" or abuse of the patent system is "a root cause of the high cost of medicines."

Moreover, following the publication of my essay detailing these massive discrepancies between I-MAK's numbers of drug patents and the number of listed patents in the Orange Book, and the publication of other essays raising similar concerns,[11] you sent a letter on January 31, 2022 to Tahir Amin, Co-Founder and Co-Executive Director of I-MAK.[12] In this letter, you requested that Mr. Amin provide a "detailed explanation of your methodology for calculating the number of patents on a drug product that could be replicable by other researchers."[13] You also requested that I-MAK explain why its patent numbers covering drugs "differ so dramatically from public sources," as

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[9] *Statement of Corey Salsberg, Vice President and Global Head Intellectual Property Affairs for Novartis*, Listening Session on Joint USPTO-FDA Collaboration Initiatives (Jan. 19, 2023), at 6, https://www.regulations.gov/comment/PTO-P-2022-0037-0017.

[10] *Id.* (emphasis added).

[11] *See* Mossoff, *supra* note 3; *UC Hastings' Evergreen Drug Patent Search Database: A Look Behind the Statistics Reveals Problems with this Approach to Identifying and Quantifying So-Called "Evergreening,"* C-IP2 BLOG (Mar. 4, 2021), https://cip2.gmu.edu/2021/03/04/uc-hastings-evergreen-drug-patent-search-database-a-look-behind-the-statistics-reveals-problems-with-this-approach-to-identifying-and-quantifying-so-called-evergreening/.

[12] Letter from Senator Thom Tillis to Tahir Amin, Jan. 31, 2022, https://s3.amazonaws.com/media.hudson.org/1.31.2022-%20LTR%20from%20Senator%20Tillis%20to%20IMAK%20re%20Patent%20Data%20Sources.pdf.

[13] Letter from Senator Thom Tillis to Tahir Amin, Jan. 31, 2022, https://s3.amazonaws.com/media.hudson.org/1.31.2022-%20LTR%20from%20Senator%20Tillis%20to%20IMAK%20re%20Patent%20Data%20Sources.pdf.

well as explain why I-MAK claimed in its 2018 and 2019 reports that some patented drugs will retain market exclusivity for decades into the future when generic versions were already made available to patients in the healthcare market.[14]

In a lengthy letter, dated March 9, 2022, Mr. Amin was unresponsive to your specific requests, neither disclosing I-MAK's data nor detailing I-MAK's methods or analytics used to derive the massive numbers of patents for specific drugs listed in its white papers.[15] Mr. Amin instead argued that not all patents "asserted in litigation" are listed in the Orange Book.[16] In this letter, Mr. Amin decried "the hidden real-world workings of the industry when it comes to patents" and argued that the "system has deliberately been kept opaque by the pharmaceutical industry."[17] While accusing drug innovators of being "opaque" and "hidden [in their] real-world workings," it is notable that Mr. Amin never publicly disclosed I-MAK's data and the specific methods of calculation and analysis I-MAK used to reach the colossal patent numbers it claimed in its 2018 and 2019 white papers, keeping I-MAK's data and methods "hidden" and "deliberately opaque."

In letters sent to the PTO and to the FDA at the same time, you also requested that the agencies undertake an "objective, measured, and appropriate" analysis to address legitimate questions raised about a "false narrative" driven by "unreliable" and "biased" sources like I-MAK and the Evergreen Drug Patent Search database.[18] (Please see my answer to your second question in which I describe problems with this second source of patent numbers in the drug price and patent policy debates). In response to your queries, the PTO just released its *Drug Patent and Exclusivity Study*,[19] and the study does not replicate or confirm any of the massive numbers of patents attributed by I-MAK to the specific drugs in its white papers that it has published over the years.

Despite in the following years posting a large file listing patent and patent application numbers and providing a very generalized description of how I-MAK carefully counts patents in its past and recent white papers, I-MAK still has not responded to your specific request in 2022 that it disclose the *specific patents*—and apparently the specific abandoned patent applications—for the *specific drugs* that it has used to assert vast *total numbers of patents* covering these specific drugs. These are numbers I-MAK, activists, and academics have used to accuse drug innovators of "patent thickets" and "product hopping" that have been repeated in academic scholarship, policy publications, and in driving legislation and regulatory processes by agencies at the PTO, the FDA, and now the FTC. The recent study released by the PTO does not replicate or confirm its numbers

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[14] *Id.*

[15] *See* Letter from Tamir Amin to Senator Thom Tillis, Mar. 9, 2022, https://ipwatchdog.com/wp-content/uploads/2022/03/Letter-to-Senator-Tillis-re-I-MAK-Patent-Data-9-March-2022-1.pdf.

[16] *Id.* at 4.

[17] *Id.* at 1, 3.

[18] *See* Letter from Senator Thom Tillis to Janet Woodcock and Drew Hirschfeld, Jan. 31, 2022, https://ipwatchdog.com/wp-content/uploads/2022/02/1.31.2022-LTR-from-Senator-Tillis-to-FDA-and-USPTO-re-Patent-Data-Sources.pdf. *See also* Letter from Senator Thom Tillis to Janet Woodcock and Drew Hirschfeld, Apr. 1, 2022, https://ipwatchdog.com/wp-content/uploads/2022/04/4.1.2022-TT-Ltr-to-USPTO-FDA-re-IMAK-patent-data-Final.pdf.

[19] *See Drug Patent and Exclusivity Study* (June 2024), https://www.uspto.gov/initiatives/fda-collaboration/drug-patent-and-exclusivity-study-available.

of patents either. In sum, I-MAK's numbers of patents remain contradicted by official, publicly available sources of data on drug patents, and they remain unverified and unreliable, especially for purposes of evidence-based policymaking.

2. As an academic, do you believe that the body of recent academic literature that attempts to link patents to high drug prices meets the normal standards of academic rigor in terms of data publication, data reliability, and peer review? If not, please explain.

There are significant concerns that published articles and reports by academics are infected with basic statistical errors and other fundamental methodological deficiencies similar to those identified about I-MAK's numbers of patents and exclusivity periods. This is important because some government officials, Senators, and academics have relied on and used I-MAK's patent numbers to support claims about drug patents and to support proposed policies and laws.[20]

There are other sources of numbers of patents and exclusivity periods that reflect similar concerns as those raised about the I-MAK numbers, even though these sources are created by academics and even published in academic journals. For example, a recent empirical analysis of Robin Feldman's article, *May Your Drug Price Be Evergreen*,[21] has revealed an important distinction between the underlying data and the dataset used by Professor Feldman in her article (and by others) and made available to other researchers, called the Evergreen Drug Patent Search database.[22] In their 2023 article, *Solutions Still Searching for a Problem: A Call for Relevant Data*

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[20] *See, e.g.*, Kevin J. Hickey, Erin H. Ward, & Wen S. Shen, *Drug Pricing and Intellectual Property Law: A Legal Overview for the 116th Congress* (Congressional Research Service, Apr. 4, 2019), https://fas.org/sgp/crs/misc/R45666.pdf; *Durbin, Cassidy Introduce REMEDY Act To Lower Drug Prices By Curbing Patent Manipulation, Promoting Generic Competition* (Apr. 11, 2019), https://www.durbin.senate.gov/newsroom/press-releases/durbin-cassidy-introduce-remedy-act-to-lower-drug-prices-by-curbing-patent-manipulation-promoting-generic-competition; Michael A. Carrier, Response to Senator Grassley's Questions for the Record: Sen. Jud. Comm. Hearing on "IP and the Price of Prescription Drugs: Balancing Innovation and Competition" (May 28, 2019), https://www.judiciary.senate.gov/imo/media/doc/Carrier%20Responses%20to%20QFRs.pdf.

[21] Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590 (2018).

[22] https://sites.uclawsf.edu/evergreensearch/.

to Support "Evergreening" Allegations,[23] Professor Erika Lietzan and Dr. Kristina Acri found the "raw data" to be "largely accurate," but Professor Feldman then converted this raw data into the Evergreen Drug Patent Search database. This is the database that is available online to researchers and has been used by policymakers; the raw data itself is not available for use in the Evergreen Drug Patent Search database. The Evergreen Drug Patent Search database, according to Professor Lietzan and Dr. Acri, "includes metrics that reflect selection, interpretation, and characterization of the data in the raw dataset" that raise questions about its reliability.[24] More specifically, Professor Lietzan and Dr. Acri write that

> we determined that when reporting on the number of unique patents associated with a new drug application, the [Evergreen Drug Patent Search database] consistently counts a patent that has been reissued by the Patent and Trademark Office as two patents—even though the reissued patent replaces the original patent (which has been surrendered) and expires on the same date. *This approach biases their results towards higher patent counts, which supports their claims [about evergreening].* Again, the database reflects selection, interpretation, and characterization of the data, and policymakers should understand the difference between the raw data and these interpretive metrics.[25]

In sum, the Evergreen Drug Patent Search database inaccurately raises patent counts by counting original and reissued patents as two patents—in patent law and in the real world, all lawyers and businesspersons know that the reissue patent *replaces* the original patent—and I-MAK inaccurately counts abandoned patent applications as issued patents in creating patent numbers covering specific drugs. In both instances, this is not rigorous empirical analysis that reflects the facts of patent law, life sciences research, and the patenting practices of drug innovators.

Academics and others using the unreliable and unverified numbers of patents created by I-MAK and the Evergreen Drug Patent Search database should not be able to claim that publication of their own studies in law journals or peer review journals in healthcare journals are proxies for their veracity. As noted, the problem with these sources of patent numbers—I-MAK and the Evergreen Drug Patent Search database—is that they are not rigorous in accounting for well-known facts of patent law and of patenting practices. The editors and professors operating healthcare journals that publish articles using these unreliable sources of numbers of patents, such as the Journal of the American Medical Association, Health, Science, and others, are not experts in patent law. Thus, these journals lack the expertise, as also their peer reviewers, such as in knowing the legal difference between an original issued patent and a reissue patent. The same can be said for the law students who work as editors and run law journals in which professors have similarly published articles relying on I-MAK or the Evergreen Drug Patent Search numbers of patents.

Thus, peer review and academic publication—traditional scholarly sources that ensure the veracity of data, the rigorousness of the analysis of this data, and ultimately the legitimacy of the claims

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[23] Erika Lietzan & Kristina Acri née Lybecker, *Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations*, 73 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 788 (2023).

[24] *Id.*, at 794.

[25] *Id.*, at 794-95 (emphasis added).

derived from this data—cannot and should not be invoked as a basis for policymakers to rely on numbers of patents used to justify allegations of "evergreening" or "patent thickets." This is not a unique problem in the drug patent policy debates, as there have been media reports of academic publications by highly regard professors and researchers at Harvard University and other universities who committed plagiarism, falsified data, or both. There have been similar problems in other areas of patent policy with "junk science" data relied on by academics and policymakers, such as the infamous claim by two professors at Boston University in 2011 that patent trolls allegedly caused $29 billion in costs to the economy.[26] There is a serious concern in the drug patent policy debates that similar "junk science" data has been created as a matter of policy-based evidence-making, undermining the role of Congress to engage in evidence-based policymaking.

3. What are your thoughts regarding the persistent claim that companies are abusing the patent system to prevent competition far beyond the 20 years Congress intended in the Patent Act? What are the facts behind this debate?

At the hearing on May 21, 2024, and elsewhere, there were many claims of persistent and widespread abuse of the patent system by drug innovators. One example is that drug innovators are receiving more than the statutory 20 years of exclusivity in the patent system. These claims are often supported by reference to I-MAK numbers or numbers derived from the bias Evergreen Drug Patent Search database, or by reference to articles that rely on these studies. The problem is that this rhetoric is not confirmed by the actual patents or rigorous statistical studies.

In terms of specific patents and drugs, the claim of *decades* of market exclusivity is contradicted by the facts. For example, in its 2018 *Overpatented, Overpriced* white paper, I-MAK asserts that Pfizer, the owner of the patents covering Lyrica, will have exclusive rights over Lyrica in the healthcare marketplace until 2038—a whopping 20 years from the publication date of I-MAK's white paper in 2018 and 11 years after the expiration date in 2027 of the patents listed in the Orange Book for Lyrica CR.[27]

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[26] *See* Adam Mossoff, *Repetition of Junk Science and Epithets Does Not Make Them True*, IPWATCHDOG (Nov. 19, 2015), https://ipwatchdog.com/2015/11/19/repetition-of-make-them-true/id=63302/; Adam Mossoff, *The SHIELD Act: When Bad Economic Studies Make Bad Laws*, TRUTH ON THE MARKET (Mar. 15, 2013), https://truthonthemarket.com/2013/03/15/the-shield-act-when-bad-studies-make-bad-laws/. *See also* David L. Schwartz & Jay Kesan, *Analyzing the Role of Non-Practicing Entities in the Patent System*, 99 CORNELL L. REV. 425 (2014).

[27] *See* Mossoff, *supra* note 3, at 3.

Despite I-MAK's claims, the patent covering Lyrica's active ingredient expired in December 2018, the same year that I-MAK published its claim that Pfizer would have market exclusivity over this drug until 2038. In fact, the FDA approved *nine generic versions* of Lyrica the next year in 2019. Generic drug competition against Lyrica began that very same year: the generic drug company, Amneal Pharmaceuticals, announced in July 2019 that it had "received approval for, and launched, its generic version of Lyrica."[28] One media outlet reported in July 2019 that, for Pfizer's Lyrica, "its patent cliff is here."[29] Yet, according to I-MAK's 2018 white paper, none of this would happen for another 19 years. The facts flatly contradict I-MAK's assertions of vast periods of market exclusivity on top-selling drugs.

This has been further confirmed by *multiple* statistical studies of drug patents published over a period of more than a decade. These studies have consistently reported average market exclusivity periods of approximately 11-13 years, not the 2-4 decades asserted by I-MAK or suggested by Professor Feldman and others. It is notable that this is almost *one-half less* than the total 20-year patent term that drug innovators should receive under the patent laws. In *Solutions Still Searching for a Problem*, Professor Lietzan and Dr. Acri studied 224 New Drug Applications, and they found an average length of time before generic entry for each of these original drugs of 11.3 years.[30] Another study by Professor Lietzan and Dr. Acri of 227 new drugs that had received patent term extensions under the patent laws between 1984 and 2018 had an average period of market exclusivity of only 12.62 years.[31] A separate study in 2021 by Professor Charu Gupta found an average period of market exclusivity of only 13.3 years before market entry of a competitor generic drug for a set of 370 new drugs.[32] Another study published in 2019 by several other scholars of 170 top-selling drugs found an average period of market exclusivity of only 13.75 years for drugs that had received patent term extensions, and only 10 years of market exclusivity for drugs that were ineligible for patent term extensions.[33] Another study published in 2015 found an average period of market exclusivity of only 12.5 years for 175 new drugs.[34] Lastly, a study by Professor Scott Hemphill and Dr. Bhaven Sampat found an average period of market exclusivity of 12.1

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[28] Amneal Announces Launch of Generic Lyrica® (July 22, 2019), https://investors.amneal.com/news/press-releases/press-release-details/2019/Amneal-Announces-Launch-of-Generic-Lyrica/default.aspx.

[29] Eric Sagonowsky, *Lyrica generics roll: Pfizer blockbuster finally hits patent cliff*, Fierce Pharma (July 22, 2019), https://www.fiercepharma.com/pharma/lyrica-generics-roll-pfizer-finally-hits-patent-cliff-for-nerve-pain-and-fibromyalgia.

[30] Lietzan & Acri, *supra* note 23, at 840.

[31] The statute authorizing patent term extensions is 35 U.S.C. § 156. Their study is Erika Lietzan & Kristina Acri, *Distorted Drug Patents*, 95 WASH. L. REV. 1317, 1326-29 (2020).

[32] *See* Charu Gupta, *One Product, Many Patents: Imperfect Intellectual Property Rights in the Pharmaceutical Industry* (2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3748158.

[33] *See* Reed F. Beall et al., *Patent Term Restoration for Top-Selling Drugs in the United States*, 24 DRUG DISCOVERY TODAY 20, 20 (2019).

[34] *See* B. Wang et al., *Variations in Time of Market Exclusivity Among Top-Selling Prescription Drugs in the United States*, 175 JAMA INTERN MED. 635 (2015).

years before generic entry for a set of 119 drugs that were approved by the FDA between 2001-2010.[35]

In sum, there is no evidence of systemic manipulation of the patent system by drug innovators—they are not engaging in "product hopping" or "evergreening" to wrongly extend periods of exclusivity beyond the 20-year paten term. Claims about "product hopping" and "evergreening" are policy rhetoric employed by activists like I-MAK and some academics to create a moral panic in Congress and agencies about alleged abuse of the patent system. They do this to reduce a complex set of legal, regulatory, and economic determinants of drug prices down to an overly simplistic, sound-bite boogeyman: the patent system.

If Congress follows the principle of good governance in evidence-based policymaking, then it should recognize that numerous, multiple studies by different scholars engaging in over a decade of research consistently found average market exclusivity periods for new drugs ranging between 11-13 years. This is far less than the total period of 20 years of exclusivity promised to all innovators by the patent system. More important, it directly contradicts I-MAK's unverified and unreliable claims in its own white papers that there are 2-4 decades of market exclusivity. These published studies all follow rigorous statistical and other empirical methods of analysis, they are transparent in their analytical methods in the articles reporting their results, and their underlying data is clearly available for replication analyses. None of this can be said about I-MAK's numbers.

[35] *See* C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327 (2012).

Senate Judiciary Committee Hearing "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market, May 21, 2024

Professor Rai's Answers to Senator Grassley's questions

1. Do you believe there is anti-competitive conduct occurring in the PBM marketplace that leads to higher drug costs for consumers? Please explain.

The PBM marketplace is highly concentrated, and oligopoly power creates the conditions necessary for anti-competitive behavior of various sorts. For example, PBMs can use their oligopoly power to negotiate rebates with drug manufacturers that are not passed on to consumers. My understanding is that PBMs also engage in anti-competitive practices in their negotiations with pharmacies. However, the study of PBM-pharmacy contracting is not my area of expertise.

2. Senator Cantwell and I have a bill, the Pharmacy Benefit Manager Transparency Act, to prevent unfair, anti-competitive practices by PBMs and to bring about greater transparency. Do you believe that this bill would help address competition concerns and lower the price of drugs for patients?

My understanding is that this bill focuses on PBM contracting with pharmacies. As noted in my answer to question 1, the study of PBM contracting with pharmacies is not my area of expertise. In general, however, particularly in oligopolistic markets, contract transparency of the sort promoted by the PBM Transparency Act is likely to promote competition.

3. Chairman Durbin and I have attempted to pass our bill, the Drug Price Transparency for Consumers (DTC) Act, to require drug companies to list the price of a drug in their ads to empower consumers. The Trump Administration attempted to require it through rule-making, but Big Pharma opposed it. Why do you think Big Pharma opposes this policy?

Although insured consumers are not fully exposed to list prices, they are exposed to co-payments that are often calculated based on these list prices. To the extent consumers are aware of this connection, direct-to-consumer advertising by

pharmaceutical firms will presumably fail to generate the increases in consumer demand it currently generates.

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Senator Richard J. Durbin, Illinois, Chair
United States Senate
Committee on the Judiciary
Washington, DC 20510-6275

June 12, 2024

Dear Chair Durbin,

Thank you again for the opportunity to testify on behalf of PhRMA. Please find our responses to the written questions from Committee members following my testimony on Tuesday, May 21, 2024.

Senator Tillis' Question: a) Given the complexity of the science and manufacturing in the biologics space and the fact that products often need decades to go from groundbreaking research to human interaction, how should we be looking at this question of incremental innovation? b) Is it different in this area, particularly when the development process can involve not just the method of treatment, but also complex manufacturing and patient delivery?

The investment necessary to develop a new medicine can cost an average of $2.6 billion and take 10-15 years, and only 12% of medicines entering clinical trials ever obtain an FDA approval.[1] Manufacturers seek the certainty and predictability provided by intellectual property (IP) protections to make the decades long investments in new technologies, and in building and expanding upon state-of-the-art manufacturing facilities. Strong and reliable IP protections are also critical to fostering public-private partnerships and other forms of collaboration, including investment in emerging innovator companies.

Innovation shouldn't stop once a new drug becomes available to patients, in fact, many advancements for patients are realized through continued investment in R&D after initial approval, known as post-approval R&D. Whether adding a new use in an earlier treatment line or disease stage, or finding new diseases a medicine can treat, patent protections incentivize manufacturers to

[1] 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.

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continue working to improve their medicines and make them more effective for patients. R&D investment in medicines is an ongoing process that continues long past initial FDA approval, resulting in innovations that improve the lives of patients, including new uses, novel delivery mechanisms and new dosing schedules. These advances can involve significant R&D investments and lengthy and resource-intensive clinical trials, with no guarantees of success. Post-approval R&D can lead to new or improved treatment options for patients that may enable better health, quality of life, or reduce treatment burdens improving treatment adherence and health outcomes.

Post-approval R&D is particularly important in advancing new treatments for cancer patients, as much of the unprecedented progress seen in the fight against cancer over the past decade has been the result of this form of R&D.[2] In fact, the majority of cancer medicines receive approval for more than one indication, with many post-approval indications approved years after the medicine's initial FDA approval. [3,4] In addition to post-approval R&D driving new uses, it also brings greater knowledge on the benefits of medicines. Due to the life-threatening and progressive nature of cancer, long-term follow-up of patients in clinical studies is often needed to evaluate overall survival, which is the length of time that patients with the disease are still alive since beginning treatment. These additional studies conducted after approval are critical to understanding and realizing the full therapeutic value of cancer treatments.[5]

This additional R&D can also be directed to improving methods of manufacturing, developing new manufacturing processes or to developing a more complex form of a medicine. Such manufacturing advances can improve medicines, for example by removing potential impurities. Investment in these innovations similarly is incentivized by IP protections. For R&D

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[2] IQVIA Institute. "Global Oncology Trends 2022." https://www. iqvia.com/-/media/iqvia/pdfs/institute-reports/global-oncologytrends-2022/iqvia-institute-global-oncology-trends-2022-forweb.pdf. Published May 26, 2022. Accessed June 11, 2023.
[3] Partnership for Health Analytic Research. "Implications of the Inflation Reduction Act Price Setting Provisions on Post-Approval Indications for Small Molecule Medicines." https://www.pharllc.com/ publication/implications-of-the-ira-price-setting-provisions-on-postapproval-indications-for-small-molecule-medicines/. Published June 2023. Accessed June 11, 2023
[4] Partnership for Health Analytic Research. "Implications of the Inflation Reduction Act on Post-Approval Research & Development of Biopharmaceutical Medicines." https://www.pharllc.com/wp-content/ uploads/2022/11/Clinical-Benefits-of-Post-Authorization-ResearchBrief.pdf. Published November 9, 2022. Accessed June 13, 2023.
[5] National Cancer Institute, NCI Dictionary of Cancer Terms. "Overall Survival." https://www.cancer.gov/publications/dictionaries/cancerterms/def/overall-survival. Accessed June 11, 2023.

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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 their inventions to the public, through patents.

In contrast to patents that cover the composition of a new compound, new uses, new dosage forms, patents that cover new methods of manufacturing can be invented throughout the product lifecycle, and thus patent applications for them can also be filed throughout this lifecycle. For instance, new methods of manufacturing that reduce the potential for immunogenicity are often invented years after a biologic is discovered or has obtained FDA 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 benefit patients and should be incentivized through robust IP protections.

It is also important to note, IP protection on post-approval advances do not block approval of generic copies or biosimilar versions of an earlier approved version of that medicine. If, as is often alleged, a manufacturer introduced a meaningless change to an existing product, this change would do nothing to delay or prevent FDA from approving a generic or biosimilar of the earlier product. In this way, the patent system continues to reward and incentivize new innovations without extending exclusivity on earlier inventions.

Senator Grassley's Question 1: I'm concerned about the Biden Administration's lack of leadership in protecting intellectual property rights abroad. What's your opinion? How does this impact the industry and the development of new cures?

The Biden Administration has demonstrated limited ambition to further advance, or even maintain, strong intellectual property (IP) policies internationally. Instead, the Administration has departed from longstanding and bipartisan U.S. trade objectives to promote strong IP policies by altogether deprioritizing an agenda to protect American innovation abroad.

U.S. biopharmaceutical innovators face serious IP challenges in foreign markets. As documented in PhRMA's annual Special 301 and National Trade Estimate submissions to the United States Trade Representative (USTR), many foreign governments fail to provide the IP protections

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necessary to support biopharmaceutical innovation, despite their commitments under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and U.S. free trade agreements.[6] Unfortunately, the Administration has not adequately enforced trading partners' commitments to protect American innovation, allowing harmful policies and practices in key jurisdictions to go unaddressed. For example, China has not implemented its WTO obligation to provide regulatory data protection for new biopharmaceutical products, and Mexico has not implemented key IP obligations required by the United States-Mexico-Canada Agreement (USMCA).

Worse, the Administration has adopted IP policies that materially harm U.S. innovators. The Administration actively undermined international commitments to protect IP at the WTO's Twelfth Ministerial Conference by agreeing to an unnecessary TRIPS waiver that effectively handed over American COVID-19 vaccine innovations to countries looking to overtake U.S. leadership in biopharmaceutical development. Most recently, Ambassador Tai stated in a press release announcing the 2024 USTR Special 301 Report that the "Administration has continued its policy of declining to call out countries for exercising TRIPS flexibilities, including with respect to compulsory licensing." Despite continued serious concerns, the Report reverses decades of bipartisan precedent and now eliminates all references of compulsory licensing by key trading partners and omits previously included concerns on egregious restrictive patentability practices – further emboldening foreign governments to erode IP protections for American innovators.

Put simply, the Biden Administration's lack of leadership in protecting IP abroad and its unambitious trade agenda is harming America's global competitiveness and patients around the world.

Senator Grassley's Question 2: The Biden Administration is considering changing march-in rights policy under the Bayh-Dole Act as a way to reduce the price of prescription drugs. Professor Rai testified that she believed this was a "careful" approach and would provide a "gentle nudge" to

[6] PhRMA comments on the 2024 National Trade Estimate Report on Foreign Trade Barriers (NTE), available at: https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/P-R/PhRMA-2024-NTE-Comments.pdf

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deal with high prescription drugs costs. Do you agree with Professor Rai? What's your opinion on the Administration's proposed changes with respect to march-in rights?

Strong and reliable IP protections are critical to fostering public-private partnerships and other forms of collaboration. Congress passed the Bayh-Dole Act in 1980 with bipartisan support to incentivize the private sector to transform discoveries resulting from government-funded early-stage research into useful products in any sector. By allowing grant recipients such as universities to retain the title to the patents covering their inventions and enabling them to license the patents and right to use those inventions to private sector partners, the Bayh-Dole Act facilitates the development of commercially available medical treatments. Prior to enactment of the Bayh-Dole Act, the government retained the patents on federally-funded inventions – and only 5% of those patents were ever licensed for use in the private sector.[7] Collaboration was further incentivized by The Federal Technology Transfer Act of 1986, which authorized Federal laboratories to enter into cooperative research and development agreements (CRADAs) with private businesses and other entities. These policies have proven critical to maximizing taxpayer benefit for government-funded research.[8]

The Biden Administration's National Institute of Standards and Technology (NIST) recently issued a Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights ("the Draft Framework").[9] Far from a "careful" approach that would provide a "gentle nudge" to address drug pricing, the Draft Framework misinterprets the Bayh-Dole Act of 1980 and uses a vague approach that is already causing uncertainty. The Draft Framework ignores the intent of the law, as stated by the bill's sponsors,[10] as well as decades of policy precedent by encouraging federal agencies to explicitly consider the price of a product incorporating federally funded inventions when evaluating the statutory march-in

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[7] Government Accountability Office (GAO). Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions, 2009. Available at: www.gao.gov/products/GAO-09-742.
[8] Wendy H. Schacht, *Federal R&D, Drug Discovery, and Pricing: Insights From the NIH-University-Industry Relationship*, Report RL32324 (Congressional Research Service), November 30, 2012.
[9] 88 Fed. Reg. 85593–605 (Dec. 8, 2023).
[10] *See* Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," Washington Post, April 11, 2002 (Bayh-Dole did not intend that the government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government.")

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criteria. If finalized in its present form, NIST's proposal would create an environment of uncertainty in Bayh-Dole's technology transfer scheme that could discourage companies from investing funds in the already highly risky endeavor of drug development as well as the development of other important technologies.

When companies first license a new technology, they often don't know whether a finished product will even be viable, let alone how much it will cost to develop and what pricing will be viable in the highly competitive biopharmaceutical market. As such, march-in is a particularly blunt tool, and if wielded, a company could be stripped of all its economic interest in a product and risk a near total loss of its investment. Worse, the Administration's plan gives no clear guidance as to what price could trigger this loss. Faced with this uncertainty, companies may well conclude that reliance on government funding is too risky. As a result, NIST's march-in proposal could send the U.S. innovation ecosystem back to a time before Bayh-Dole when government-funded research sat on a shelf, undeveloped and unused. The significant negative consequences that may flow from this uncertainty, and from fundamentally undercutting the very purpose of Bayh-Dole, are offset by no measurable, practical, or realistic gain for the American people or the U.S. innovation ecosystem.

Senator Grassley's Question 3: In Dr. Feldman's written and oral testimony, he suggests that the Committee consider policies dealing with orange book listings, re-examination, litigation, generic approval standards, and incentives for patent challenges. Do you agree with these 5 specific proposals as ways to address the high cost of drugs? Why or why not?

Please find our response to the 5 specific proposals Dr. Feldman outlined in his testimony that the Committee should consider below:

1. *Grant the FDA the authority and resources to evaluate all patents submitted for listing in the Orange Book to determine eligibility for inclusion as well as direct the FDA to provide additional guidance on the types of patents that should be listed.*

The industry does not support the listing of inappropriate patents in the Orange Book. Instead, the industry seeks to comply with the statutory Orange Book listing requirements implemented by the FDA. PhRMA therefore agrees with Dr. Feldman that Congress should direct FDA to provide additional guidance on whether certain types of patents should be listed, and

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furthermore PhRMA believes that the FDA already has adequate authority to provide clarification on types of patents and the resources to do so. FDA has not, however, provided clear guidance on device-related patents that should be listed, even though PhRMA and companies have for years requested guidance from FDA concerning whether such patents must be listed. FDA already has the authority to provide clarification on the listing of various patents and should do so.[11]

Generally, the patent listing system has operated effectively over the almost 40 years since enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman). There have been times when FDA has clarified types of patents required to be listed, including changing its regulations in 2003 with respect to, for example, patents on intermediates. There also are existing mechanisms for challenges to listings. FDA has not, however, provided clear guidance on device-related patents that should be listed, even though PhRMA and companies have requested guidance from FDA over many years concerning listing of these patents. FDA already has the authority to provide clarification on types of patents and should do so. There is no need for FDA to take on the significant resource burdens of substantively evaluating all patents submitted for listing in the Orange Book when providing requested clarity on listing would address concerns.

2. *Require that patents submitted to the FDA for listing in the Orange Book are also submitted to the USPTO for re-examination.*

PhRMA disagrees with this proposal, which would slow down the Hatch-Waxman process and create uncertainty for innovators. Patents in any sector have a presumption of validity, and requiring all listed patents to be submitted for reexamination suggests there is a particular validity or patent quality problem in the pharmaceutical sector that is not borne out by data. The proposal would also create a huge resource burden for U.S. Patent and Trademark Office (USPTO) given the number of patents listed in the Orange Book. The proposal also appears to be based on the mistaken premise that listing a patent in the Orange Book is somehow suspect. Patents are legally

[11] Indeed, case law in this area has demonstrated that the patent listing requirements require further clarification by FDA, as the decisions in these cases have led to further confusion including regarding the meaning of "claim." *See, e.g., In re Lantus Direct Purchaser Antitrust Litigation*, 950 F.3d 1 (1st Cir. 2020); Opinion & Order, *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., LLC*, Civ. No. 23-20964 (SRC) (D.N.J. June 10, 2024) ; *Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman*, 109 F.3d 756 (Fed. Cir. 1997); *Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC*, 60 F.4th 1373 (Fed. Cir. 2023).

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required to be listed in the Orange Book, and this listing process provides generic manufacturers with clarity about the patents covering the reference product that are relevant to generic entry. Generic manufacturers also are able to challenge Orange Book listed patents before launch of their products to resolve patent issues without the risk of incurring damages from selling an infringing product. Using the reexamination process for every Orange Book listed patent would drain USPTO resources without clear benefit, given the existing mechanisms for challenging patent listing and patent validity.

3. *Limit the number of patents that brand-name manufacturers can assert to one patent per family when suing for infringement, for example based on the presence of terminal disclaimers.*

PhRMA disagrees with this proposal. Aside from the impact on property rights by prohibiting enforcement of valid patent rights, the proposal fails to recognize the reality of the patent system. Terminal disclaimers reduce the term for an entire patent, even if it is used to address an issue with a particular claim in a patent. This proposal would eliminate patent rights in valid claims to distinct inventions. Terminal disclaimers are also addressed below in the response to Question 4.

4. *Grant the FDA more resources and flexibility to approve generic drug-device combinations that differ slightly from brand-name reference products (while still containing the same active ingredients) and require the FDA to ensure that postmarketing surveillance studies are conducted to confirm similar outcomes for patients receiving generic and brand-name versions.*

FDA already has authority to approve these generic drug-device combination products, but we support clarifying FDA's authority to do so. However, any legislation on this should be appropriately tailored to this objective. Per FDA's Legislative Proposal, the agency aims to clarify "that differences in labeling between the [reference listed drug] (RLD) and the proposed generic as a result of permissible differences in the device are also permissible." Although this clarification would seem appropriate, there is no need for the legislation to go further. Any legislation should simply clarify that labeling changes are a result of differences in a device for use with the generic drug are allowed, in line with FDA's objective.

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5. *Increase the 180-day exclusivity periods for the first generic firms to file paragraph IV certifications on complex products like drug-device combinations and decrease the 30-month stays awarded to brand-name firms that sue for infringement.*

PhRMA disagrees with decreasing the 30-month stay. The 30-month stay is an integral part of the Hatch-Waxman framework that allows for resolution of patent disputes prior to generics entering the market. After generics enter the market, the patent litigation becomes more complex given the potential for damages and an injunction. The 30-month stay is already a balanced provision, and the 30-month length was crafted to provide sufficient time to allow the court to rule in the patent infringement suit. If a generic wins in the district court prior to the end of 30 months, the stay ends. In addition, if innovators obtain and list patents after a generic application has been submitted, there is no separate 30-month stay for litigation over such patents.

PhRMA does not have a position on increasing the 180-day exclusivity periods for the first filing generics on complex products.

Senator Grassley's Question 4: Do you agree with the various proposals to address issues with terminal disclaimers and obviousness-type double patenting? Please explain.

PhRMA disagrees with the recent proposals to "address issues with terminal disclaimers and obviousness-type double patenting." Terminal disclaimers (TD) require the applicant to agree to a common expiration date and common ownership of "disclaimed" patents of obvious variants. TDs were designed to overcome the judicial doctrine of obviousness-type double patenting (OTDP), which was established when patent terms were 17 years from issuance, and later issued patents would always last longer.[12] TDs provide a straightforward solution to address concerns about patents that were seen to claim obvious variants from being enforced by multiple assignees and from providing extended patent term. They have been an integral part of the U.S. patent system across industries and technologies.

[12] This has profoundly changed. On June 8, 1995, the Uruguay Round Agreements Act (URAA) took effect. Patents with effective filing dates after that date are entitled to a term that lasts 20 years from the relevant filing date, regardless of when they issue.

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A Senate bill (S.3583) is targeted specifically to the pharmaceutical industry and only permits companies to assert one patent per "Patent Group," which are patents linked by a terminal disclaimer, against a party with a copied product.[13] The bill's stated purpose is "to address patent thickets," which allegedly "come at a high cost to the American people."[14] The bill impacts patents linked by a TD and the underlying suggestion is that these are bad, low quality, invalid patents. But in fact, these patents all have the same expiration date, so they do not prolong the patent term, and pharmaceutical patents are not broadly invalid. PhRMA does not support the currently pending proposals addressing obviousness-type double patenting and TDs because they undermine the values of our intellectual property system in promoting innovation and incentivize gamesmanship. Further, the rhetoric that terminal disclaimers are increasing drug costs has been built on seriously flawed data including those from I-MAK and the Hastings database.[15] Academics have repeatedly criticized these sources for the "serious questions of reliability and accuracy" they raise.[16]

Despite the strong rhetoric around so-called patent thickets, data shows that the number of patents covering a pharmaceutical product is not a general concern across the industry. Pharmaceutical products (i.e. drugs) are covered by ***fewer*** patents per product than other products such as golf balls/clubs and cell phones.[17] Pharmaceutical patents are not "bad patents" either. Instead, they are upheld at higher rates in district courts and PTAB than other types of patents.[18]

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[13] "S.3583 - A bill to address patent thickets" was introduced in the Senate on Jan 11, 2024. *See* https://www.congress.gov/bill/118th-congress/senate-bill/3583.
[14] Statement of Purpose of the "One invention one patent" act, which was a predecessor of S.3583.
[15] *See*, I-MAK, *Overpatented, Overpriced: Curbing patent abuse: Tackling the root of the drug pricing crisis*, (Sept. 2022); Evergreen Drug Patent Database.
[16] *See,* Adam Mossoff, *Unreliable Data Have Infected the Policy Debates Over Drug Patents* (Jan. 2022); Erika Lietzan & Kristina Acri née Lybecker, *Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations*, 33 FORDHAM INTELL. PROP., MEDIA & ENT. L.J. 788, 788 (2023).
[17] *See, e.g.*, Titleist Patent Marking (last visited June 4, 2024) (noting, for example, 24 patents covering the 2023 Pro V1 golf balls, 40 patents covering the 2021 Pro V1x golf balls, and 90 patents covering "irons" golf clubs); Building a Better Golf Ball, Popular Science (Nov. 24, 2008) (noting that a golf ball may contain as many as 70 separate inventions); TaylorMade Golf Patent Marking (listing over 100 patents for certain golf clubs); Apple-Samsung Case Shows Smartphones as Legal Magnet, New York Times (August 25, 2012) ("By one estimate, as many as 250,000 patents can be used to claim ownership of some technical or design element in a smartphone."); LG Patent Marking (last visited June 4, 2024) (listening hundreds of patents as covering LG's smartphones); Alison Noon, *Puma Must Face Nike's Flyknit Patent Infringement Claims*, Law360 (Oct. 10, 2018) ("Nike claimed to have acquired more than 300 utility patents to protect the knit-upper shoe trend it launched in 2012.").
[18] Tu & Lemley, *What litigators can teach the Patent Office about pharmaceutical patents*, Wash Law Rev. 2022; 99:1673, 1692. The article looked at so-called "secondary patents" but acknowledged based on its own data that "even the numbers for secondary patents involve a much higher win rate than for non-pharmaceutical patents."

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Additionally, multiple studies failed to demonstrate that the number of existing pharmaceutical patents impacts competition.[19]

Further, the patent system already has a carefully crafted framework to challenge the validity of pharmaceutical patents that balances the need to incentivize research and development in important new drugs, while also allowing lower cost generic drug entry. Under the framework created by the Hatch-Waxman Act, litigation typically resolves validity disputes within two years to ensure the issues are addressed before the end of the 30-month regulatory stay.[20] Given this quick timeline, courts already have mechanisms to limit the number of claims litigated,[21] and judges often require the parties to limit the number of litigated patents and claims.

The quick timing of Hatch Waxman litigation also impacts PTAB proceedings. Within the one-year time bar under 35 U.S.C. §315(b), defendants often already have a narrowed list of the patents and claims that will be litigated, and they can target those claims in any post-grant petitions. Further, if the patents linked by terminal disclaimer are truly similar to each other, then the arguments and expert testimony should be similar across the patents. Thus, the increased cost for multiple patents should be minimal since the inter partes review (IPR) costs are largely in preparing the papers and arguments with experts, not in the filing fees. And if the petitions require different arguments and experts, which increases the cost, this also indicates that the patents have unique validity positions and emphasizes that their validity should be considered independently of one another.

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[19] *See* Jonathan M. Barnett, Are There Really Patent Thickets?, 39 Regulation 14, 15 (Winter 2016-2017); *see also* Erika Lietzan & Kristina Acri née Lybecker, Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations, 33 Fordham Intell. Prop., Media & Ent. L.J. 788, 789 (noting that the U.C. Hastings Evergreen Drug Patent Database did not accurately capture when generic drugs enter the market, and "generic competition launched on average eighty-four months (seven years) before the Hastings Database implied it would"); Global Biosimilars Market Growing to Exhibit a Noteworthy CAGR of 22.9% by 2033, Key Drivers, Growth and Opportunity Analysis - Research Nester, Global News Wire (Oct. 12, 2022); The Global Biologics Market Is Projected to Grow at a CAGR of 8.82% By 2032: Visiongain Reports Ltd, Global News Wire (Aug. 9, 2022) (finding that approval of biosimilars and interchangeable biologics have contributed to growth in the biologics and biosimilar market, which is projected to continue).

[20] ANDA cases reaching trial between 2016 and 2017 did so at a median time of 759 days, and many ANDA cases were terminated before reaching trial. *See,* Lex Machina, Hatch-Waxman ANDA Litigation Report 2018, at 10.

[21] *See, e.g.*, https://www.txed.uscourts.gov/sites/default/files/forms/ModelPatentOrder.pdf (Eastern District of Texas) and https://www.ded.uscourts.gov/sites/ded/files/chambers/Scheduling%20Order%20for%20Hatch-Waxman%20Patent%20Infringement%20Cases.pdf (District of Delaware).

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Instead of providing a more efficient system, S.3583 creates an incentive for gamesmanship. In Hatch-Waxman litigation the patent owner plaintiff rarely knows the details of the generic product before filing the complaint. If the plaintiff is forced to select only one patent per "Patent Group" for assertion, generic companies could be incentivized to hide the specifics of their product in a paragraph IV letter and not address infringement at all, and then only reveal product details and non-infringement theories after the patent has been selected.[22] This could neuter pharmaceutical patents and does not serve the policy objective.[23]

Additionally, the bill is problematic because it would *de facto* also take away a patent owner's rights in asserting patently *distinct* inventions. A "Patent Group" is defined in the bill as two or more commonly owned patents that are linked by a "terminal disclaimer." Under current OTDP/TD practice, even if only a single claim in a patent application is subject to an OTDP rejection, the applicant is required to file a terminal disclaimer that applies to the *entire patent*. Therefore, by allowing the assertion of only one patent in a "Patent Group," the bill forces a choice not only between the patentably indistinct claims, but also between patentably *distinct* claims embodying *separate* inventions that are completely unrelated to the original OTDP rejection.

In short, PhRMA does not support the currently pending legislative proposal addressing obviousness-type double patenting and terminal disclaimers because it undermines support for innovation and promotes gamesmanship.

The USPTO also issued a proposed rule that would make a patent subject to a TD unenforceable should the patent it is linked to by TD be found unpatentable or invalid as anticipated or obvious.[24] PhRMA will be submitting comments in response to this proposed rule.

Thank you for the opportunity to respond to the Committee's questions. I can be reached at julrich@phrma.org with any additional questions.

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[22] A generic drug company must address non-infringement and offer confidential access to its ANDA in its paragraph IV letter only to preserve the ability to seek a declaratory judgment. See 21 C.F.R. 314.95(c)(8).
[23] A similar dynamic could also occur with respect to patent litigation over biosimilars.
[24] *See* Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting, 80 Fed. Reg. 40439 (proposed May 10, 2024).

Statement for the Record by the Association for Accessible Medicines
Senate Committee on the Judiciary, Hearing on Drug Pricing
May 21, 2024

The Association for Accessible Medicines and its Biosimilars Council (collectively, "AAM") thank the Committee for holding a hearing on the important issue of combating higher drug prices. Forty years of experience show that protecting timely patient access to affordable generic medicines—and now, biosimilars as well—is the best way to use market competition to hold down drug prices. But generic and biosimilar access is threatened. AAM strongly supports the statutory safe harbor for carve-outs proposed by the Food and Drug Administration in its fiscal year (FY) 2024 budget and urges its adoption.

Since the enactment of the Hatch-Waxman Amendments in 1984, Congress has made sure that a narrow patent on one way of *using* a drug does not block access to generic substitutes entirely. When a drug's formulation and one or more ways of using it have moved into the public domain, patents should no longer prevent the marketing of a generic version. As the Supreme Court has rightly recognized, Congress provided for carve-outs so "that one patented use will not foreclose marketing a generic drug for other unpatented ones."

Hatch-Waxman accomplished that goal through the "skinny labeling" mechanism, which has allowed generic manufacturers to bring numerous generic drugs to the market. A skinny label allows the generic manufacturer to "carve-out" a brand drug sponsor's patented methods of use from the generic's FDA-approved labeling. For example, if a brand-name drug is approved for treating four different diseases, only one of which is covered by a patent, generic manufacturers can "carve-out" that patented method, gain FDA approval for the remaining three diseases, and bring to market a more affordable generic alternative.

The rationale for Hatch-Waxman's carve-out process is straightforward: it facilitates generic competition on unpatented uses of brand-name drugs and ensures patients have timely access to more affordable medicine. Indeed, Hatch-Waxman's carve-out process has served the public interest for over 40 years by increasing access to generic medicines, saving the healthcare system billions of dollars. In 2010, Congress added a pathway for biosimilars, which achieve similar savings through alternatives to some of the most expensive biologic medicines. Biosimilars, too, can sometimes avoid a patent block by omitting portions of the labeling of the brand-name reference product.

Despite this well-established practice, a recent decision from the U.S. Court of Appeals for the Federal Circuit threatens to undermine Hatch-Waxman's carve-out process. That decision, *GSK v. Teva*, holds that a generic can be liable for infringing the brand's patented method that the generic carved-out from its label, based on arguments that the carve-out was supposedly not broad enough, and that the generic publicly described its product as the equivalent of the brand product—something that is true of *every* generic. Although the federal government filed a brief to the Supreme Court explaining that the Federal Circuit's decision was wrong, the Supreme Court has declined to review the decision at this time.

As a result, the Federal Circuit's *GSK* decision threatens to nullify the longstanding carve-out mechanism that

allows generic manufacturers to quickly get affordable, FDA-approved medicines to patients. Many well-known generics currently on the market (including Crestor®, Abilify®, and Zytiga®) were able to launch years before expiration of the brand's method patents because of the carve-out mechanism. With the viability of carve-outs thrown into uncertainty, manufacturers will be discouraged from attempting early launch of generic drugs and biosimilars in the future, and patients will be forced to wait longer for lower-cost generics to be approved. And there is a risk that the uncertainty over carve-outs will become even worse, as the Federal Circuit is currently considering a case concerning a generic for an expensive triglyceride medicine (Vascepa®) that may lead the court to broaden the mistaken rule it announced in *GSK*. Absent a legislative change, brands will be able to grow larger and larger patent estates that delay access to more affordable medicines.

The FDA's FY2024 budget included a reasonable and targeted proposal to correct the mistaken *GSK* decision and provide a safe harbor so that generics can rely on carve-outs. It ensures that just submitting a generic application with a carve-out statement does not infringe the carved-out patent. It also ensures that if FDA approves the carved-out labeling—a decision that FDA will make based on the brand company's own descriptions of what parts of its labeling are protected by a method patent—marketing the generic product with that labeling does not infringe the method patent. The proposal also ensures that generics will not be accused of infringement simply for describing themselves as generics. In the *GSK* case and the new carve-out case before the Federal Circuit, the brand companies have argued that communications describing a generic with carved-out labeling as the "generic of" or "generic equivalent of" the brand product are in essence code words—that a jury could interpret them as urging the listener to prescribe the generic *for the carved-out use* without mentioning it. If such ordinary statements can carry nine-figure liability, generics and biosimilars cannot market their products and the carve-out system will not function.

We encourage the Committee to adopt the proposed statutory safe harbor. Enactment of this proposal will safeguard future generic competition through the carve-out mechanism as originally intended under Hatch-Waxman, thus ensuring that patients continue to have ready access to safe and lower-priced generic medicines and biosimilars.

Bayh-Dole COALITION

Celebrating the past. Protecting the future.

May 20, 2024

The Honorable Dick Durbin
Chairman
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Lindsey Graham
Ranking Member
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Durbin and Ranking Member Graham:

On behalf of the Bayh-Dole Coalition, I'd like to comment in advance of your upcoming hearing on drug pricing. The Bayh-Dole Coalition is a diverse group of innovation-oriented organizations and individuals committed to celebrating and protecting the Bayh-Dole Act, as well as informing policymakers and the public of its many benefits.

It is largely due to the leadership of the Senate Judiciary Committee that the United States became the innovation leader of the world, including in the life sciences. In the 1970's, we were rapidly losing markets to foreign competitors, and many predicted that trend would only accelerate and we should resign ourselves to second or third place.

However, that didn't happen because this Committee helped unleash American innovation by strengthening our patent laws and using its incentives to commercialize the results of billions of dollars of federally-funded R&D. That was done by passage of the Bayh-Dole Act in 1980 and creation of the Court of Appeals for the Federal Circuit in 1982. These actions helped ignite the greatest innovation boom in history. The Economist Technology Quarterly said: "Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980... More than anything, this simple policy measure helped reverse America's precipitous slide into industrial irrelevance."

The Bayh-Dole Act and our patent system are intended to provide confidence that the rules of the game are understood and consistently enforced, regardless of who's in power. That is particularly important to us because, unlike our competitors, our system, even in the life sciences, is driven by small companies which must raise high-risk venture capital while knowing that the odds against success are formidable.

Thus, suggestions that the Bayh-Dole Act should be misused for Washington-imposed price controls or that the government can arbitrarily seize privately funded inventions as a price control mechanism pose fundamental threats to our innovation engine. And, once unleashed, such misuse cannot be confined to

drugs, but would inevitably spread to any technology. The Bayh-Dole Act is one of the most transformative policy reforms in U.S. history. By empowering academic institutions and small companies to own the patents on inventions they make with federal funding, it sparked an innovation boom that brought thousands of new products to American consumers.

Bayh-Dole had a particularly significant impact in the life sciences. To date, over 200 new drugs and vaccines — including revolutionary treatments for cancer, HIV/AIDS, Covid-19, Ebola, pneumonia, psoriasis, rotavirus, and multiple sclerosis — have been developed thanks to the academic tech transfer system created by the law. Before Bayh-Dole was enacted, fewer than 10% of new drugs were first introduced in the United States. Today, more than six in 10 are.

Countless patients around the world now have hope because of Bayh-Dole. But one much-discussed proposal to lower drug prices would destroy this important law and the pipeline of treatments it has opened. The proposal, put forth by the National Institute of Standards and Technology (NIST) in December, would allow government agencies to misuse Bayh-Dole's "march-in" rights, allowing copiers to make any product that someone feels is not "reasonably priced," a completely undefined term.

In reality, this strategy would be ineffective at reducing drug prices, as even its advocates now admit. The vast majority of drugs — including more than 97% of those approved since 1985 — rely on at least one private-sector patent — that is, one or more patents that did not involve government funding. Such drugs could not be copied through march-in rights, which only applies to patents made with federal funding.

The misuse of march-in would actually *reduce* access to affordable drugs, because it would undermine crucial incentives for generic drug manufacturing. Thus, the generic drug industry, which would be the prime beneficiary of this policy, wrote to NIST opposing the proposed change, because of the danger it poses to the availability of less expensive generics as drugs go off-patent — a process that reduced overall expenditures on prescription drugs by $402 billion in 2022 alone.

But beyond its inability to achieve its stated objective, NIST's proposal would do extensive damage to the intellectual property incentives that have made America the world leader in life science innovation, and every other field. Senators Bayh and Dole, as members of this Committee, carefully crafted the march-in provision and stated many times that it does not allow for imposing price controls on a successfully commercialized invention. I was privileged to serve as a Senate Judiciary Committee staffer to Senator Bayh and organized its hearings, and wrote the Committee's report on the law. Nowhere did it sanction the use of march-in rights for price controls. And that is not just our opinion. Every administration over the past 25 years has uniformly rejected every attempt to misuse the march-in rights provision for lowering the costs of drugs based on federally funded inventions. That includes the Biden administration, which rejected the most recent petition to misuse march-in rights for price control and the appeal of the denial.

If this misuse is allowed now, private companies and investors will no longer have reason to take risks on commercializing early-stage drugs whose discovery involved federal funding. We should remember that unlike any other country in the world, over 50% of our new drugs originate in small companies. New drug breakthroughs would collect dust on laboratory shelves, as they did before 1980. Policymakers seeking to serve the needs of patients must recognize this concern, which has been echoed by leading patient advocacy groups like the World Patients Alliance.

I also want to briefly address another pernicious drug pricing proposal. Some have implored the government to attempt to apply Section 1498 of Title 28 of the U.S. Code to ignore patents on drugs and make them cheaply available to federal healthcare programs like Medicare and Medicaid.

Like the proposed misuse of Bayh-Dole, this is a misreading of the law that would have a devastating impact on innovation. Section 1498 has roots more than a century old. The clear purpose of the statute is to allow the government to manufacture, or contract for, urgently needed products for its own use during times of crisis, such as a world war. It applies only under narrow circumstances and requires the government to provide "reasonable and entire compensation" to the patent holder.

Twisting Section 1498 to become a price control mechanism plainly contravenes the purpose and history of the law. Not only that, it would introduce a dangerous precedent that would further weaken the reliability of patent rights and corrupt the incentives responsible for bringing new medicines to patients.

Because of the subject matter of today's hearing, I have largely confined my comments to the effects of misuse of march-in and Section 1498 on life sciences innovation.

But the danger here is much broader.

The NIST proposal openly states that it is technology-agnostic, meaning that patents stemming from government funding in any area could be subject to march-in if officials decide the resulting commercial products are too expensive. If the law is allowed to be misused for drug price control, that weapon will also be used against products in any field against entrepreneurs who took the risk and expense to commercialize a product. Most times that will be a small business. And misapplying Sec. 1498 means that not even privately funded inventions are safe from federal expropriation attempts on the whims of the moment. Such actions not only destroy investment and innovation in the life sciences but across the board.

I respectfully urge members of this committee to sound a warning about this catastrophic threat to our economy. The executive branch should immediately withdraw the NIST march-in proposal and forswear the use of Section 1498 as a mechanism for government price controls.

Sincerely,

Joseph P. Allen
Executive Director
Bayh-Dole Coalition

the campaign for
SUSTAINABLE Rx PRICING

Testimony Submitted for the Record
U.S. Senate Committee on the Judiciary
Hearing: "Ensuring Affordable and Accessible Medications: Examining Competition in the Prescription Drug Market"
May 21, 2024

Lauren Aronson
Executive Director, The Campaign for Sustainable Rx Pricing (CSRxP)

Chairman Durbin, Ranking Member Graham, and members of the U.S. Senate Committee on the Judiciary, the Campaign for Sustainable Rx Pricing (CSRxP) thanks you for the opportunity to submit testimony for the record on fostering competition in the prescription drug market to make medications more affordable and accessible for consumers. We commend your bipartisan leadership in seeking to address this critical issue that impacts far too many Americans today.

CSRxP is a broad-based nonpartisan coalition of leaders committed to fostering an informed discussion on sustainable drug pricing. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit companies, and health plans. We are committed to the goal of lowering the cost of prescription drugs for patients. We support bipartisan, market-based solutions that promote competition, improve affordability, and enhance list price transparency while maintaining patient access to innovative medications that improve health outcomes and save lives.

Prescription Drug Prices are Unsustainable; Net Spending Increased 9.9 Percent in 2023

Prescription drug pricing trends simply are not sustainable for U.S. patients, families, taxpayers, businesses, and our economy as whole. Twenty-two cents of every health care dollar go toward prescription drugs – with prescription drugs contributing more to health care costs than any other type of health care service.[1] The median annual list price among drugs newly approved by the Food and Drug Administration (FDA) in 2023 was more than $300,000 – a significant increase from 2022 when the median launch price was $220,000.[2] For one-time gene therapy treatments, list prices were even higher in 2023 ranging from $2.2 million to $3.2 million.[3]

Drug makers increased prices on 775 drugs to start 2024 even though many Americans cannot afford the medications they need to get well and remain healthy.[4] [5] The price increases implemented at the outset of the year follow years of unsustainable price increases imposed by Big Pharma on consumers and taxpayers. During the period of July 2021 to July 2022, for example, drug makers raised prices in

[1] AHIP. Where Does Your Health Care Dollar Go? September 6, 2022.
[2] Beasley, D. "Prices for new US drugs rose 35% in 2023, more than previous year." Reuters. February 23, 2024.
[3] *Ibid.*
[4] Calfas, J. Drug Makers Raise Prices of Ozempic, Mounjaro, and Hundreds of Other Drugs. *The Wall Street Journal*. January 18, 2024.
[5] Kirzinger A et al. Public Opinion on Prescription Drugs and Their Prices . Kaiser Family Foundation. August 21, 2023.

excess of inflation for 1,216 drugs, with an average price increase of 31.6 percent.[6] The average price increase was nearly $150 per drug (10.0 percent) in January 2022 and was $250 (7.8 percent) in July 2022.[7]

Despite efforts from the branded pharmaceutical industry to suggest otherwise, drug makers – and drug makers alone – are the drivers of the unsustainable growth in drug prices and excessive spending on prescription drugs today. In fact, net spending on prescription drugs increased 9.9 percent in 2023, excluding a decline in COVID-19 vaccines and therapeutics, rising to $435 billion and representing "a significant acceleration in spending growth," according to IQVIA's latest annual report.[8] Drug companies set excessively high list prices at launch for new drugs and raise those prices every year oftentimes at rates that far exceed inflation. Spending on high-priced drugs places significant strain on patients, federal health programs, and taxpayers. High-priced drugs also substantially burden the many small businesses and large employers who seek to offer affordable health insurance to their employees because, as prescription drug expenditures increase, cost-sharing and premium costs also rise.[9] Far too often consumers experience the unfortunate and unfair choice of purchasing medications and paying their bills for food and housing. Patients and their families simply should never be presented with such a choice.

Patent Abuse Delays Competition and Patient Access to More Affordable Medicines

Importantly, published research shows that the brand biopharmaceutical industry's abuse of the patent system to undermine competition particularly contributes to high drug costs and spending. The analysis found that, despite representing less than one percent of U.S. prescriptions, high-priced brand biologics account for nearly half of all drug spending largely because they face less competition from biosimilars due to differences in how the marketplace is regulated and how the brand industry games the patent system to undermine competition.[10] The study estimates that the anti-competitive nature of the U.S. biologic market cost patients approximately $5 billion from 2015 through 2020.[11] Without action, the study projects that patients needlessly will pay an extra $25 billion in excess drug spending through 2029.[12]

One of the most common strategies that drug makers employ to abuse the patent system is the construction of so-called patent thickets. Under this practice, drug companies apply for and obtain dozens or even hundreds of patents for their branded drugs *after* FDA approval to prevent and delay market entry from less costly generics and biosimilars. Secondary, often non-innovative, patents covering additional indications, dosing and delivery, manufacturing and packaging, and patient safety protocols are obtained to create a thicket of patents. These patent thickets create a nearly

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[6] U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation Office of Health Policy. "Price Increases for Prescription Drugs, 2016 – 2022." September 30, 2022.
[7] *Ibid.*
[8] IQVIA. "The Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028." May 2024.
[9] American Academy of Actuaries. "Prescription Drug Spending in the U.S. Health Care System." March 2018.
[10] Roy, Avik. "The Growing Power of Biotech Monopolies Threatens Affordable Care." Foundation for Research on Equal Opportunity. September 15, 2020.
[11] *Ibid.*
[12] *Ibid.*

insurmountable barrier to competition from lower cost generics and biosimilars for years and, in some cases, decades due to the threat of lengthy, costly, and time-intensive litigation.

Newly published research illustrates how brand drug makers construct patent thickets to prevent and delay competition from lower cost generic and biosimilar medicines. The study found that **nearly three-quarters of all patents were filed for the top-10 selling drugs in the U.S. in 2021 *after* FDA approval.** Patent thicket density peaked 13 years following FDA approval of these top-10 selling medicines, at which time they were protected by a median of 42 (18 – 83) active patents, 66 percent of which were filed after FDA approval.[13] Critically, most of the 465 patents issued for applications filed after FDA approval for these top-10 selling drugs were for secondary, typically non-innovative, patents: 189 (41 percent) for method of use claims, 127 (27 percent) for formulation claims, and 103 (22 percent) for process or synthesis claims compared to 86 (19 percent) for chemical composition claims and 46 (10 percent) for device claims. Notably, research from the Initiative for Medicines, Access, and Knowledge (I-MAK) reached similar conclusions.[14]

Anti-competitive patent thickets impose substantial and unnecessary costs on consumers and taxpayers: **patent thickets on just five brand drugs resulted in more than $16 billion in excessive costs in single year.**[15] For example, Merck's blockbuster cancer drug *Keytruda* attained $25 billion in sales in 2023.[16] Merck filed 129 patent applications for *Keytruda* and 53 have been granted; 50 percent were filed after *Keytruda* approval and reporting suggests that Merck is seeking a new formulation of the drug to protect it from competition expected as soon as 2028.[17] [18] I-MAK estimates the cost of delayed competition for *Keytruda* could be at least $137 billion.[19]

Patent Thickets, Evergreening and Product Hopping are Anti-Competitive and Distort the Market

In addition to patent thickets, brand name drug makers abuse the U.S. intellectual property system through other anti-competitive tactics that keep drug costs needlessly high. Under practices commonly referred to as "evergreening" or "product hopping," for instance, brand drug makers lengthen monopolies by seeking approval of "new" products that are essentially the same as original brand products – but with patents covering relatively minor changes like reformulations, such as an extended-release version of the medication, or a combination therapy that combines two existing drugs into one pill. One analysis concluded that **consumers can lose up to $2 billion per year per each anti-competitive product reformulation.**[20] Critically, "product hopping" practices not only lead to higher costs, but also can harm patients: an investigation from the *New York Times* found, for example, that

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[1313] Horrow et al. Patent Portfolios Protecting 10 Top-Selling Prescription Drugs. *JAMA Intern Med.* Published online May 13, 2024. doi:10.1001/jamainternmed.2024.0836

[14] I-MAK and the American Economic Liberties Project. The Costs of Pharma Cheating. May 16, 2023.

[15] Matrix Global Advisors. Patent Thickets and Lost Drug Savings. January 26, 2023.

[16] Dunleavy, Kevin. Who's No. 1? With $25B in sales, Merck's Keytruda looks to be the top-selling drug of 2023. Fierce Pharma. February 1, 2024.

[17] I-MAK. Overpatented, Overpriced: Keytruda's Patent Wall. May 2021.

[18] Erman, Michael. Focus: Merck could keep its patent edge by shifting Keytruda cancer drug to a simple shot. *Reuters.* December 2, 2022.

[19] I-MAK. Overpatented, Overpriced: Keytruda's Patent Wall. May 2021.

[20] Shadowen, Steve et. al. "Anticompetitive Product Changes in the Pharmaceutical Industry." Rutgers Law Journal, Vol. 41, No. 1-2, Fall/Winter 2009.

drug maker Gilead employed an egregious "product hopping" strategy around a pair of blockbuster HIV treatments to maximize profits while blocking access to newer versions of those treatments proven to be safer for patients.[21]

Importantly, a report from the House Committee on Oversight and Reform demonstrates the significant cost to taxpayers and the Medicare program of Big Pharma's abuse of the U.S. intellectual property system. Upon reviewing the price histories of 12 of the best-selling drugs in Medicare, the Committee found that more than 600 patents were obtained for these 12 drugs, effectively blocking competition from more affordable alternative therapies for decades.[22] Patents already secured for these 12 drugs could potentially extend their monopoly periods to a combined total of nearly 300 years.[23] Moreover, the manufacturers collectively raised prices more than 250 times on the top-selling Medicare drugs using strategies including "product hopping" to maintain product monopolies – leading to median prices almost 500 percent higher than when they were brought to market.[24]

Thus, put simply, the brand biopharmaceutical industry is engaging in a variety of anti-competitive practices that abuse the U.S. intellectual property system to inappropriately prolong market monopolies for costly brand name drugs. These practices needlessly raise drug costs for consumers and taxpayers and significantly contribute to the overall unsustainable growth in prescription drug prices and spending that exists today. **Given today's critical prescription drug pricing crisis and the substantial contribution of Big Pharma's abuse of the intellectual property system to this crisis, CSRxP welcomes actions from the Committee and the Congress to foster greater competition and access to more affordable medications in the prescription drug marketplace.** To that end, we commend the Senate Judiciary Committee for its bipartisan efforts to advance the Affordable Prescriptions for Patients Act, the Stop STALLING Act, the Preserve Access to Affordable Generics and Biosimilars Act, and Interagency Patent Coordination and Improvement Act in February 2023. CSRxP respectfully urges enactment of these bills and other bipartisan legislation as outlined below:

Thwart Patent Abuse

1. **Affordable Prescriptions for Patients Act (S.150):** This bill introduced in the 118th Congress would target abusive "product hopping" practices, as well as address anti-competitive patent thickets by placing limits on the number of patents a biologic manufacturer can use to prevent competition from lower cost biosimilars. CBO estimated savings of $1.1 billion in 2022.[25]

2. **Legislation to Address Patent Thickets (S.3583 and H.R.6986):** This bill introduced in the 118th Congress would streamline patent litigation by limiting the number of patents per patent thicket that a pharmaceutical company can assert in litigation to one.

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[21] Robbins R and Stolberg S. How a Drugmaker Profited by Slow-Walking a Promising H.I.V. Therapy. *The New York Times*. July 23, 2023.
[22] *Ibid*.
[23] *Ibid*.
[24] House Committee on Oversight and Reform. "Drug Pricing Investigation: Majority Staff Report." December 2021.
[25] Congressional Budget Office. "Estimated Budgetary Effects of S. 1435, the Affordable Prescriptions for Patients Act of 2021." June 2022.

3. **Interagency Patent Coordination and Improvement Act (S.79 and H.R.1717):** This legislation introduced in the 118th Congress would improve coordination and communication between the FDA and the U.S. Patent and Trademark Office (USPTO) on prescription drug-related issues.

4. **Patent Examination and Improvement Act (S.4704):** This bill from 117th Congress would help to improve the quality of patents issued and improve the overall USPTO patent examination process.

5. **Medication Affordability and Patent Integrity Act (S.2780 and H.R.5429):** This legislation introduced in the 118th Congress would help to prevent abuses of the patent system by requiring biopharmaceutical manufacturers to provide consistent and additional information to the FDA and the USPTO on newly submitted or approved drug applications.

6. **Restoring the America Invents Act (S.2891):** The American Invents Act established the USPTO's Patent Trial and Appeal Board (PTAB) inter partes review (IPR) process with the goals of improving patent quality and serving as a quicker and less expensive alternative to district court patent litigation. Since enactment of the AIA, certain administrative actions have created new challenges for generic and biosimilar developers. This bill from the 117th Congress would make reforms to the PTAB process and other USPTO procedures to promote generic and biosimilar competition as originally intended by the AIA.

7. **Biologic Patent Transparency Act (S.659 and H.R.4850):** This legislation from the 116th Congress would improve the quality of patent information available to biosimilar developers.

8. **Reforming Evergreening and Manipulation that Extends Drug Years Act (S.1209):** This bill from the 116th Congress would help to thwart anti-competitive "evergreening" practices in which brand name drug manufacturers make minor modifications to existing drugs to maintain market dominance and limit competition from more affordable therapies.

Promote Biosimilar and Generic Competition

9. **Stop STALLING Act (S.148):** This legislation introduced in the 118th Congress would provide the Federal Trade Commission (FTC) with enhanced authority to stop brand name drug companies from exploiting FDA's "citizen petition" process to file sham petitions that delay and prevent FDA approval of more affordable generic and biosimilar medicines. CBO estimated savings of $401 million in 2024.[26]

10. **Ensuring Timely Access to Generics Act (S.1067):** This bill from the 118th Congress would give FDA new oversight authority to reject sham citizen petitions from drug makers.

[26] Congressional Budget Office. "S. 148, Stop STALLING Act." March 2024.

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11. **Increasing Transparency in Generic Drug Applications Act (S.775 and H.R.3839):** This legislation introduced in the 118th Congress would streamline the FDA approval process for generic drugs. CBO estimated savings of $871 million in 2023.[27]

12. **Preserving Access to Affordable Generics and Biosimilars Act (S.142):** This bill introduced in the 118th Congress would give the Federal Trade Commission (FTC) more authority to ensure patent settlement agreements facilitate timely patient access to more affordable generic and biosimilar medicines. CBO estimated savings of $1.6 billion in 2024.[28]

13. **Retaining Access and Restoring Exclusivity (RARE) Act (S.1214):** While FDA has approved hundreds of orphan drugs that have helped patients suffering from rare diseases, drug companies have abused the Orphan Drug Act in many instances to generate billions of dollars in sales for orphan drugs with "non-orphan" indications.[29] This legislation introduced in the 118th Congress would help prevent drug makers from exploiting the Orphan Drug Act.

14. **Reduce the market exclusivity period for brand biologics.** The overly generous 12-year market exclusivity period that brand name biologics currently have should be reduced to 7 years to better reflect the appropriate balance of incentives for pharmaceutical companies to continue innovating while also improving access to biosimilar drugs that will help alleviate cost pressures for consumers and taxpayers. Bipartisan legislation – the PRICED Act – has been introduced in previous sessions to do so.

Conclusion

In conclusion, CSRxP again thanks the Committee for your bipartisan leadership in aiming to enhance competition in the prescription drug marketplace to lower drugs costs and improve affordability for consumers. CSRxP firmly believes that without major actions by this Committee and others, the brand name pharmaceutical industry will continue to excessively profit from their unsustainable pricing practices that increase drugs costs and risk access for the patients who need them. CSRxP looks forward to our continued work with the Committee and the Congress to develop bipartisan, market-based policies that promote transparency, foster competition, and incentivize value to improve affordability for consumers while at the same time maintaining access to the treatments that can improve health outcomes and save lives. We look forward to continuing to work with you to address the drug pricing problem and advance solutions to rein in high drug prices.

[27] Congressional Budget Office. "Estimated Direct Spending and Revenue Effects of H.R. 5378, the Lower Costs, More Transparency Act." December 2023.
[28] Congressional Budget Office. "S. 142, Preserve Access to Affordable Generics and Biosimilars Act." March 2024.
[29] Tribble S and Lupkin S. Drugmakers Manipulate Orphan Drug Rules To Create Prized Monopolies. *KFF Health News*. January 17, 2017.

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Statement for Senate Judiciary Committee hearing
on "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market"
May 21, 2024

I. Introduction

A. Drug prices too high; consumers unable to afford needed medicines. Why?
   1. Brand drug companies abuse system by delaying generic entry
      a) Examples: product hopping, pay-for-delay settlements, citizen petitions, patent thicketing
      b) None of this conduct can be justified by patents or innovation
         (1) Like the proverbial boy who cried wolf, the pharmaceutical industry for at least the past 60 years has claimed that every legislative proposal to restrict patents or apply antitrust would decimate innovation.[1]
   2. Pharmacy benefit managers (PBMs) benefit from an opaque business model, "spread" pricing, and relationships with pharmacies
   3. Government agencies like FDA and PTO have not communicated sufficiently to address these issues

B. Congress can address all of this conduct through legislation

II. Product Hopping

A. Brand firms have switched drugs so generics can't be substituted and migrated patients before generic entry
   1. Examples: capsule to tablet; different dosage; single- and dual-scored tablet

B. Every time brand changes drug slightly, generic cannot be substituted because generic is not "therapeutically equivalent" to brand (same active ingredient, form, dosage, strength, safety/efficacy profile) or "bioequivalent" (absorbed into body at same rate).[2]
   1. Harms from both "hard switches" (original drug pulled from market) and "soft switches" (original remains)

C. Product hopping harms consumers
   1. 2009 empirical analysis found $28 billion worth of drugs subject to product hopping, including Advair, Allegra, Augmentin, Caduet, Clarinex, Kapidex, Lexapro, Nexium, Prozac, Risperdal.[3]
      a) For $1 billion blockbuster drug, consumers pay extra $765 million each year from delayed competition.[4]
   2. *E.g.*: Opioid-dependence-treating Suboxone was switched from tablet to sublingual (under-the-tongue) film
      a) Reckitt publicly announced removal of tablets for safety reasons (even though safer than film), waited 6 months to remove, disparaged (and raised price of) tablets, and promoted film to doctors.[5]

D. Product hopping can harm innovation as brand firms often withhold incremental innovations from market to use later as part of product hop
   1. *E.g.*: In *TriCor*, Abbott delayed seeking new indication for original product, reserving it for reformulation, even though "data necessary to get the new indication was available much earlier."[6]

E. S. 150, Affordable Prescriptions for Patients Act of 2023, offers effective approach to product hopping
   1. Gives FTC power under Section 5 to challenge anticompetitive hard and soft switches
   2. Ensures courts recognize harms of soft switches when only reason for change is to harm generic
      a) *Walgreen's* court asserted that AstraZeneca did not "eliminate[] any consumer choices" but instead "added choices," with superiority determinations "left to the marketplace."[7]
         (1) This ignores "price disconnect" that characterizes pharmaceutical industry as doctor who prescribes product does not pay and consumer/insurer who pays for it does not choose
         (2) This characteristic could reduce choice when patients are switched from original drug (expiring patent, impending generics) to reformulated version (patented, no generics)

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[1] Michael A. Carrier & Genevieve Tung, *The Industry that Cries Wolf: Pharma and Innovation*, STAT (Sept. 26, 2019).

[2] FDA, *Orange Book Preface*.

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

[4] FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010) (multiple generics take 90% of sales at average 85% discount).

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

[6] For other examples, see Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 202 (2016).

[7] *Walgreen v. AstraZeneca Pharmaceuticals*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008).

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b) *Doryx* court upheld product hop, focusing on competitor rather than consumer even though company "made . . . 'hops' primarily to 'delay generic market entry.'"[8]
c) Congress is uniquely situated to recognize the harms of soft switches not acknowledged by courts

III. Pay-for-Delay Settlements

A. Brand firms have colluded with generic companies, paying them to delay entering the market
1. Alone among anticompetitive pharmaceutical conduct, settling generics align with brands against consumers
B. Patients harmed from collusion, not innovation, as generics delay entry from payment, not patent
1. Generics agree to delay entry in return for dropping patent challenge
a) But most (89%) of the patents at issue in settlements are secondary patents on which the brand firm is less likely to win (32%), as compared to active-ingredient (92%) patents.[9]
C. S. 142, Preserve Access to Affordable Generics and Biosimilars Act, would play a critical role in stopping anticompetitive settlements
1. Legislation provides that generic receiving "anything of value" for delayed entry is presumptively illegal
a) Common-sense approach reflects Supreme Court's *Actavis* ruling, which broadly considered payment.[10]
b) Legislation helpfully rejects mistaken presumptions that courts have adopted that entry will not occur until patent expires and that pre-expiration entry is procompetitive
D. Benefit 1: Standard makes clear that pay-for-delay settlements anticompetitive and helps FTC prove cases in court
1. Payments are taking the form not of cash but of compensation hidden in increasingly obscure corners
2. Treating pay-for-delay settlements as presumptively anticompetitive will deter blatantly illegal conduct that courts do not always recognize and that bogs down the FTC for years in resource-intensive litigation
a) *E.g.*: The FTC's *Actavis* litigation, which did not even involve a trial, took 10 years to settle.[11]
E. Benefit 2: Legislation addresses judicial errors relating to payment and "scope of patent." *E.g.*:
1. *AbbVie*: Brand provided generic with drug at price "well below what is customary" but court (despite recognizing deal's "large value") concluded that it "was not a reverse payment."[12]
2. *AbbVie* and Administrative Law Judge in *Impax*: Assumed entry before patent expiration procompetitive (despite Supreme Court's overturning of scope-of-patent test).[13]

IV. Citizen Petitions

A. Citizen petitions harm consumers: Meant to raise legitimate concerns, but used to delay generic entry; my empirical study showed that FDA denies 92% of "505(q)" petitions (against pending generic), 98% of late-filed petitions.[14]
B. Concerning examples: Shire ViroPharma's 46 filings, Teva's multiple Copaxone petitions, Bayer's Mirena petition 1 day before patent expiration, Mylan's delayed filing of petition on EpiPen alternative.[15]
C. From 2011 to 2015, 118 petitioners filed 505(q) petitions: 108 brand firms, 4 generic firms, 4 law firms or consultants, but only 2 public interest groups and 0 individuals
D. FDA has shown "concern[] that section 505(q) may not be discouraging the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues."[16]
1. FDA "remains concerned" that the resources it is forced to incur come "at the expense of completing the other work of the Agency."[17]
E. S. 148, Stop STALLING Act, is helpful in giving the FTC authority to bring Section 5 claim (and obtain strong penalties) against sham petitions. Benefits:
1. Finding that delaying conduct is sham could help courts cut through firewall of *Noerr-Pennington* immunity.[18]

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[8] *Mylan Pharmaceuticals v. Warner Chilcott*, 838 F.3d 421, 431 (3d Cir. 2016).

[9] C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1387 (2013).

[10] *FTC v. Actavis*, 570 U.S. 136 (2013).

[11] FTC, *Last Remaining Defendant Settles FTC Suit that Led to Landmark Supreme Court Ruling on Drug Company "Reverse Payments,"* Feb. 28, 2019.

[12] *FTC v. AbbVie*, 107 F. Supp. 3d 428, 436 (E.D. Pa. 2015), *aff'd*, 976 F.3d 327 (3d Cir. 2020).

[13] *In the Matter of Impax Labs.*, Dkt. No. 9373, at 144, 146 (FTC ALJ Chappell May 18, 2018).

[14] Michael A. Carrier & Carl J. Minniti III, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305 (2016).

[15] *See id.* at 344–47; Michael A. Carrier & Carl J. Minniti III, *The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals*, 102 CORNELL L. REV. ONLINE 53, 64–66 (2017).

[16] FDA, REPORT TO CONGRESS: EIGHTH ANNUAL REPORT ON DELAYS IN APPROVALS OF APPLICATIONS RELATED TO CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION FOR FISCAL YEAR 2015, at 8 (2016).

[17] *Id.*

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2. Helpful to include as "sham" not only individual petitions but also "series" of such petitions
3. Beneficial to give FTC Section 5 authority and put stamp of disapproval on abusive citizen petitions
4. Useful deterrent to impose penalty of drug revenue (while petition under review) or (if larger) $50,000 a day

V. Patent Thicketing

A. Patent thicketing becoming common
   1. Humira has 138 patents, including 53 obtained in 2015-16, just before the active-ingredient patent expired[19]
      a) Humira patents cover indication/method of treatment (24), formulation (14), manufacturing (24)
   2. J&J's Remicade also protected by more than 100 patents

B. S. 3583, A Bill To Address Patent Thickets, would address these issues
   1. Limiting number of patents per patent group that could be asserted in infringement litigation would allow the drug company to protect its true innovation without abusing the system through duplicative patents
   2. Recent empirical work has shown that half of biologic patents had terminal disclaimers, which reflect only "trivial changes" but make it harder for biosimilars to enter the market.[20]

VI. PBMs

A. The black box of PBMs' business models creates opportunities to make coverage decisions based not on therapeutic and cost-effective options but on rebates from drug companies
   1. *E.g.*: pharmacies not able to view contracts with insurers, and vice versa, with PBM agreements audited in secure rooms with few contracts reviewed, restricted notetaking, and only client-specific information.[21]

B. PBMs reap rewards from, among other actions:
   1. a "pharmacy spread" by which they charge payers a higher amount than they reimburse pharmacies and
   2. steering patients to pharmacies in which they have an ownership interest.[22]

C. S. 113, Prescription Pricing for the People Act of 2023, would allow information on these anticompetitive practices to be collected, which could reduce PBMs' power, offering patients more cost-effective options

VII. Lack of Coordination Between Government Agencies

A. FDA and the PTO do not coordinate as much as they could
   1. FDA's knowledge of drugs' advances could be helpful to the PTO in deciding whether to issue patents
   2. FDA's ministerial role in listing patents in the Orange Book has long been criticized and has played a role in recent FTC actions challenging improper listings.[23]

B. S. 79, Interagency Patent Coordination and Improvement Act of 2023, would address these problems
   1. Interagency Task Force on Patents could encourage agencies to coordinate, allowing useful information to be shared
   2. PTO report could be helpful in providing information on whether, and to what extent, FDA provides information to PTO, and on recommendations that could improve coordination
   3. Coordination could make it more likely that invalid patents would not be granted, which would reduce prices

VIII. Conclusion

A. Legislation on product hopping, pay-for-delay settlements, citizen petitions, patent thicketing, PBMs, and agency coordination would make patients' lives better without harming innovation

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[18] *Prof'l Real Estate Investors v. Columbia Pictures Indus.*, 508 U.S. 49 (1993); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965); *E.R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127 (1961).

[19] Cynthia Koons, *This Shield of Patents Protects the World's Best-Selling Drug*, BLOOMBERG, Sept. 7, 2017.

[20] S. Sean Tu et al., *Biologic Patent Thickets and Terminal Disclaimers*, 331 JAMA 355 (2024).

[21] Neil Weinberg & Robert Langreth, *Pharmacy Benefits Managers Exert Much Control*, SALT LAKE TRIBUNE, May 5, 2017.

[22] Michael Carrier, *A Six-Step Solution to the PBM Problem*, HEALTH AFFAIRS BLOG, Aug. 30, 2018 (offering examples).

[23] FTC, *FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book*, Nov. 7, 2023; FTC, *FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs*, Apr. 30, 2024.

May 21, 2024

The Honorable Richard Durbin
Chairman
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Lindsey Graham
Ranking Member
Senate Committee on the Judiciary
290 Russell Senate Office Building
Washington, D.C. 20510

Dear Chairman Durbin and Ranking Member Graham:

Conservatives for Property Rights (CPR), a coalition of public policy organizations that represent millions of Americans, is pleased to provide input in regard to the Judiciary Committee's May 21 hearing, "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market."

Private property in all its forms — physical, personal, and intellectual — holds central importance under the U.S. Constitution and the American free enterprise model. The right to private property ranks among the unalienable rights the Founders referenced in the Declaration of Independence. Indeed, secure property rights are vital for human flourishing. Without secure private property rights, innovation, consumer choice, and competition do not blossom.

CPR is concerned about aggressive antitrust measures and government price controls, while overlooked is innovation's role in constantly driving dynamic competition by providing more, new, and improved products whose market entry leads to affordability and accessibility.

This imbalance of competition and innovation leads to misguided legislation and policies. That has certainly been the case in recent Congresses. The Stop STALLING Act, Preserve Access to Affordable Generics and Biosimilars Act, and Affordable Prescriptions for Patients Act epitomize such an overbroad and heavy-handed approach. Such measures would actually reduce innovation and thereby reduce biopharmaceutical competition.

The government should not subject to Federal Trade Commission (FTC) heavy-handedness virtually any improvement to existing pharmaceutical products that have intellectual property (IP) protection. Follow-on innovation, such as new formulations, more tolerable versions, those easier to take and stay on schedule, versions having fewer side effects, better manufacturing processes, etc., should not face unreasonable, severe antitrust scrutiny. The heightened regulatory approach would have a chilling effect on pharmaceutical innovation and deprive patients suffering serious medical conditions and diseases of new and improved medication options.

Labeling normal, constructive modifications and iterative improvements to a pharmaceutical as anticompetitive diminishes property rights and short-circuits innovation. What practically every inventor does in any other art would be castigated as "product hopping" in one targeted art.

Going after bad actors who deliberately block generic competition by very modestly changing their existing products is one thing. However, "follow-on product" should not mean "a change, modification, or reformulation to the same manufacturer's previously approved drug or biological product that shares an indication, in whole or in part, with the same manufacturer's previously approved drug or biological product." This type of approach far exceeds minuscule modifications. It encompasses significant improvements, such as changes for treating new diseases and changes the Food and Drug Administration (FDA) classifies as new treatments.

The committee must avoid covering a broad set of medicines and thereby bringing unintended consequences. What about new indications that superficially relate to the original indication, but involve significantly different diseases or patient populations? A reasonable view would not qualify such innovations for FTC examination or enforcement. To do that would discourage developing new drugs for indications with unmet medical needs, including cancers.

The FTC under Chairwoman Lina Khan has rapidly moved to consolidate naked power. Her leadership has overstepped the agency's authorities, diminished professional staff morale, operated in a hyperpartisan manner, and pursued an unbounded, wildly novel litigation strategy that has led to successive loses because it ignores settled legal principles. Process matters, but the FTC has diminished institutional process and denied parties due process. In addition, the Executive Order on Competition (E.O.) involves an outsized role for the FTC, along with directives that further reduce due process and undermine the objective Consumer Welfare Standard.[1]

Given the FTC's recent, unbridled record, in which it has wielded and exceeded its powers, the agency should not be handed an antitrust hammer to use against bonafide innovation. No agency, especially not the FTC, should be able to veto a Patent and Trademark Office (PTO) finding that improvements meet the criteria of novelty, usefulness, and nonobviousness. In light of PTO examination and patent issuance and FDA approval for safety and effectiveness, there is no room for presuming anticompetitiveness from such innovative progress. This is a matter of fundamental property rights — exclusivity under a patent. Such a move would throw market competition into a state that would limit patients to older biopharmaceuticals.

A reasonable approach to drug affordability and accessibility would be to regard FDA determinations of a new product as being a new product. If PTO issues a patent on a new version of a drug, it should be regarded as a new, valid invention and thus a bonafide new product.

Moreover, an aggressive posture toward drug patent settlements would risk disrupting the Hatch-Waxman Act framework. Hatch-Waxman employs patent litigation as a vehicle for generic drug entry into the market created through the drug innovator's patent exclusivity. Hatch-Waxman's structure balances respect for the patent rights of innovators with introduction of generic versions of those patented medicines in a reasonable timeframe. An undue emphasis on novel antitrust measures directly threatens this law's innovation-introducing-dynamic-competition model that has worked well for four decades.

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[1] See CPR statement, "Statement on Biden Executive Order on Market Concentration" (July 12. 2021); and James Edwards, "Biden's Assault on Property Rights Is an Odd Way to Boost Competition," Real Clear Markets (July 20, 2021).

The Hatch-Waxman model is generally settled and predictable. It serves the interests of drug innovators, generic drugmakers, patients, payers, medical providers, and society. Today, about 90 percent of all U.S. prescriptions are filled with generic medicines, while U.S pharmaceutical firms lead the world in drug innovation. Overreaching legislation or regulation would risk upsetting this balance. Another risk is diminishing the property rights interests of patients, payers, and both brand and generic drug companies.

In closing, then-Assistant Attorney General for Antitrust Makan Delrahim said, "It is a perverse result indeed when the misapplication of the competition laws results in less innovation, less competition, and ultimately, fewer consumer choices."[2] We caution the committee against hurting innovation, competition, and consumer choice. It would be hazardous to misassume static competition in the area of pharmaceuticals. Rather, this art stands among the most "dynamic competition" fields. Patent exclusivity fosters progress in the state of the art, including in the arduous fields of medical innovation, adding a dynamism unmatched in many other sectors of our economy and in the world. Mr. Delrahim noted, "[C]ompetition and consumers both benefit when inventors have full incentives to exploit their patent rights." That lesson should inform the committee's treatment of IP exclusivity. IP exclusivity is not monopolistic conduct in a static competitive setting; rather, it is the pathway to dynamic competition, consumer choice, and affordability as new, competitive products enter the market.

Conservatives for Property Rights appreciates the opportunity to share its perspective on the subject of this hearing.

Respectfully,

James Edwards, Ph.D.
Executive Director
Conservatives for Property Rights

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[2] See CPR comments to FTC, "Pharmaceutical Task Force, Project No. P212900" (June 25, 2021).

May 20, 2024

The Honorable Dick Durbin
Chairman
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Lindsey Graham
Ranking Member
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224 Dirksen Senate Office Building
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Dear Chairman Durbin and Ranking Member Graham:

On behalf of the Council for Innovation Promotion (C4IP), we write in advance of your Tuesday, May 21, 2024, hearing on drug prices to dispel common myths about pharmaceutical patents that remain pervasive on Capitol Hill.

C4IP is a bipartisan organization chaired by two former directors of the U.S. Patent and Trademark Office, who respectively served under Presidents Obama and Trump. We aim to foster strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere.[1]

We recognize the need for Congress to implement reforms that expand access to life-saving medicines. Unfortunately, some Members of Congress mistakenly believe they can lower drug prices by undermining the patent protections responsible for creating those medicines in the first place. These lawmakers are often misled by activists who accuse biotech companies of abusing intellectual property law through practices like "patent thicketing" and "evergreening."

Proponents of the "patent thicket" myth contend that biopharma companies file superfluous patents on the same drug to construct an impenetrable legal barrier that prevents generic drug manufacturers from introducing cheaper competitors.

The practice of securing numerous patents on a single drug may sound scandalous,

[1] Council for Innovation Promotion, *About C4IP*, https://c4ip.org/about/.

but it is not. Many highly complex inventions, from cell phones to medicines, combine multiple different technologies, discoveries, and insights into a single product. The original iPhone, for instance, had roughly 200 patents protecting all its different components and capabilities.[2]

Similarly, it is common for a single medicine to be protected by basic composition of matter patents, method of manufacture patents, method of formulation patents, and so on. Each of these represent individual, yet related, insights and discoveries.

Activists also accuse drug companies of "evergreening," the practice of supposedly filing new patents on existing drugs or trivial variations of them to extend the life of the original patent.

These accusations are false, and fundamentally misrepresent how the patent system works. The USPTO only grants patents to inventions that are novel, useful, and non-obvious. "New" patents covering old inventions are rejected, as are such patents covering trivial variations.

Definitionally, any newly granted patents are for genuine improvements to existing therapies.[3] An updated drug incorporating inventions that allow for greater dosing flexibility or include a time-release function that reduces the risk of an adverse reaction *should* be patentable, and Congress absolutely should ensure companies investing in creating such innovations are encouraged and rewarded with strong patent protection.

And new patents for improved versions of medicines have *no effect whatsoever* on the expiration date of the original patents. Generic competitors are entirely free to produce the original medicine once the original patents expire, the existence of an updated version of such medicine notwithstanding.

Contrary to what activists claim, the current patent system is not unduly deterring generic competition. In fact, the United States has the highest generic penetration rate in the developed world. Nine in 10 U.S. prescriptions are filled with generics.[4]

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[2] *Apple's iPhone Well Protected by Patents*, MacDailyNews (May 25, 2007), https://macdailynews.com/2007/05/25/apples_iphone_well_protected_by_patents/comment-page-3/.
[3] 35 U.S.C. §§ 102, 203; *see also Patents: Make Sure Your Idea Is Useful, Novel, and Non-Obvious*, FindLaw (Aug. 9, 2023), https://www.findlaw.com/smallbusiness/intellectual-property/idea-must-be-useful-novel-or-non-obvious.html.
[4] FDA, *Generic Drugs*, https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs#:~:text=In%20the%20United%20States%2C%209,to%20healthcare%20for%20more%20patients (last visited May 20, 2024).

"Evergreening" and "patent thicketing" aren't keeping cheaper generics out of patients' hands.

But this evidence hasn't dissuaded some lawmakers from advocating for policies that would undermine IP protections on life-saving medicines -- and violate federal law.

At the urging of several Members of Congress, the Biden administration could soon try misusing the Bayh-Dole Act of 1980 to "march in," confiscate patents and licenses, and forcibly relicense patents on drugs developed by private companies based on upstream scientific research conducted with even minuscule amounts of federal funding. This plan would do nothing to lower drug prices -- in fact, only around 1% of drugs would be legally eligible for march-in at all.[5]

Others have urged the administration to misuse a statute called Section 1498, which allows the federal government to make and use a product protected by patents without a license from the owner, provided that the product is utilized *by or for the United States itself*.[6] For decades, legal scholars have almost uniformly agreed that Section 1498 authorizes the government to infringe only on patented technology it uses directly, such as for military purposes.[7] Under no honest reading could one conclude it applies to sales to consumers in private markets of drugs covered by active patents.

Rather than making drugs more accessible, these proposals would rob patients of future treatments by kneecapping research and development. It costs an average of $2.6 billion to bring a single new drug to market.[8] Shorn of patent protections, biotech companies and investors will have no ability to protect their inventions from copycats or recoup their enormous upfront expenses. Many will pull out of pharmaceutical development altogether.

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[5] *March-in Rights Under the Bayh-Dole Act & NIH Contributions to Pharmaceutical Patents*, Vital Transformation, https://vitaltransformation.com/2023/11/march-in-rights-under-the-bayh-dole-act-nih-contributions-to-pharmaceutical-patents/ (last visited May 20, 2024).

[6] Amy Kapczynski, Professor of Law, Yale School of Law, *et al.*, Letter to Sen. Warren 1 (Apr. 20, 2022), https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf.

[7] Jonathan M. Barnett, Professor, Gould School of Law, University of Southern California, *et al.*, Letter to Chairman Sanders and Ranking Member Cassidy, Senate Committee on Health, Education, Labor and Pensions; Chairman Smith and Ranking Member Neal, House Committee on Ways and Means 10 (Sept. 28, 2023), https://s3.amazonaws.com/media.hudson.org/Letter+to+Congress+-+Bayh-Dole+and+1498+Not+Basis+for+Price+Controls+on+Drugs.pdf.

[8] *What's the Average Time to Bring a Drug to Market in 2022?* N-Side, https://lifesciences.n-side.com/blog/what-is-the-average-time-to-bring-a-drug-to-market-in-2022#:~:text=How%20much%20does%20it%20cost,high%20as%20%242.6%20billion%20USD (last visited May 20, 2024).

There are other, more constructive ways to help those consumers who struggle to pay the cost of their drugs, like insurance reforms. As you consider potential drug pricing legislation, we urge you to defend the patent protections that make groundbreaking medical innovation possible.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)

cc:

Sen. Alex Padilla, Member, Senate Committee on the Judiciary
Sen. Amy Klobuchar, Member, Senate Committee on the Judiciary
Sen. Chris Coons, Member, Senate Committee on the Judiciary
Sen. Chuck Grassley, Member, Senate Committee on the Judiciary
Sen. Cory Booker, Member, Senate Committee on the Judiciary
Sen. John Cornyn, Member, Senate Committee on the Judiciary
Sen. John Kennedy, Member, Senate Committee on the Judiciary
Sen. Jon Ossoff, Member, Senate Committee on the Judiciary
Sen. Josh Hawley, Member, Senate Committee on the Judiciary
Sen. Laphonza Butler, Member, Senate Committee on the Judiciary
Sen. Marsha Blackburn, Member, Senate Committee on the Judiciary
Sen. Mazie Hirono, Member, Senate Committee on the Judiciary
Sen. Mike Lee, Member, Senate Committee on the Judiciary
Sen. Peter Welch, Member, Senate Committee on the Judiciary
Sen. Richard Blumenthal, Member, Senate Committee on the Judiciary
Sen. Sheldon Whitehouse, Member, Senate Committee on the Judiciary
Sen. Ted Cruz, Member, Senate Committee on the Judiciary
Sen. Thom Tillis, Member, Senate Committee on the Judiciary
Sen. Tom Cotton, Member, Senate Committee on the Judiciary

FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

Statement for the Record

Senate Judiciary Committee

Hearing on "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market"

Prepared by Families USA

May 21, 2024

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Chair Durbin and Ranking Member Graham, on behalf of Families USA, thank you for holding this important and timely hearing highlighting the reality of high drug costs and lack of healthy prescription drug competition in the United States. Families USA, a leading national, nonpartisan voice for health care consumers, is dedicated to achieving high-quality, affordable health care and improved health for all. Central to that work is ensuring people have access to lifesaving and life sustaining medication at a price they can afford. We appreciate the important work being done by the Senate Judiciary Committee to explore ways to strengthen our patent system, so it more appropriately incentivizes and protects true innovation while ensuring that affordable versions of pharmaceuticals are available to people who need them.

Currently, 60% of adults in America take at least one prescription medication and 25% take four or more.[1] But many people who rely on prescription drugs for their health are forced to make the choice between filling their prescription or filling their refrigerator because of the cost. Over the past 15 years, launch prices – the initial prices of drugs set by manufacturers – grew more than 20% each year.[2] And even after launching, prices continue to increase at staggering rates, leaving families and individuals paying more and more, year after year, for their needed medications. For example, the price of Victoza (a popular diabetes and weight loss medication launched in 2010) increased a staggering 42% in just five years, rising from $7,936 per year in 2015 to $11,300 per year in 2020.[3]

Without question, one of the fundamental drivers of soaring prescription drug prices is widescale abuses of federal patent and market exclusivity laws by drug companies. Drug companies intentionally manipulate the patent system to minimize competition, delay the entrance of generic drugs to the market, increase prices, and drive excessive profit margins on decades-old drugs.[4] But there is a wide array of bipartisan and well-vetted solutions to rein in these abuses, and Congress has the power to take significant steps in making medications accessible and affordable for our nation's families and individuals.

Families USA supports several bills introduced to the Committee, including many that have advanced to the full Senate. Ensuring passage of these bills is an essential step to stop big drug companies from gaming the patent system and adopting abusive price increases.

Big Drug Companies Abuse U.S. Patent System to Protect Profit and Limit Competition

The entire business model of big drug companies is rooted in creating a monopolistic drug market and abusing it for exorbitant profit though price-gouging, anticompetitive behavior to extend drug exclusivity, and increasing profits on old drugs rather than investing in new and innovative treatments to help our nation's families.[5]

One of the biggest challenges in drug patent policy has been the need to balance innovation of new products with increasing access to generic drugs to allow for greater affordability for families. High prices for brand name medicines are an unintended result of the Drug Price Competition and Patent Term Restoration Act of 1984 – also known as the Hatch-Waxman Act.[6] This law established the modern system of generic drug regulation in the U.S. by attempting to facilitate the entry of new generic drugs into the market in order to increase competition to enable more affordable drug

prices. However, drug companies have unabashedly gamed the system and undermined the intent of this law to make outsized profits through their efforts to limit competition and keep generics off the market.

Common examples of tactics drug companies use to extend exclusivity include blanketing one drug with multiple and overlapping patents to create a "patent thicket," or "product hopping" from one patent to the next by making minor tweaks to existing drugs that typically confer no additional clinical benefit but allow for extended patent protections. In fact, the 10 top-selling drugs on the market today have been granted an average of 74 patents per drug, with an average of 140 patents filed for each of them.[7] And three quarters of new patents are for existing drugs. From 2005 until 2015, 5,369 patents were granted to manufacturers for drugs that already had patents, representing 74% of new drug patents.[8] Companies also reduce competition by offering patent settlements that pay generic companies *not* to bring lower-cost alternatives to market through "pay-for-delay" schemes. According to annual reports by the Federal Trade Commission (FTC), as many as 142 generic versions of brand-name drugs have been delayed by pay-for-delay arrangements between drug manufacturers since 2005; in an analysis of 20 of these drugs, the companies made an estimated $98 billion in total sales while the generic versions were delayed.[9]

Just looking at drug companies' dwindling investment in innovation can highlight how much they are not incentivized to participate in promising drug research. From 2012-2021, the top 14 drug companies spent $747 billion in distributions to stakeholders (including stock buybacks and dividends) and only $660 billion on research and development (R&D), a shocking 13% less on doing their truly important job of finding new treatments for families and individuals than paying their stakeholders.[10]

Once big drug companies have blocked competition, they are free to raise prices year after year at shocking rates, long after the drug's release. This pattern is pervasive across the drug market. Between July 2021 and July 2022, 1,216 drug products had price increases that were higher than the inflation rate (8.5%). Some increased by more than 500%.[11] These price increases are not justified by additional benefits or effectiveness of the drug. In fact, one study of high-spend drugs showed that seven of the 10 drugs reviewed provided no additional clinical benefit relative to other available drugs.[12] Rather, these abuses occur because drug companies exploit loopholes in our patent system.

Patent systems should spur innovation and rewarding investment in and the discovery of new cures. Instead, drug companies demonstrate time and time again that it is easier and more profitable for them to abuse patent law, limit competition, and raise prices rather than investing in new, innovative treatments that will help people live longer, healthier lives.[13]

Existing Legislation Provides Solutions to Patent Abuses

There are several pieces of proposed legislation to address these abuses, a number of which of which have been considered and advanced by this Committee on a bipartisan basis. Families USA strongly supports these efforts, including:

- *Preserve Access to Affordable Generics and Biosimilars Act* (S.142), which curbs pay-for-delay practices.

- *Affordable Prescriptions for Patients Act of 2023* (S.150), which cracks down on patent thickets and product hopping.
- *Stop STALLING Act* (S. 148), which stops drug company abuse of citizen petitions before the Food and Drug Administration (FDA) to delay generic and biosimilar market entry.
- *Interagency Patent Coordination and Improvement Act of 2023* (S. 79), which establishes a task force between the U.S. Patent and Trademark Office and the FDA in order to strengthen and improve each agency's patent-related activities.
- *A Bill to Address Patent Thickets* (S.3583), which would rein in drug company ability to utilize patent thickets.

Families USA commends the work of the Judiciary Committee to move forward these bipartisan reforms. It is critical that they all be moved by the Committee and immediately be brought to a vote for the full Senate.

Conclusion

The high and rising prices of prescription drugs threaten the financial security of families and individuals and, by extension, their health. Under the current system, big drug companies abuse patents, delay the entry of generic drugs into the market, and price gouge to support their greed, all while families and individuals go into medical debt, ration or skip medications, and have to choose between their medications and paying for daily necessities. Even those not taking prescription drugs are left with difficult financial decisions due to rising insurance premiums, higher deductibles, and stagnant wages — all of which can be tied back to rising drug prices. Only Congress can end these egregious practices and bring much needed relief to millions of families across the country.

We appreciate the important work of this Committee to address these concerns and look forward to continuing to work with you to ensure all families can achieve affordable health care and improved health.

[1] Ashley Kirzinger et al., "Public Opinion on Prescription Drugs and Their Prices," KFF, August 21, 2023, https://www.kff. org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/.
[2] Benjamin N. Rome, Alexander C. Egilman, and Aaron S. Kesselheim, "Trends in Prescription Drug Launch Prices, 2008- 2021," JAMA 327, no. 21 (2022): 2145–2147, https://jamanetwork.com/journals/jama/article-abstract/2792986.
[3] Dena Bunis, "Drugmakers Face Penalties for Price Hikes Above Inflation," AARP, February 15, 2023, https://www.aarp. org/politics-society/advocacy/info-2022/drugmakers-penalties-price-hikes.html#:~:text=The%20report%20also%20found%2C%20for,rising%20from%20%247%2C936%20to%20%2411%2C300.
[4] Berkeley Lovelace Jr., "'Gaming' of U.S. patent system is keeping drug prices sky high, report says." NBC News, September 15, 2022. https://www.nbcnews.com/health/health-news/gaming-us-patent-system-keeping-drug-prices-sky-high-report-says-rcna47507
[5] Bailey Reavis and Hazel Law, "The Reality of Prescription Drug Innovation: Drug Manufacturers Limit Innovation to Protect Patents and Profits," Families USA, August 2023, https://familiesusa.org/wp-content/uploads/2023/08/Drug-Companies-Limit-Innovation-for-Profit-2.pdf.
[6] "The Hatch-Waxman Act: A Primer," EveryCRSReport.com, September 28, 2016, https://www.everycrsreport.com/reports/R44643.html
[7] Tahir Amin and David Mitchell, "Big Pharma's Patent Abuses Are Fueling the Drug Pricing Crisis," Time, February 24, 2023, https://time.com/6257866/big-pharma-patent-abuse-drug-pricing-crisis/#:~:text=A%20recent%20national%20 report%20reveals,for%20very%20minor%20product%20modifications.
[8] Feldman, Robin. "May Your Drug Price Be Evergreen." Journal of Law and the Biosciences, December 7, 2018. https://academic.oup.com/jlb/advance-article/doi/10.1093/jlb/lsy022/5232981.
[9] "Top Twenty Pay-For-Delay Drugs: How Drug Industry Payoffs Delay Generics, Inflate Prices and Hurt Consumers," Community Catalyst, US PIRG, July 2013, https://publicinterestnetwork.org/wp-content/uploads/2013/07/Top_Twenty_Pay_For_Delay_Drugs_USPIRG.pdf
[10] William Lazonick and Oner Tulum, "Sick with 'Shareholder Value': US Pharma's Financialized Business Model During the Pandemic," Institute for Economic Thinking, December 2022, https://www.ineteconomics.org/perspectives/blog/sick-with-shareholder-value-us-pharmas-financialized-business-model-during-the-pandemic
[11] Bailey Reavis and Hazel Law, "The Reality of Prescription Drug Innovation: Drug Manufacturers Limit Innovation to Protect Patents and Profits," Families USA, August 2023, https://familiesusa.org/wp-content/uploads/2023/08/Drug-Companies-Limit-Innovation-for-Profit-2.pdf.
[12] Eliot Fishman, "Our Broken Drug Pricing and Patent System Diverts Resources Away From Innovation and Into Mergers, Patent Gaming and Price Gouging," Families USA, August 2021, https://familiesusa.org/wp-content/uploads/2021/08/RX-2021-209_Innovation-Drug-Pricing-Issue-Brief.pdf.
[13] Fishman, Drug Pricing and Patent System

GenerAtion patient

Dear Chair Durbin, Ranking Member Graham, and Senate Judiciary Members:

We write to you as a generation of patients living with chronic and rare conditions such as Crohn's disease, lupus, arthritis, and many others. For too long, young adult patients have been left out of conversations to address the high costs of medications that we rely on not only to survive but to thrive as we enter adulthood. Many of us know that a cure is not attainable in our lifetime, and we will rely on incredibly high-cost medications for our entire lives, meaning that innovation and fair prices are crucial to reaching our potential. As a young adult patient-led organization, we believe strongly that reforming the patent system to promote competition, incentivize innovation, and create more ways for the public to challenge patents is an opportune way for our community to have better futures.

We implore you to personally consider the profound impact that reforming the patent system could have on young adult patients like us. We are finding work for the first time, navigating insurance changes, the possibility of pursuing further higher education, and financial instability, with the added stress of affording our prescription medicines.

We see clear opportunities to address patent abuses that are keeping the price of critical prescription drugs high, including *pay-for-delay tactics*, *patent thickets*, and *product hopping*. We also are thrilled to see steps in the right direction, such as the collaboration between the *United States Patent and Trademark Office* and the *Food and Drug Administration*. These reforms would benefit patients and foster a more competitive and innovative pharmaceutical industry.

Competition will lower our drug prices: Our community members are on high-cost medications such as Nurtec ODT, Stelara, and Eliquis - all of which have extremely high prices and tremendous patent abuse. Many of us are also living with highly complex conditions requiring multiple prescription medicines. And the price relief we expect from competition through biosimilars and generics being introduced into the market has been delayed for far too long. Access to prescription medications is a basic human need. According to the Georgetown University McCourt School of Public Policy, 53% of people ages 18-34 use prescription drugs. Moreover, 21% of people ages 18-49 years old say they have difficulty affording their medication. The share is likely to be even higher for younger adults, given that the subgroup 18-24 has one of the highest poverty rates. This is a moment to ensure our community is well-represented as you consider the impact of high drug prices on the current and next generation of patients.

Innovation is particularly crucial for young adult patients: As young adult patients who will rely on therapeutics throughout our lifetime, we hope for new and better inventions that can benefit our community. Many of us cycle through therapeutics frequently, meaning that what is in the pipeline could be life-saving and life-changing. For patients in our community with rare conditions without prescription medicines left for us to try, we are navigating many changes in

treatment options. Promoting true innovation could give many people the tools to increase their functionality and ease the pains of living with a chronic illness.

Increase public participation in the patent system: Patients and public interest groups should have clearer opportunities to engage in the patent system. Instead of scaling back opportunities to challenge invalid patents, we need to create more opportunities. While we spoke at the USPTO-FDA listening session in January 2023 and have engaged in other ways, we look forward to seeing more meaningful opportunities for patients to be included.

Indeed, we are grateful for the research and development of public-private partnerships that have contributed to bringing life-saving therapeutics to market. Over 85% of young people with chronic conditions are now surviving into adulthood, many of whom live with complex, lifelong conditions. However, pharmaceutical companies exploiting loopholes in the patent system make these life-saving drugs unaffordable and inaccessible. As more young people are being diagnosed with chronic conditions, it is crucial that we urgently activate policies that can reform the patent system for now and in years to come. Thank you for your time and for including our perspectives on this critical and timely issue.

Sincerely,

Generation Patient
admin@generationpatient.org

incubate
INVEST · INNOVATE · CURE

May 20, 2024

The Honorable Dick Durbin
Chair
Senate Judiciary Committee
U.S. Senate
Washington, D.C. 20510

The Honorable Lindsey Graham
Ranking Member
Senate Judiciary Committee
U.S. Senate
Washington, D.C. 20510

Dear Chair Durbin and Ranking Member Graham:

We write to share our perspective in advance of the Committee's May 21 hearing on "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market."

Incubate is a nonprofit, nonpartisan coalition of early-stage life sciences investors committed to educating policymakers on the role of venture capital in bringing promising, innovative treatments to patients in need.

We are writing today to underscore the vital role patents play in promoting life-science innovation and attracting critical investment.

Patents are the cornerstone of investment in early-stage life sciences firms. When investors are weighing whether to risk their capital on startups striving to develop new medicines, patent portfolios are typically the first thing they examine.

About 9 in 10 candidate medicines fail in clinical trials. Once one accounts for these inevitable failures, bringing a single new medicine to market costs upwards of $3 billion.

Patent rights help investors tolerate these immense risks. Selling just one successful, patent-protected medicine can help firms and their investors recoup losses from dozens of costly failures. Without reliable patent protections, however, this investment calculus fundamentally changes.

We empathize with and understand the frustration many patients face paying at the pharmacy counter, and we support solutions that address all players in the supply chain without jeopardizing future development.

However, we believe it is essential for policymakers to recognize that patents are not to blame for the access challenges too many patients face. On the contrary, patents incentivize the research and development necessary to bring life-saving therapies to consumers in the first place.

Creating uncertainty around patent protections would disproportionately impact small firms. Larger life science companies can leverage established product lines to court investors. But small startups typically rely heavily – and sometimes, entirely – on their IP portfolios to attract venture funding.

If lawmakers weaken IP rights, these startups will struggle to secure funding. This would stifle innovation precisely where it matters most. Small firms are the lifeblood of new drug development. Historically, the majority of new therapies have originated at small companies.

We are concerned that the May 21 hearing may amplify long-debunked myths about the patent system, such as "patent thickets" and "patent evergreening." Both of these myths are rooted in fundamental misconceptions about the patent system, such as the idea that drug makers can file "follow-on" patents that extend the patent term of a drug's original version, or the notion that firms file multiple patents for one medicine in order to "game" the system. Similarly, we worry that certain witnesses or lawmakers could use the hearing to misrepresent efforts to misuse the Bayh-Dole Act's march-in provision or 28 U.S. Code § 1498 to weaken drug patents. It is crucial to remember that neither the Bayh-Dole Act nor Section 1498 was ever intended to be used in this way.

We urge the Senate Judiciary Committee to consider how ill-considered changes to the patent system could chill early-stage investment in life sciences. Strong, reliable patent protections helped America become the world's leader in biopharmaceutical innovation. If we weaken those protections now, start-ups investigating promising compounds will struggle to find investors willing to support them.

Thank you for considering our perspective. We welcome the opportunity to meet and discuss any of these issues in greater detail.

Sincerely,

John Stanford
Executive Director
Incubate Coalition

NATIONAL ASSOCIATION OF Manufacturers

Charles Crain

Vice President,
Domestic Policy

May 21, 2024

The Honorable Dick Durbin
Chair
Committee on the Judiciary
U.S. Senate
Washington, DC 20510

The Honorable Lindsey Graham
Ranking Member
Committee on the Judiciary
U.S. Senate
Washington, DC 20510

Dear Chair Durbin and Ranking Member Graham,

The National Association of Manufacturers appreciates the opportunity to share manufacturers' perspectives on today's Judiciary Committee hearing titled "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market."

The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturers make significant investments in research and development, accounting for more than half of all private-sector R&D in the United States. This research results in groundbreaking inventions that improve the quality of life for all Americans; it also supports well-paying jobs for the 13 million people who make things in America.

Biopharmaceutical manufacturers are a critical part of the manufacturing economy. These manufacturers accounted for $355 billion in value-added output to the U.S. economy in 2021 and directly employed 291,000 workers in the United States, with each of these jobs supporting an additional 4.1 jobs.[1] The average employee in the biopharmaceutical industry earns roughly 3.5 times the U.S. workforce average income, and roughly 25% of all jobs in pharmaceutical and medicine manufacturing are STEM-related.[2] These manufacturers discover and bring to market incredible new medicines to treat and cure challenging conditions. In 2023, the Food and Drug Administration approved a record-breaking 71 new medicines that will improve the lives of patients.[3] The investment necessary to bring these treatments to patients is immense: the average cost of developing a new drug was $2.3 billion as of 2022.[4]

These high development costs are reflective of the complex nature of groundbreaking R&D. Only 12% of investigational drugs that enter a phase I clinical trial ultimately receive FDA approval[5]—to say nothing of the hundreds of discoveries that never make it into clinical trials. Further, breakthrough scientific discoveries take immense time, with early-stage research, clinical trials, FDA

[1] National Association of Manufacturers. "Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing" (October 2023). *Available at* https://documents.nam.org/COMM/NAM-Creating%20Cures,%20Saving%20Lives_FINAL3.pdf.

[2] *Ibid.*

[3] Senior, M. "Fresh from the biotech pipeline: record-breaking FDA approvals." *Nature Biotechnology* (February 2024). *Available at* https://doi.org/10.1038/s41587-024-02166-7.

[4] Deloitte. "Seize the digital momentum: Measuring the return from pharmaceutical innovation 2022" (January 2023). *Available at* https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-seize-digital-momentum-rd-roi-2022.pdf.

[5] Dimasi, Joseph A., Henry G. Grabowski, Ronald W. Hansen. "Innovation in the pharmaceutical industry: New estimates of R&D costs." J Health Econ. 2016; 47:20-33.

approval and manufacturing accounting for 10-15 years in most cases. Biopharmaceutical companies are committed to these extraordinary efforts, which in recent years have revolutionized treatments for COVID, cancer, HIV/AIDS, sickle cell disease, diabetes, obesity and more. Across the industry, biopharmaceutical manufacturers spent $139 billion on R&D in 2022 alone.[6]

Biopharmaceutical companies and all innovative manufacturers depend on a regulatory environment that is conducive to innovation and R&D—and robust intellectual property protections are a cornerstone of a pro-innovation policy ecosystem. Strong IP rights enable innovators to develop and commercialize their discoveries, while weak IP frameworks disincentivize research into, investment in and commercialization of potentially revolutionary technologies.

Unfortunately, the Biden Administration took a step in the wrong direction last year when the National Institute of Standards and Technology proposed a new framework that would expand the government's ability to "march in" and seize manufacturers' IP rights. NIST's march-in proposal is fundamentally flawed and would have disastrous consequences on manufacturers, American innovation and the U.S. economy. The NAM respectfully encourages members of this Committee to call on the Administration to provide certainty to manufacturers and other stakeholders in the innovation economy by affirmatively and unequivocally withdrawing the proposed framework and making clear that the none of its recommendations will be implemented.

The Bayh-Dole Act, passed in 1980, allows recipients of federal research dollars to license groundbreaking technologies to private-sector companies to commercialize them. Prior to the act's passage, the government held approximately 28,000 patents—yet fewer than 4% of those patents were licensed to the private sector. Bayh-Dole includes a narrow march-in provision that allows the government to step in to ensure consumer access to certain products during times of crisis—but march-in has never previously been used during the 44 years since the law's enactment.

Allowing march-in based on the price of a product or technology, as the NIST guidance proposes, would not only violate the letter and intent of the Bayh-Dole Act: it would undermine manufacturers' IP rights and have sweeping ramifications for innovation in the United States and America's world-leading innovation economy. These impacts would be felt in the biopharmaceutical sector and at innovative companies across the country. In particular, start-ups and small businesses would bear the brunt of the drastic changes proposed, as the spectre of government march-in would disincentivize early-stage entrepreneurship and dissuade much-needed capital formation from outside investors. It would also hinder industry collaborations with research universities and laboratories across the country, stymieing manufacturers' efforts to develop the products and technologies of the future and bring them to the public.

In the biopharmaceutical sector, NIST's proposed march-in guidance will substantially weaken the incentives for companies to engage in, and for investors to fund, the work that goes into transforming a federally funded researcher's newly patented discovery into a commercialized medicine. Biopharmaceutical investors—both venture capitalists and larger biopharmaceutical companies that partner with or acquire smaller businesses—understand the uncertain and difficult nature of scientific advancement. They often fund a broad portfolio of projects, many with federally funded research at their core, knowing that many will never make it to FDA approval. These investors need to know that the projects that do become life-changing treatments will be able to succeed in a fair marketplace and benefit from robust IP protections. The proposed march-in guidance puts this early-stage capital under threat—as well as the therapeutic development pipeline that may include the secrets to unlocking treatments and cures for even more devastating diseases.

[6] Deloitte, "Seize the Digital Momentum," *supra* note 4.

In short, IP protections are critical to biopharmaceutical innovation. Biopharmaceutical manufacturers fuel the American economy, and biopharmaceutical products change and save lives around the world. Policies that threaten IP protections, like NIST's proposed march-in guidance, will cede one of our greatest advantages to our competitors. Manufacturers stand ready to work with the Committee to ensure the U.S. maintains the strongest IP protections in the world in order to spur the discovery and commercialization of inventions that improve health and quality of life for all people.

Sincerely,

Charles Crain
Vice President, Domestic Policy

TAXPAYERS PROTECTION ALLIANCE

May 20, 2024

The Honorable Dick Durbin
Chair
Committee on the Judiciary
U.S. Senate
224 Dirksen Senate Office Building
Washington D.C. 20510

The Honorable Lindsey Graham
Ranking Member
Committee on the Judiciary
U.S. Senate
224 Dirksen Senate Office Building
Washington, D.C. 20510

Re: Hearing Entitled "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market"

Chair Durbin, Ranking Member Graham, and Members of the Senate Judiciary Committee,

On behalf of the millions of taxpayers and consumers represented by the Taxpayers Protection Alliance (TPA), we write today in support of America's longstanding system of robust Intellectual Property (IP) protections.

These protections are crucial to the American economy, as IP intensive industries play a vital role in supporting America's economic growth.[1] As noted by the U.S. Patent and Trademark Office (USPTO), these industries generate more than 40 percent of total GDP, supporting almost half of total employment.[2] The benefits are felt directly. As of 2019, workers in IP intensive industries earned on average nearly $600 more per week than did workers in non-IP intensive industries.[3]

Specifically, within the healthcare sector, strong patent protections act as the foundation for lifesaving innovation. Since 1980, the framework established by the Bayh-Dole Act (P.L. 96-517) has led to the development of more than 200 new drugs.[4] Congress must continue to leverage the private incentives that come from strong patent protections and encourage public-private partnerships that significantly strengthen the advances made through federally funded research. As a result, more than 200 new drugs have been developed through the Bayh-Dole framework.

Calls to undermine this system with the goal of reducing healthcare costs are misguided and would ultimately harm patient outcomes. For example, abusing the Bayh-Dole Act's "march-in" provisions as a backdoor means to implement government price controls on prescription drugs would scare off public-private partnerships and limit necessary investments in medical research. Innovation, especially in areas such as cancer research, would be drastically reduced.

Similarly, misusing Bayh-Dole's Sec. 1498 to manipulate drug pricing would set a dangerous precedent. Section 1498 was not intended to be used to weaken patent protections for government overreach into the commercial market. This approach would only create more uncertainty and restrict the pipeline of future cures and treatments, leading to worse patient outcomes.

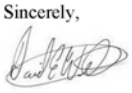
[1] https://www.protectingtaxpayers.org/wp-content/uploads/TPA_04262024_WorldIPDay.pdf
[2] https://www.uspto.gov/about-us/news-updates/latest-uspto-report-finds-industries-intensively-use-intellectual-property-0
[3] https://www.uspto.gov/ip-policy/economic-research/intellectual-property-and-us-economy#:~:text=Intellectual%20property%20(IP)%20protection%20affects,investments%20in%20innovation%3B%20supporting%20startup
[4] https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf

TAXPAYERS PROTECTION ALLIANCE

As the Judiciary Committee considers impediments to affordable and accessible medications for American patients, the detrimental role that Pharmacy Benefit Managers (PBMs) play cannot be ignored. PBMs remain pervasive middlemen in the healthcare sector, often marking-up generic drugs by as much as 20 percent, or exclude generic alternatives entirely in favor of name-brand options that allow them to receive higher rebates.[5] This market influence, especially in taxpayer-funded healthcare plans, puts greater pressure on patients, inflates costs and makes it more difficult to maintain medication adherence, harming health outcomes in the long-run.[6]

While lowering prescription drug prices is a laudable goal, TPA urges lawmakers to reject ill-advised calls to undermine America's historic respect for patent protections and instead focus on the real culprits behind rising prices.

Sincerely,



David Williams
President

[5] https://www.realclearhealth.com/blog/2024/01/10/small_business_needs_pbm_reform_now_1003974.html
[6] https://www.concordmonitor.com/My-Turn-PBMs-vs-Patients-Congress-Can-Help-Decide-the-Winner-53576953

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COLLEGE OF LAW

S. Sean Tu
Arthur S. Dayton Professor of Law
West Virginia University College of Law

May 15, 2024

Senator Richard Durbin
Chairman, Committee on the Judiciary
711 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Durbin,

I am writing to address a critical issue in our healthcare system: the interplay between patents and pharmaceutical innovation, and the unintended consequences of current patent practices on generic and biosimilar market entry. While patents are essential for driving pharmaceutical innovation, recent developments have highlighted significant challenges that threaten to undermine the balance between innovation and competition.

It is essential to first recognize that patents and competition can coexist. A well-functioning patent system should protect genuine innovations while ensuring that once patents expire, generics can enter the market promptly to drive prices down and increase access to essential medicines. However, the exploitation of the patent system to delay generic competition undermines the balance between innovation and competition.

Patents are designed to incentivize innovation by granting inventors exclusive rights to their inventions for a limited period. This exclusivity allows pharmaceutical companies to recoup the substantial costs associated with research and development (R&D) and to fund future innovation. The high-risk nature of pharmaceutical R&D—where only a small fraction of investigational drugs make it to market—makes the promise of patent protection a crucial motivator for investment in new therapies.

The Hatch-Waxman Act of 1984 struck a careful balance between fostering innovation and promoting competition. By creating an abbreviated pathway for generic drug approval, the Act facilitated the entry of lower-cost generics into the market once the patent life of branded drugs expired. In the early years of the Hatch-Waxman Act, this framework worked well, spurring both innovation and competition, and delivering significant cost savings to consumers.

However, in recent years, branded pharmaceutical firms have increasingly exploited the patent system to extend their monopoly power beyond the intended patent term. Strategies such as "evergreening," where companies make minor modifications to existing drugs to obtain new patents, and "patent thickets," where multiple overlapping patents are filed for the same product, effectively block and delay generic/biosimilar competitors.

These practices have raised concerns about the original intent of the patent system and the Hatch-Waxman Act. Instead of serving as a temporary reward for innovation, patents are being used strategically to extend market exclusivity and maximize profits. This not only delays access to affordable generic drugs but also deters competition, ultimately harming patients who rely on these medications.

To address these challenges, several policy measures could be considered:

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1. **Strengthening Patent Examination Processes**: Ensuring that patents are granted only for truly novel and non-obvious inventions can prevent the issuance of low-quality patents that are used to block competition.

2. **Promoting Transparency**: Increased transparency in patent listings and patent litigation settlements can help identify and address anti-competitive practices.

3. **Encouraging Competition**: Policies that promote the entry of generics and biosimilars, such as reducing regulatory barriers and supporting market entry, can enhance competition and lower drug prices.

4. **Revisiting the Hatch-Waxman Act**: Modernizing the Hatch-Waxman Act to close existing loopholes and reinforce its original intent can help restore the balance between innovation and competition.

It is crucial for policymakers to recognize the importance of maintaining a patent system that both incentivizes innovation and promotes competition. By addressing the current challenges and ensuring that patents are used as intended, we can foster a healthcare environment that supports the development of new therapies while ensuring that patients have timely access to affordable medications.

Thank you for your attention to this important issue. I look forward to seeing progress in fostering both innovation and competition in the pharmaceutical industry.

Sincerely,

S. Sean Tu
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March 12, 2024

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EAGLE FORUM EDUCATION & LEGAL DEFENSE FUND

Chairman Richard Durbin
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, D.C. 20510

Ranking Member Lindsey Graham
Senate Committee on the Judiciary
290 Russell Senate Office Building
Washington, D.C. 20510

Dear Chairman Durbin and Ranking Member Graham:

Eagle Forum Education & Legal Defense Fund, a nonprofit organization founded by Phyllis Schlafly in 1981, writes regarding the hearing, "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market." Our perspective on these matters is based upon the constitutionally grounded intellectual property rights that have led to an unsurpassed record of innovation in our great nation and inventors' ability to exercise the exclusivity their patents afford.

Policies must strike an appropriate balance between intellectual property (IP) and antitrust. Policies that put the fulcrum in favor of antitrust enforcement and the disadvantage of patent owners actually harm both competition and innovation. Such imbalance is ill advised, especially when focusing on a single industry, such as pharmaceuticals. It would be unwise to presume that follow-on invention in this or any art is anticompetitive under antitrust law. That approach here would treat U.S. innovation in the pharmaceutical field in such a manner that once one medicine goes on the market, new and improved versions of that medicine would add undue risk to developing improvements. Thus, if a patient could better tolerate or more easily comply with a newer form of the medicine, such as a gel tablet or a one-a-day version, that version may not be developed because of the grave threat of antitrust action.

The fact is that inventors in every art pursue improvements on their initial invention. They routinely continue to experiment with different materials, different methods of manufacture, different uses, etc. that may well constitute a new and improved version that is therefore patentable. Were the Federal Trade Commission (FTC) enabled to presume that innovation in this one important segment of our economy is anticompetitive, that power would foreclose much constructive, beneficial"progress of science and useful arts." That policy would erect a stop sign halting medical innovation. Perversely, such "one and done" pharmaceutical invention, under threat of antitrust liability for researching and developing new, better versions, would bring adverse consequences for invention and for others. Generic firms, which produce drugs without bearing the burden of front-end sunk costs in biomedical R&D, would see a dwindling pipeline. Relatively easier advancements in product lines closer to their existing manufacturing capabilities would be unlikely to follow.

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It is vital that the committee appreciate the difference between static competition and dynamic competition. There is a false presumption that the dynamic competition of an innovative area like pharmaceuticals is a static market with static competition. This inaccurately conflates a patent's exclusivity of limited duration with anticompetitive monopoly power. Then-Assistant Attorney General Makan Delrahim urged "a more symmetric balance between the seemingly dueling policy concerns between intellectual property and antitrust law." His approach is the most prudent, evidence-based one. Mr. Delrahim said, "Antitrust enforcers should . . . enforce the antitrust laws in a manner that best promotes dynamic competition for the benefit of consumers." Quashing innovation in the biopharmaceutical sector would not benefit health care consumers. The harm they would suffer under unwise policies would far exceed economic harm. Patients' health would suffer because some cannot tolerate the initial drug, for others the method by which a drug is delivered is not compatible, for still others the dosage needs monitoring with periodic adjustments.

Antitrust enforcement threat could preclude the discovery and development of new pain medicines that reduce opioid addiction, but would not be pursued because of the risk from being considered "follow-on" inventions, "product hopping," "patent thickets" and the like. In the eyes of a zealous FTC, legitimate improvements to existing medications could become subject to antitrust enforcement under unadvised legislative measures.

Therefore, we would warn of the adverse effects of an unreasonable, myopically focused, out of balance policy approach. Such policies would further set back U.S. pharmaceutical innovation, cost American jobs, quash risk capital investment in this critical area, and put dangerous tools in the hands of an enforcement agency that has shown itself to lack good judgment where innovation and dynamic competition are concerned.

Faithfully,

Ed Martin

Ed Martin, President

Statement for the Record

The Alliance of U.S. Startups and Inventors for Jobs

Before the

Committee on the Judiciary

United States Senate

Hearing on

Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market

May 21, 2024

The Alliance of U.S. Startups and Inventors for Jobs (USIJ) appreciates this opportunity to provide a Statement for the Record at this important hearing. USIJ is a group of inventors, startup companies, venture capitalists, incubators, and research institutions representing diverse industries from software to biotech.[1]

Our members depend on a reliable patent system to attract investment necessary to bring new and disruptive products to the market. In the case of startups in the life sciences sector this often means hundreds of millions of dollars of venture investment before a product is even commercially viable. This entire process can also often take up to a decade and the likelihood of failure is much greater than success. But American inventors, entrepreneurs and investors still take these risks to a greater extent than in any other country, and from 2016-2020, nearly two thirds of new drugs originated at small companies.[2] This is due to a number of factors, but a predictable and secure patent system is chief among them.

We realize there is tension between the unique protections afforded by the U.S. patent system and the desire to increase patient access to life-saving drugs. The relationship between the patent system and the unprecedented advancement of life saving medicine in the U.S. deserves your careful consideration, but we believe there are a number of myths driven more by misleading efforts to weaken the patent system than by an objective assessment of market realities and sound policy.

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[1] https://www.usij.org/about

[2] https://www.pharmavoice.com/news/2020-01-pharma-innovation/612330/

One such myth is that of "evergreening," the alleged practice of delaying patent expiration by securing additional, minor patents on a particular drug. However, experts in the field of drug development tell a much different story regarding the constant and very beneficial incremental innovations that require significant research, safety evaluation, time and resources. The motivation of researchers and those involved in product development is to constantly improve the health impact and quality of life for patients. If we limit patent protections to only radical new discoveries we will stifle the countless new ways in which existing (formerly radical) science can be deployed to make improvements that may seem less dramatic, but will have profound impacts. It is also often true that incremental improvements within therapeutic drugs can reduce the long-term cost of treatment, particularly if these improvements result in lower rates of adverse effects, improved efficacy and more sustainable and predictable dosage options for patients.

Vilifying an entire category of patents and health care advancement as “evergreening” will ultimately dissuade investment and development that stands to benefit patients.

Another related concern revolves around "patent thickets," or inter-related patents that some claim serve only to extend patent protection on a drug and prevent generic competition. It is important to note in the first instance that every U.S. patent that is granted must show that the underlying invention is novel and non-obvious. And while many classes of drugs and biologics do have a number of valid patents associated with them, it is also true that the number of patents correlated to a specific product is, by no means, unique to life sciences. The construction of patent families in complex areas like life sciences and consumer electronics does not automatically reflect a desire to hinder competition as stated by some, but it is often the result of significant R&D investments, hundreds of clinical trials, and thousands of hours of research made over years, if not decades. It is also uniquely true in disciplines such as biologics that genetically engineered protiens are extremely difficult to formulate and manufacture. These processes improve over time and result in patentable breakthroughs that often also lead to the ability to treat additional diseases.

Because of these widespread misperceptions, many activists and some policymakers believe that weakening patent protections would make drugs more accessible to patients. This could not be further from the truth. Without strong patents, innovative startups and small companies would have difficulty obtaining funding and have little ability to pursue expensive and risky new projects -- such as developing novel medicines.

In addition to perpetuating harmful myths, some have also proposed misusing two long-standing and well-understood statutes to weaken patent protection in the name of lowering drug prices.

A proposal from the Biden administration would misuse the Bayh-Dole Act's "march-in" rights to relicense the patents on drugs developed with the help of federal funding purely based on market price. This is not only completely at odds with the statutory language and intent of the Bayh-Dole Act, it would also be highly ineffective -- just 1% of new drugs approved from 2011-2020 would be plausibly subject to march-in petitions. This proposal would, however, apply to

all federally-supported research, as well as programs such as Small Business Innovation Research (SBIR) and would chill investment in many industries, not just biotech.[3]

In the wake of the proposal, USIJ surveyed a large venture capital firm and found that nearly 40% of its health care investments, worth nearly $2 billion in total, rely on patent licenses facilitated by the Bayh-Dole Act.[4] Those startups could see their funding sources dry up if this law is rewritten.

Some have also urged the misuse of Section 1498 of Title 28 of the U.S. Code, a wartime statute allowing the U.S. government to appropriate patents for its own direct use, as another means to control drug prices. This interpretation contradicts the conclusions of numerous legal scholars and would likewise damage the patent protections that small innovators rely on.[5] [6]

Patients need innovative new drugs. And the development of those new drugs depends heavily on secure intellectual property protections. During your deliberations, we urge you to keep in mind the critical importance of these protections.

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[3] https://vitaltransformation.com/2023/11/march-in-rights-under-the-bayh-dole-act-nih-contributions-to-pharmaceutical-patents/

[4] https://static1.squarespace.com/static/5746149f86db43995675b6bb/t/65c291d0e5eee76544e7ef38/1707250128589/USIJ+Response+to+NIST+Bayh+Dole+Guidance+RFI+.pdf

[5] https://s3.amazonaws.com/media.hudson.org/Letter+to+Congress+-+Bayh-Dole+and+1498+Not+Basis+for+Price+Controls+on+Drugs.pdf

[6] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4348499

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