

**REDUCING PRESCRIPTION DRUG PRICES:
HOW COMPETITION CAN MAKE
MEDICATIONS AFFORDABLE FOR PATIENTS**

HEARING
BEFORE THE
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE
ONE HUNDRED EIGHTEENTH CONGRESS

SECOND SESSION

OCTOBER 29, 2024

CHICAGO, ILLINOIS

Serial No. J-118-82

Printed for the use of the Committee on the Judiciary



www.judiciary.senate.gov
www.govinfo.gov

U.S. GOVERNMENT PUBLISHING OFFICE

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REDUCING PRESCRIPTION DRUG PRICES: HOW COMPETITION CAN MAKE MEDICATIONS AFFORDABLE FOR PATIENTS

TUESDAY, OCTOBER 29, 2024

UNITED STATES SENATE,
COMMITTEE ON THE JUDICIARY,
Chicago, IL.

The Committee met, pursuant to notice at 10 a.m., in Everett McKinley Dirksen United States Courthouse in Chicago, Illinois, Hon. Richard J. Durbin, Chair of the Committee, presiding.

Present: Senators Durbin [presiding].

Also present: Representatives Davis, Schakowsky, Foster, Krishnamoorthi, Casten, García, and Ramirez.

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

Chair DURBIN. I just want to thank the judges, the clerks of the court martial service, and all the staff and personnel for today's hearing at the Dirksen Federal Courthouse.

Today, the Committee will examine an issue on lives of many people in Illinois and across the country; the high price of prescription drugs. It is a scandalous situation in America. People in the United States pay the highest prescription drug prices in the world. On average, four times more than people in similar countries pay for brand name medications.

For example, a well-known blood thinner, Eliquis, entered the market in 2013, 11 years ago, and it cost \$3,100 annually in the United States. Same drug made by the same company for sale in Japan was not \$3,100, it was \$1,000. And over the past decade, the price in the United States has more than doubled from \$3,100 to \$7,100. Meanwhile, in Japan, the price has dropped. Same drug, same company.

Why? For years, Big Pharma has abused our patent system to obtain monopolies and medications so they can charge these sky-high prices. At the same time, they spend billions of dollars to fill the airwaves with ads. So, patients tell their doctors they need drugs like Eliquis, so they can go skiing, fishing, white water rafting. By fueling demand for expensive medications that are walled off from competition by clever patent schemes, Big Pharma has made American patients their profit engine.

Thankfully, this administration and Democrats in Congress decided to do something about it. In 2022, Congress passed and President signed the Inflation Reduction Act. Not one single Republican

voted for it. Under this law, we have capped the price of insulin at \$35 a month, saving 50,000 seniors in Illinois about \$500 a year. We have made vaccines under Medicare free.

When shingles or RSV vaccines can cost up to \$300 a dose, this change creates real savings for 1.4 million seniors in Illinois. Starting in January, there'll be a \$2,000 annual cap on out-of-pocket costs for seniors. Meaning, no matter how expensive your medications are, you will not pay more than \$2,000 in copay.

I want to show you a chart. In August, the Biden/Harris Administration started negotiating with Big Pharma, to lower prices for 10 of the most expensive drugs under Medicare, resulting in price savings of up to 79 percent. I know it's impossible to read, trust me, that's what it says.

[Poster is displayed.]

[Laughter.]

As a result of this negotiation, 9 million seniors will save a total of \$1.5 billion in annual out-of-pocket costs, including nearly 300,000 seniors in Illinois who take one of these 10 drugs. Remember Eliquis, the one I talked about earlier? Thanks to this new law, Medicare was able to permanently cut its price in half, taking nearly \$300 off the monthly price tag for more than 100,000 seniors in our State. This is just the beginning. Next year, Medicare will negotiate to lower prices for another 15 drugs, and 20 in the year after that.

But just as these historic savings are starting to take effect, there are great threats to their progress. Eight pharmaceutical companies raced to Federal courthouses to stop the price negotiation. And former President Trump and his Republican allies want to repeal this provision altogether.

In this Committee, we often hear cries that these reforms will freeze innovation because the high cost of research and development for new drugs justifies these astronomical prices. That's the former argument. But these critics failed to mention that taxpayer-funded new research at the National Institutes of Health benefited 99 percent of all drugs approved by the FDA in the last decade. In other words, our tax dollars being spent by the National Institutes of Health are establishing the research necessary to develop these drugs.

They also fail to mention that many pharmaceutical companies spend more on sales and marketing than they do on research and development. Too often, the prices Big Pharma charges do not reflect scientific breakthroughs, but rather manipulation by lawyers and marketers. In fact, the top 10 bestselling drugs in 2021 were covered by an average of 42 active patents that block competition and create windfall profits.

The Judiciary Committee has taken a leading role in addressing Big Pharma schemes. Last year, the Committee unanimously reported five bipartisan bills that address these anti-competitive tactics. This includes my bill with Senator Tillis, Republican, of North Carolina, to improve information sharing between the FDA and the patent office to prevent gamesmanship. Congress needs to pass these bills into law.

Drugs are not effective in treating disease if a patient can't afford to buy them. Our hearing today will explore how legislation

like IRA and the Judiciary Committee bills will help ensure patient access to lifesaving medications.

Let me lay out the mechanics for today's hearings. I'm joined today by seven members of the Illinois congressional delegation. Some arriving a little late with early morning appointments in other places, but I'm glad you're here. I have first recognized them to give brief statements. After we hear from our House colleagues, we will turn to our outside witness panel. After I introduce and swear in the witnesses, each witness has a 5-minute opening statement, and then we'll have questions and answers.

I'll now turn to our first panel. I will call my colleagues from Congress in order of seniority unless they are late in arriving due to scheduling conflicts. But the first was here early, and I will welcome him. Congressman Danny K. Davis, you may make an opening statement if you wish.

**STATEMENT OF HON. DANNY K. DAVIS,
UNITED STATES REPRESENTATIVE (IL-07), WASHINGTON, DC**

Representative DAVIS. Thank you, Mr. Chairman, Senator Durbin, and Ranking Member, Senator Graham, and Members of the Judiciary Committee. Let me, first of all, thank you for holding this field hearing to discuss an important issue to my constituents and the Nation about prescription drug prices.

Back in 2010 when our Nation did not have affordable insurance plans for the poor and the needy, my colleagues and I on the Committee of Ways and Means, Energy and Commerce, Education and Workforce, and others in the House, helped produce legislation for President Barack Obama to sign into law on March 23, the Affordable Care Act that overhauled the U.S. healthcare system.

Healthcare reform is not health insurance, but a law that made changes to the insurance system to allow many uninsured, underinsured, and employer-based insured individuals to receive at least 10 essential health benefits in their planned coverages. The historic ACA reduced the number of uninsured Americans by more than 20 million, extended critical consumer protections to more than 100 million individuals strengthened our health system by lowering the cost and requiring all marketplace insurance plans to cover treatment for preexisting medical conditions that affects up to 129 million Americans.

The ACA is a good first step and framework to strengthen and improve our healthcare system that we can build upon through future policy initiatives to provide greater access, quality services, and lower cost drugs to underserved and needy Americans throughout our country.

This law staged our reform efforts to alter and change prescription drug accessibility and affordability, especially when we are confronted with drug manufacturers and pharmacy benefit managers who are producing certain medications and managing prescription drug benefits on behalf of insurers that cost too much money.

One of those policy initiatives I'm talking about is the Build Back Better Act, where my colleagues and I developed a legislative language with respect to high priced drugs that are included in the

Inflation Reduction Act that President Biden and Vice-President Harris managed and signed into law on August 16, 2022.

Through the IRA, we legislated brought changes to Medicare prescription drugs coverage and specific changes to Medicaid, the State Children's Health Insurance Coverage Program, CHIP, and private health insurance. It requires Secretary Becerra of Health and Human Services to negotiate prices for certain prescription drugs covered under Medicare, Part B, physician-administered drugs, and part D, retail prescription drugs.

By law, he is required to negotiate maximum fair prices with 10 different drug producers for 2026 and increase to 15 drugs for 2027 and 2028, and 20 drugs for 2029 and each following year. It is important that Medicare continue to negotiate low prices on behalf of the American people.

Historically, negotiating prices will not limit companies' innovation and development of better medications and cures for the American people. The Inflation Reduction Act through the leadership of President Biden, Vice-President Harris, and Democrats in Congress took on Big Pharma and won a decade long battle to lower the cost for millions of seniors with new benefits that cap a \$35 monthly out-of-pocket cost for insulin for 4 million Americans on Medicare who use it, three singles and other essential vaccinations, \$2,000 out-of-pocket caps on prescriptions drugs to get it in 2025. That would save 19 million Americans an average of \$400 each year in protections from drug company price hikes.

Additionally, the IRA companies now must pay Medicare or rebate if their prices rise faster than inflation. From 2019 to 2020, half of all drugs covered by Medicare had prices rise faster. In the State of Illinois, 59,718 Illinoisans on Medicare who use insulin are now saving on average \$519 annually, thanks to the \$35 per month insulin cap. 275,956 Illinoisans are saving an average of \$542 on monthly insurance premiums. For the State of Illinois, 597,880 Illinoisans are saving an average of \$432.70 thanks to the inflation reduction tax, \$2,000 annual out of pocket cost cap effective in 2025.

I thank you, Mr. Chairman, for this hearing, and yield back the balance of my time.

Chair DURBIN. Thanks, Congressman Davis. Appreciate your attendance and your testimony. I know you all been wondering, I've just put on the record, I had a bowl of cereal this morning for breakfast. Before I poured the milk on the cereal. I checked the expiration date on the product and it was okay.

Why is there an expiration date on dairy products? The next witness is responsible for it. She led the consumer effort to put expiration dates on dairy products as a mom and as an activist, and led her to a career in government. She is the ultimate voice in our delegation when it comes to consumer protection, and it's my honor to recognize my colleague, Congresswoman Schakowsky.

**STATEMENT OF HON. JAN SCHAKOWSKY,
UNITED STATES REPRESENTATIVE (IL-09), WASHINGTON, DC**

Representative SCHAKOWSKY. Well, thank you so much, Senator Durbin, and for having this hearing today. It's so incredibly important.

I agree with everything that you said and what my colleague has said, but it's never said enough. And I want to say that in 2020, 5 of the largest pharmaceutical companies made in profits, \$80 billion. This is larger than any other company in the United States of America, Big Tech, or any other organization. They made more money.

And yet, Americans are paying twice to three times as much for pharmaceuticals, the exact same pharmaceuticals that are available around the world. I mean, I think that the American consumer is really viewed as kind of a chump by the pharmaceutical industry. I am very, very concerned about the kinds of activities that Big Pharma has done to make sure that they protect their own profits.

We saw during the pandemic that Big Pharma refused to let countries around the world develop their own pharmaceuticals for the Covid vaccine. They said, no, we want to make sure that you can't get any of the information in order to be able to produce your own. So, I think that the fact that many people died around the world, that the pharmaceutical companies have been responsible for that.

We also know that when it comes to what—that we are seeing that the pharmaceutical companies have gone to the a number of the hospitals and changed the rules around 340B and made it harder for the hospitals to be able to make sure when there are low income patients and they're trying to provide to them, the pharmaceutical companies had changed some of the rules. And maybe we'll hear from some of our experts about that.

I've also been very concerned about the role that the pharmaceutical companies have played to help to raise the prices. And you heard and you mentioned about the Affordable—not the Affordable Care Act, but about the what the Biden Administration has done, what Kamala Harris has done to make sure that we were able to provide in the Inflation Reduction Act to lower the cost, to negotiate the cost of prescription drugs to lower them that had been done on 10 drugs. And we want to see those prices go down.

And I assure you that the pharmaceutical companies have not been happy about doing that. That we have made insulin so available to Americans at \$35 a month. You know, that insulin costs about a buck to make. And yet, we have seen in the past hundreds of dollars being charged by the pharmaceutical companies.

Unfortunately, these benefits have only gone to people that are getting Medicare right now. And I know that the administration, our Democratic administration has said they want it applied to all Americans. So we can make serious progress, and we should, and we need to, and we need to hold accountable Big Pharma.

I want to say also that I have offered legislation that I hope will pass in the in the next session that will allow people to import from certain countries like Canada to be able to have lower cost drugs, and to import them into the United States of America. And I also am introducing legislation that would allow the Department of Health and Human Services to be able to create more affordable drugs by manufacturing those drugs.

So, we should be not just handing over patents to the Big Pharma companies to do what they want with us as Americans. And I am looking forward in the next session of Congress, being

the optimist that I am, that we are going to be changing some of those rules and practices by Big Pharma, and that we are going to be able to get all Americans to be able to afford the drugs that they need for their lives and deserve.

Let me just say one more thing. I was at a drugstore where a woman before me was told by the pharmacist how much she had to pay. And very quickly she said, "Well, I simply can't." And she walked away without the drugs that she needed. This is happening all across the country. It needs to stop.

And with that, I yield back.

Chairman DURBIN. Thank you, Congresswoman, for all your work in this area. We believe in Illinois that every congressional delegation should have a physicist, and our delegation has one of those.

And Congressman Bill Foster, you're next.

**STATEMENT OF HON. BILL FOSTER,
UNITED STATES REPRESENTATIVE (IL-11), WASHINGTON, DC**

Representative FOSTER. Well, good morning, and thank you Chair Durbin for inviting me to speak today.

Over the past several years, I've heard from countless constituents who are struggling to afford the ever-rising cost of prescription drugs. And all too often this means choosing between purchasing a critical medication, or paying for rent, or groceries. As one of the richest nations in the world, no American family should have to make a choice like that. And I was proud that the House and Senate worked together and make real progress on this problem with the Inflation Reduction Act in 2022.

Starting in 2025, just a few weeks away, the Medicare Part D will not have to pay more than \$2,000 annually toward their prescription drugs. Seniors with diabetes are already getting much needed insulin for just \$35 a month, and Medicare will soon begin using negotiated drug prices with pharmaceutical companies to help bring those costs down further. However, there is still a lot of work to be done here, especially for Americans who are too young for Medicare.

You know, insulin was discovered at a university laboratory more than a century ago, and the scientists who made that discovery refused to put their names on the patent, remarking that, "Insulin belongs to the world." And now, we find people still unable to afford it despite the low production cost. So more than a century later, there's a lot of work to be done here.

But as we think about prescription drug pricing, there's an important balance that we must strike. New innovative drugs must be affordable for patients who need them, but we also need sufficient financial incentives for pharmaceutical companies to invest in developing new drugs. Research that, you know, often fails to produce anything marketable.

Now, with taxpayer-funded NIH paying much of the earliest stage and riskiest research in recent years, some of this burden has been lifted. But we still must be careful not to go too far in the other direction and potentially halt the scientific progress toward a variety of illnesses.

As we all know, the presence of competition, especially from off-patent, generic versions of a given drug, are one of the most reliable ways to keep drug prices reasonable. An important example of this is the worldwide race to develop inexpensive oral versions of GLP-1 receptor agonists, known to the public as Ozempic and Wegovy.

You know, if you're pre-diabetic and you take these drugs, you will pretty much never become diabetic. You will lose a lot of weight, your blood pressure will go down, and when competition drives down the price anywhere near the production cost of under \$100 a day though, then the world will be a better place. And the healthcare cost structure in this country will be transformed because one-third of all our healthcare costs are diabetes now. But for now, millions of Americans are unable to access these life-altering medications because of cost. But despite that, the cost in other countries is 10 times lower than it is in our country.

I also appreciate the Biden Administration that they're taking a close look at some of these, and in some cases, cracking down on potential anti-competitive abuses within the patent system that prevent or delay generic entry. Practices such as evergreening, where a pharmaceutical company makes a slight tweak through a drug to extend its patent. Or pay for delay, where a company pays a generic brand to delay their entry into the market.

That puts a risk at that careful balance within our patent system, and Congress must support efforts to ensure our patent system is operating as intended

And finally, hand in hand with affordability, prescription drugs must also be accessible to American families. Earlier this month, there were troubling reports from the New York Times that the pharmacy benefit managers, or PBMs, were systematically underpaying small independent pharmacies for patient's prescriptions.

The goal, the Times alleged, was to run these pharmacies, which compete with the PBMs in-house pharmacies out of business with techniques like cherry-picking the most profitable drugs for their in-house pharmacies, and leaving the unprofitable drugs for struggling local pharmacies. In many cases, these alleged efforts were successful, leaving many Americans, especially those in rural areas, without a local pharmacy. But I have heard exactly the same thing from local pharmacies in Aurora and in Naperville.

Congress must study this issue closely and to ensure that PBMs are not engaging in anti-competitive behavior, which could impact both the accessibility of pharmacies and the prices of drugs themselves. So, I thank the Senate Judiciary Committee for its hard work on preventing anti-competitive behavior in the healthcare space, and I hope the Committee will consider the two issues I've laid out today. Thank you, and I yield back.

Chair DURBIN. Thanks, Congressman Foster. As I mentioned at the outset, we're recognizing Members in order of seniority, and now recognize Representative Krishnamoorthi.

**STATEMENT OF HON. RAJA KRISHNAMOORTHY,
UNITED STATES REPRESENTATIVE (IL-08), WASHINGTON, DC**

Representative KRISHNAMOORTHY. Good morning, and thank you Senator Durbin for hosting this hearing focus on rising prescription drug prices.

Prescription drugs exist in one of the few industries that do not operate along the normal rules of supply and demand. The blunt truth is that if you or a loved one needs medicine, you'll pay almost any price to obtain it. This ability to squeeze every dime from those who need medicine, not only fatten corporations' bottom lines, but also leads to the creation of exploitive middlemen as surely as sharks are drawn to blood.

One of these middlemen are pharmacy benefit managers, or PBMs, for short. PBMs harm Americans in two ways. One, PBMs are helping to fuel ever rising drug prices, and then two, PBMs are killing independent pharmacies, as Congressman Foster alluded to just a second ago.

First, I want to get into drug prices. On behalf of healthcare payers like employers and insurers, PBMs negotiate with drug companies, acting as middlemen to create formulary lists that determine which medicines patients can be prescribed. To maximize their own profits, PBMs have implemented a so-called rebate system that requires drug companies to provide rebates based on their drugs list prices. In exchange, PBMs include these drugs on their formularies. The higher the prices, the higher the rebates, and the more likely that a company's drug gets on the PBMs formulary.

The glaring problem, however, is that PBMs do not appear to be passing along the rebates to their clients, namely the payers, and ultimately, the consumers. Meanwhile, PBMs pursuit of ever higher rebates drives up what they're linked to, namely drug prices. This is not some conspiracy theory. Congress, numerous States, investigative journalists, and even the FTC, as you can see from these various headlines, from even Attorney General Raul, who's been asking the supreme court and other agencies to look into this issue, have now illustrated that this is a commonly understood problem.

[Poster is displayed.]

The second way in which PBMs undermine healthcare is by killing off independent pharmacies. How? Not only do PBMs act as the middlemen between payers and drug companies, they also act as the middlemen between payers and the pharmacies. And they do it in the following way. First, pharmacies buy drugs from wholesalers in anticipation of reasonable reimbursements from the PBM after the drugs are dispensed. However, the PBMs then set these artificially low reimbursement rates.

PBMs have engaged in complex schemes to either grossly underpay pharmacies for the drugs they dispense, or by instituting clawbacks and what are called DIR fees, direct and indirect remuneration fees. These DIR fees mean that PBMs retroactively clawback money from pharmacies for drugs they have already dispensed in the past.

CMS found that DIR fees exploded by, and this is not a typo, 107,400 percent over the last decade. PBMs appear to be using any and every trick in the book to continue to make enormous profits

and kill off independent pharmacies. The result of these clawbacks and underpayments has been stark. The National Association of Community Pharmacists report that almost every day a pharmacy is permanently closing its doors. At this point, 73 percent of counties in Illinois are now a pharmacy desert, meaning there is not a pharmacy located in that county.

[Poster is displayed.]

CMS acted earlier this year to block the most egregious DIR abuses, but PBMs are still putting relentless pressure on independent pharmacies. Why? Well, surprise, surprise, the largest PBMs parent companies run their own competing pharmacies, which now dispense a whopping 80 percent of all prescriptions in the country. PBMs have the power to kill off their competition, and they are doing just that.

The result of PBM control and manipulation is that drug prices are going up, pharmacy closures are going up. And guess what? PBM profits are going way up. PBMs, I would suggest, stand for pretty big markups. That's what PBMs are at this point.

However, there's some cause for hope. Elected officials on the State and Federal level from both parties, including in Illinois, agree that PBMs need to be reined in. For instance, we should pass as soon as possible much needed PBM reform legislation like the bipartisan Pharmacist Fight Back Act. This bill is the most comprehensive approach to PBM reform yet, and I believe meaningful reform of the PBM industry is within our grasp, even within this Congress.

Senator Durbin, thank you again for your yeoman's work to lower prescription drug costs and for holding this hearing. I'm honored to have been included. Thank you.

Chair DURBIN. Thank you very much, Congressman. I'll just emphatically add, if you've been to a Walgreens drug store lately to fill a prescription; you know what you're going to find? A line of 12 people in front of you. I see some heads nodding in the audience.

And you think to yourself, they're closing drug stores, they're want to close some drug stores. And yet, the demand is so high, they can't fill the request to customers who walk into their stores. Something's wrong with this picture, and I think it's PBMs. They're stepping in and complicating this market relationship. And the consumer will pay the ultimate price. So, I thank you for raising that issue.

Mr. KRISHNAMOORTHY. Yes, sir.

Chairman DURBIN. Next, is Congressman Sean Casten.

**STATEMENT OF HON. SEAN CASTEN,
UNITED STATES REPRESENTATIVE (IL-06), WASHINGTON, DC**

Representative CASTEN. Thank you, Chair Durbin for doing this, and I'm honored to be invited.

So, a couple years ago, I had the opportunity to meet with some of the doctors and administrators at the Mayo Clinic, and was chatting with them about how they measure success as one of the more successful health clinics in our country. And they said their metric is this mortality amenable to healthcare. How many people die every year, but for their access to healthcare?

Now, maybe that's because there was an oversight in the part of the hospital. Maybe there weren't beds available. Maybe they couldn't get the right specialist. Maybe they didn't have insurance. All of these people are people who should have lived. And they measure that success for their hospital. They measure it for their State, they compare to others.

You can look at it countrywide. And in the United States, last year, a little over a million people died, should have lived but for shortcomings in our healthcare system. That's 336 per 100,000, if you want to normalize it on a per capita basis. And to put that in perspective, that is more than twice the rate of the Swiss, the Japanese, the Australians, the Swedish, the Netherlands, the French.

I could go on and on down that list. We have worse health outcomes than virtually every other industrialized country in the world. And on top of that, we pay more for healthcare than any other country in the world. About \$13,000 per capita per year. \$4 trillion. So, if we were paying a lot in getting great outcomes, okay, that's a tradeoff. As it is, we're paying a lot and not getting robust outcomes.

If we step that back, the fastest growing cost in the healthcare system is pharmaceuticals in 2004, 1 percent expenses were pharmaceuticals. Last year was 14 percent. It's growing faster than anything else in the system. I think several folks have talked about why it is that we have said that Medicare shouldn't negotiate pharmaceutical prices, and that's a rich conversation. But we should point out that it is insane. If you were to tell the American people when you go buy a car, you can't negotiate with the dealer. When you buy a house, you can't negotiate. None of us would call that a competitive market. And somehow, we've got this idea in our head that, well, competitive markets will fix this problem. They haven't. They failed.

In 2019, the House passed H.R. 3 to fix that problem; to not only give Medicare the right to negotiate, but compel them to negotiate. And I don't want to be partisan, but if we're talking about epidemiology, we need to use all the statistics. Every single Democrat voted for that bill, and only two Republicans in the House voted for it. That bill would've given Medicare the ability to negotiate prices, would've capped out-of-pocket costs, would've added dental, vision, hearing to Medicare, and a number of other reforms as well. As you know well, Chair Durbin, the Senate was led by Republicans at that time and chose not even to bring it up for a vote.

Fast forward 2 years later, and as you mentioned in the Inflation Reduction Act, we then passed several of those provisions in the bill, all of them. But now, we've got 10 drugs that are available for Medicare to negotiate, which will expand next year, out-of-pocket costs are capped to \$2,000, \$35 price on insulin, expansions on ACA subsidies.

Not a single Republican voted for any of those. I don't want that to be partisan, but it is the reality that we would not have made that progress but for who was in power in 2022. The result of that just in my district in Illinois, 6, is that there are now 23,000 more people who have health insurance, who are saving an average of \$1,000 a year. Just in one congressional district, 4,300 people who are saving \$490 a year on average on insulin. 24,000 people who

are saving on average \$533 on prescription drugs. And that's going to go to 34,000 next year.

Illinois wide, I think as Congressman Davis pointed out, the numbers I've seen is that folks are going to save over \$120 million, almost 500,000 people in Illinois. And oh, by the way, that's a \$600 a year savings in Medicare, which means that our fiscal health as a nation is better, and people are healthier, and people are saving out-of-pocket costs.

Now, having watched the Bears game this weekend, the last thing I want to do is to celebrate before the game is over. And make no mistake, this game is not over. We have made terrific progress, and maybe it's appropriate to do a shimmy in the end zone after the referee puts his hands up. But we haven't won the game yet. And I hope that as we move forward in this Congress, we can simply recognize that there is not a business in the world that comes to Washington and says, "I wish my industry was more competitive."

[Laughter.]

It is crazy that we had to give Medicare the right to negotiate. We've gotten that to 10 drugs, we'll expand it next year. They should have the right to negotiate all drugs. As Congressman Krishnamoorthi has pointed out, pharmacy benefit managers are not designed to create competition. Quite to the contrary, it appears that they're getting in the way of competition.

We need to expand the number of covered drugs. We need to make sure that these benefits cover the whole system. And I hope someday, everybody who has the privilege to serve and to have public service recognizes that you either are or someday, God willing, will be a senior citizen. Your constituents include large numbers of senior citizens. One hundred percent of Americans I've polled this would like to be healthier, would like to spend less on drugs, and would like to see our deficits fall. And I hope that that leads us all to make this a robustly, bipartisan commitment to competition markets and a healthier population in the very near future. Thank you, and I yield back.

Chair DURBIN. Thank you very much. And if I'm not mistaken, the report in the Heritage Foundation Project 2025 would've eliminated the power that we have given to our Government to negotiate lower drug prices. So, in fact, this issue is on the ballot next Tuesday for voters to decide whether to move forward with this or not.

Congressman García.

**STATEMENT OF HON. JESÚS G. "CHUY" GARCÍA,
UNITED STATES REPRESENTATIVE (IL-04), WASHINGTON, DC**

Representative GARCÍA. Thank you, Chairman Durbin, for convening this most important hearing on this critical topic. There's no reason that the wealthiest country in the history of the world at a time when we're confronting the consequences of health disparities that were laid bare by the Covid pandemic, that patients still cannot afford the everyday medications that they need to live a healthy, dignified life.

Under the Biden Administration, Congress has taken unprecedented steps in the right direction to lower the sky-high cost of pre-

scription drugs. I'm proud to have participated in a progressive push to ensure that prescription drug costs were addressed in the Inflation Reduction Act. The bill, of course, has capped, as we've discussed, a \$35 per month for seniors, and finally allowed Medicare to begin negotiating for other lower drug prices.

Prices for the first 10 drugs negotiated were released this summer. When they go into effect in 2026, they will start saving customers up to 76 percent, hundreds in cases, thousands of dollars per month. The new prices are expected to save 1.5 billion in 2026 alone. But despite remarkable progress, these gains only address a fraction of the enormous need for lower drug prices for patients not covered by these programs.

For example, I represent a congressional district that is over 65 percent Latinos, and Latinos are nearly twice as likely to have diabetes than non-Hispanic whites. So, while the insulin cap is a lifesaver for people who are covered, everyone else, even those with private insurance does not cover the insulin. And they're still paying hundreds.

That's a policy issue, and one created when Republicans blocked a broader insulin cap from the final version of the Inflation Reduction Act. That comes on top of the fact that many of my neighbors already confronting health inequities like under insurance, food deserts, and a lack of nearby health facilities that contribute to the overall well-being.

So, for the tens of thousands of individuals in my district, approximately 94,000 people are without insurance because they're immigrants, or undocumented, or otherwise ineligible. We've got to find a new approach. And while the impacts of the targeted drug pricing legislation we've passed demonstrates how far we've come, the remaining gaps show us where we need to go toward comprehensive legislation that addresses anti-competitive behavior by pharmaceutical companies at its root.

That's why I'm proud to be here at this Senate Judiciary hearing. And as a new Member of the House Judiciary Committee, it's an important issue that we've got to tackle together. We must confront practices that corporations use to prolong market exclusivity for profitable drugs. We must call out the billion spent on lobbying, campaign contributions and stock buybacks by Big Pharma companies that simultaneously claim they cannot afford to lower drug prices. It's price gouging, plain and simple, and it's got to stop.

So, again, I deeply appreciate the opportunity to be here today with my colleagues, and I look forward to working together with everyone here, panelists, and my colleagues in the House and Senate to work toward a common goal of affordable healthcare for all. Thank you.

Chair DURBIN. Thank you, Congressman. Congresswoman Ramirez.

**STATEMENT OF HON. DELIA C. RAMIREZ,
UNITED STATES REPRESENTATIVE (IL-03), WASHINGTON, DC**

Representative RAMIREZ. Thank you, Chair Durbin for holding this important hearing. I'm really honored to join my colleagues here in the House and listen to expert testimony around an issue that deeply affects my constituents and the words of my father,

Luis Ramirez, “la medicina está muy cara,” The cost of prescription drugs in America is too darn, we’ll say, high.

Too often, I hear from my constituents talk about the impossible choices they have to make between paying rent, paying for groceries, or affording their inhalers. And in our Nation, a person with asthma pays about \$1,830 for year, just for lifesaving emergency. And I’m grateful to have been part of the movement in Illinois to cap the prices of prescription drugs. I was in the Illinois State legislature when SB 667 came to the floor to cap the price of insulin. And I had the honor to be a co-sponsor and vote yes on that bill.

And of course, I’m grateful for the historic legislation passed by Democrats to cap the price of insulin and allow Medicare to negotiate the price of prescription drugs. The folks we’re here because we know we have to do so much more. Too many lives are on the line. You’ve heard it from my colleagues today, our family, our friends, our neighbors, our constituents, they depend on us to continue to advance efforts that reduce the cost of and increase access to medication.

You see, in Illinois, my District 3, is comprised of working people who depend on these efforts. Twelve percent of my residents have income below the poverty line. Over 82,000 people have no healthcare insurance coverage whatsoever. Two hundred and thirty three thousand of them, rely on public programs for coverage, and multiple communities qualify as medically underserved. But when the unchecked corporate greed of pharmaceutical companies meets the lack of proper regulation of prescription drug prices, families in my district and all of our districts suffer.

In my district, families have found relief in community health centers like Erie Humboldt Park Health Center, that provide essential comprehensive healthcare and regulatory programs created by Congress like the 340B drug discount program where healthcare providers that serve low income and uninsured communities are able to purchase drugs at a lower cost and help patients afford their medication, their insulin, their inhalers, their blood pressure medication, their Narcan, their Prep, and more.

In addition to helping patients afford their medicine, we know that community health centers provide the high-quality comprehensive care patients with chronic conditions needs to thrive. Programs like the 340B Drug Discount Program and high rates of utilization of community health centers across Illinois, show us how critical it is for Congress to take action to address how unregulated, greed-driven drug pricing holds our families back from realizing a better healthcare outcome, and fuller and more vibrant lives.

And look, the truth is that the prescription drug pricing system is intentionally complicated and confusing. That’s why we need all those charts, Raja. It’s a predatory practice, and everyday Americans struggle to understand what is covered and how much it’s going to cost them. It’s clear we have both the opportunity and the responsibility to address this broken system that regularly puts profits over people’s well-being.

And for the last 2 years, I’ve had the privilege to serve on the Veteran Affairs Committee, where I’ve seen firsthand the potential of models that prioritize coverage and lifesaving medications for

our communities. And as I work with my colleagues in the Committee to ensure the proper implementation of the historic PACT Act, it is clear that we have the models, we have the tools, and we have the capacities to ensure that every family has access to care and the assistance they need.

But we have to continue to advocate for Medicare for all, to provide comprehensive benefits to every person in the United States, including primary care, including vision, dental, prescription drugs, and more. We have to bring the full power of the Federal Government regulation, legislation, and the word you've heard here for my colleagues over and over, negotiation, to fight for our constituents so they never have to forego necessary prescriptions.

Today, I look forward to listening to experts about the crucial steps we can take together to ensure that everyone, regardless of ZIP Code, regardless of migration status, have access to the medicine they need, and the care that they deserve, and the help that we know our Nation can provide.

Thank you, Senator Durbin, for this opportunity and for this hearing.

Chair DURBIN. Thank you, Congresswoman.

Each morning in the Senate, the Republican leader and Democratic leader make statements, and I am usually there to hear them. One recent statement made by the Republican leader, Mitch McConnell, was in reference to the negotiation of drug prices. He referred to it as, "Pharmaceutical socialism," pharmaceutical socialism.

I'm glad you brought up the fact that the Veterans Administration has been negotiating drug prices for decades, saving the taxpayers a lot of money in the process, and making sure that the men and women who served our country still receive the very best when it comes to medical assistance. I don't think that's socialism. I think that's basic to America and our democracy. I thank you for raising that issue.

I want to thank my colleagues for joining me this morning. All of your contributions were very positive and will be part of the record. And in the process of changing out the panel to the second panel, I want to thank healthcare leaders from around our State who had joined us here at this hearing, including Illinois Public Health Director, Dr. Sameer Vohra, State Senator Mike Simmons, a former intern in Durbin's Office, and representatives from hospitals and health centers; Lawndale Christian Access, PCC, ATT, AHS, Family, Rush, Sinai, and Lurie Children's, along with the Illinois pharmacists who've joined us as well.

So, I thank my colleagues for joining me this morning, and you are now officially dismissed. If the five members of the second panel would approach the table, I'd appreciate it very much, and remain standing for a moment. If you would please raise your right hand. Do you affirm the testimony you're about to give before the Committee will be the truth, the whole truth, and nothing but the truth, so help you God?

[Witnesses are sworn in.]

Chair DURBIN. Let the record indicate that the five witnesses, luckily, all answered in the affirmative. I'd like to introduce them. Our first witness is Kwame Raoul, the 42d Attorney General of the

State of Illinois. He served as Illinois Chief Legal and Law Enforcement Officer since 2019. Assumed this role after serving for 14 years as an Illinois State Senator. Previously served as a prosecutor in Cook County and staff attorney for City Colleges of Chicago.

We're also joined by Professor Rachel Sachs, a professor of law at Washington University in St. Louis, where she also serves as a faculty scholar with the Institute for Public Health, and Faculty Fellow with Cordell Institute for Policy in Medicine & Law, and much more, I know from earlier conversation.

Our next witness is Dr. Anthony Douglas, general surgery and resident physician at the University of Chicago Medicine, where he focuses on trauma and acute care surgery. Also, the founder and first fellow of the University of Chicago Surgical Advocacy Fellowship. Thank you for being here.

Next, joined by Michael Sandsmark. Mr. Sandsmark is the Director of Pharmacy at Iroquois Memorial Hospital, and resident home in Watseka. In 2023, Iroquois Memorial Hospital was designated as a critical access hospital by the Centers for Medicare and Medicaid Services, recognizing the key role that this facility plays in providing healthcare in that part of the State.

Our final witness is Deanna Brant, a retired executive assistant from Countryside, Illinois. She's a Medicare beneficiary, and I look forward to hearing her perspective on what it's like to cope with these high cost of prescription drugs. Thank you for joining us.

I'm going to let the Attorney General kick it off. Take it away.

**STATEMENT OF HON. KWAME RAOUL,
ATTORNEY GENERAL, STATE OF ILLINOIS, CHICAGO, IL**

Mr. RAOUL. Good morning, and thank you Mr. Chairman. Thank you for inviting me to speak on this important issue. As attorney general, I take seriously my office's fundamental function to protect the health and wellness of Illinois citizens. High prescription drug prices harm Illinois patients by obstructing access to treatments needed to sustain their health and well-being. Without access to affordable medications, medical conditions worsen, patients' overall health, outcomes decline in some patient, and for some patients it can be fatal.

According to U.S. Department of Health and Human Services, from January, 2022 to January 2023, more than 4,200 drug products had price increases, of which 46 percent were larger than the rate of inflation. With these ever increasing costs, patients may stop taking their medications as prescribed or eventually abandoned treatment all altogether.

In addition to the direct burden on Illinois consumers, high prescription costs also impact the State at large because they are significant payers of healthcare services. State dollars pay for prescription drug use by State employees and their dependents, the use by people housed by the Department of Corrections, and Medicaid beneficiaries. In Illinois, about 3.9 million people are enrolled in Medicaid.

Pharmaceutical companies and pharmacy benefit managers, known as PBMs, must be more transparent about their pricing and business practices. They should also be held accountable for unnec-

essary and overly burdensome increases in prices for prescription drugs. As mentioned earlier by several speakers, the original purpose of PBMs was to negotiate on behalf of employers, government payers, and consumers, to minimize overpricing by manufacturers. Instead, PBMs have made the pharmaceutical market more opaque, and have driven up prescription drug pricing.

My office and those of other state attorneys general have worked to hold PBMs accountable. However, before expounding on the actions my office has taken, I do have to mention that the scope of what I can share and the answer is limited. Due to ongoing litigation and investigations that are subject to confidentiality agreements, I'm restricted from commenting on certain pending matters.

I want to emphasize that I have used multiple tools available to go after bad actors in the industry. We have used our authority under the Illinois Consumer Fraud and Deceptive Business Practices Act, the Illinois Voice False Claims Act, and antitrust laws to target the prescription affordability crisis from every possible angle.

PBMs profit from fees charged to market participants and by reimbursing pharmacies less than PBMs are paid for dispersing medications. We believe PBMs have engaged in practices that drive up their own profits at the expense of patients and the State actors who have contracted with them.

My office has uncovered practices that have allowed PBMs to largely overcharge State agencies through their contracts with the State, and I've been successful in bringing money back to Illinois through these investigations. For example, as a PBM for Illinois Medicaid program, Centene subsidiaries delivered pharmacy benefits to Illinois State agencies such as the Illinois Department of Healthcare and Family Services.

We initiated an investigation that determined that Centene's subsidiaries allegedly submitted inaccurate pharmaceutical reimbursement requests that failed to accurately disclose the cost of pharmacy services. In addition, requests for reimbursement did not disclose available pharmaceutical discounts in the improperly inflated dispensing fees. On September 27, 2021, my office on behalf of the State executed a settlement agreement that required Centene to pay the State over \$56 million.

As recently as June 24, this year, my office recovered \$45 million to the State through a settlement agreement with CVS after an investigation under the False Claims Act, showed that CVS as a PBM contracted with the State improperly failed to pass rebates back to the State from April 1, 2020 through September 30, 2023.

PBMs have largely been unregulated, and as recently as earlier this year, I joined a bipartisan group of AGs calling on Congress to reform the way PBMs do business. Federal legislation is needed to curb undue price increases, and to increase transparency around the way PBMs operate and set prices. In the absence of Federal regulations, States have passed their own regulations, which have been met with pushback from the industry. There's a petition pending in front of the U.S. Supreme Court to determine whether Federal laws preempt State laws that regulate PBMs.

This past summer, my office joined a bipartisan coalition States urging the court to review a decision from the 10th Circuit holding

that Federal laws preempt Oklahoma laws regulating PBMs. The coalition seeks to protect consumers by assuring that States can regulate PBMs as part of our efforts to address access and affordability to prescription drugs.

In December 2022, my office originally filed a complaint in Cook County against PBMs and manufacturers alleging violations of our Consumer Fraud And Deceptive Practices Act for engaging in an insulin pricing scheme. Our case is now in a MDL pending before the District Court in New Jersey. The complaint alleges that insulin pricing scheme has caused the cost of insulin to skyrocket. To be clear, insulin costs these manufacturers less than \$2 per unit to produce, yet prices can range from \$300 to \$700 per unit.

Our antitrust bureau investigates the conduct of brand drug manufacturers who engage in illegal activities to delay entry of generic competitors, which drives up prices for consumers. Such activities could include agreements with generic companies to delay entry into market, product hopping schemes, and exclusive contracting schemes, which prevent drug companies from accessing the components needed to manufacture these drugs.

Our bureau is working with nearly all other States on litigation against the generic drug in industry for engaging in price fixing conspiracies involving hundreds of generic drugs. The State coalition has already settled with several individuals and two corporations who have agreed to provide monetary relief and substantial cooperation.

In 2023, my bureau in partnership with the FDC, and several other State AGs, was able to secure a settlement agreement with Amgen, one of the world's largest biopharmaceutical drug companies to address the potential competitive harm that would result from Amgen's purchase of Horizon Therapeutics. The settlement resolved the potential anti-competitive acquisition and prevents Amgen from engaging in anti-competitive actions to disadvantage any product that would compete with these drugs. The agreement requires Amgen to submit annual compliance reports and monitors in place to oversee compliance.

Mr. Chairman, these are examples of how my office has worked to reign in the ongoing problem of prescription drug overpricing. They're not exhaustive, for examples. We will continue to do so. I'm thankful to the Committee for shining a light on these challenges, and I hope that we can collectively work on behalf of Illinois patients, employers, and the government payers to reduce the price of prescription drugs.

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

Chair DURBIN. Thanks, Attorney General. Professor Sachs.

STATEMENT OF RACHEL E. SACHS, JD, MPH, PROFESSOR OF LAW, WASHINGTON UNIVERSITY IN ST. LOUIS, ST. LOUIS, MO

Professor SACHS. Chair Durbin, my name is Rachel Sachs, and I'm a professor of law at Washington University in St. Louis, where my research focuses on innovation and access to new pharmaceuticals. Thank you for the opportunity to testify about the role of competition in making prescription drugs more affordable for pa-

tients, and how this Committee might address these issues. All views I offer today are my own.

Over the last 40 years, Congress has focused on competition from lower cost, generic, and biosimilar versions of branded prescription drugs as the primary tool to bring down prices and promote access to affordable medications. 1984 saw the passage of the Hatch-Waxman Act, which created a path to FDA approval for generic versions of small molecule drugs. When combined with State laws allowing pharmacists to substitute generics for branded drugs, Hatch-Waxman has been largely successful.

Today, generic drugs quickly take over 80 percent of the branded drugs market share and multiple generics can drive down prices by over 90 percent. Of course, ongoing focus on branded drug manufacturers attempts to delay generic competition matters. And I'll return to that.

The Biologics Price Competition and Innovation Act as enacted in the Affordable Care Act in 2010, created a path to approval for biosimilar versions of biological products. To date, this law has been less successful at creating competition than has Hatch-Waxman. Just 61 biosimilars for 17 biologics have been approved to date, and many have not yet been marketed. Even marketed biosimilars struggle to gain market share, and have driven down prices by a smaller amount.

The relative weakness of biosimilar competition is traceable to several factors. In my written testimony, for example, I refer to patent listing distinctions between the Orange and Purple Books, the interchangeable designation, and comparatively weak State substitution laws as legal drivers.

The Inflation Reduction Act, or IRA, and its Medicare drug price negotiation program also looks to generic and biosimilar competition as the primary tool to drive down drug prices. Recognizing that Hatch-Waxman and the Biosimilars Act have not always succeeded in enabling generic and biosimilar entry only if such competition has not emerged, does the IRA envision a role from Medicare to negotiate the prices for drugs it purchases as a market participant.

The IRA only permits a drug to qualify for negotiation after it has been FDA approved for many years, and a drug with an approved and marketed generic or biosimilar is not eligible for selection for negotiation. Hatch-Waxman and the Biosimilars Act aim to support approval of generics and biosimilars. This approval is necessary for competition, but is not sufficient to enable it.

Take the biosimilars example. Even where a biosimilar is approved and marketed, it must be covered by insurers, physicians must prescribe it, and pharmacists must substitute it. Patents matter for creating competition at the approval stage, but legal changes must go beyond patent law to include insurance coverage, physician prescribing, and pharmacy substitution.

This Committee ought to consider legislation to improve competition, but a full response will require support from other Committees with distinct jurisdictions. First, this Committee should continue to focus on the approval of generics and biosimilars where the PTO and patent law play key roles. This Committee has already taken up several bills responding to branded manufacturers

efforts to discourage generic or biometry. The Federal Trade Commission's recent challenges to over 400 patents allegedly and properly listed in the Orange Book also fall into this category.

Second; coverage. Many insurance coverage decisions are mediated through pharmacy benefit managers, or PBMs, about which we've heard already. PBMs have been criticized, including for the ways in which they sometimes appear to limit access to lower cost products. Both the Federal Trade Commission and several State attorneys general have sued the Nation's largest PBMs over their conduct, in the market for insulin in particular. This Committee should consider its role in PBM reform, including potentially supporting the commission's complaint.

Third; prescription. This Committee might work collaboratively with others to encourage the prescribing of lower cost products. For example, experts have argued for reforming the Medicare Part B payment system, arguing that it encourages clinicians to choose higher priced products over lower priced ones.

Fourth; substitution. State biosimilar substitution laws typically only permit substitution where the biosimilar is deemed interchangeable by FDA. Most approved biosimilars lack that designation. This Committee might support efforts to alter State biosimilar substitution laws, plus efforts by other Committees regarding the interchangeable designation as FDA has requested. This Committee should support competition to make prescription drugs more affordable for patients.

Chair Durbin, I appreciate your focus on this important issue, and I look forward to answering your questions.

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

Chair DURBIN. Thank you very much. Dr. Douglas.

STATEMENT OF ANTHONY D. DOUGLAS II, MD, GENERAL SURGERY RESIDENT, UNIVERSITY OF CHICAGO, CITIZEN ACTION ILLINOIS, CHICAGO, IL

Dr. DOUGLAS. Good morning. Thank you, Senator Durbin, and the Members of your Judiciary Committee for the opportunity to testify today. Also, for your investment in this important issue. My name is Dr. Anthony Douglas II, I'm a general surgery resident physician at the University of Chicago. I'm here on behalf of my patients, as well as Citizens Actions, Illinois, and my thoughts are my own.

As physicians on the front lines, we have a pulse on how everyday Americans are affected by high out-of-pocket prescription costs. We make and carry out the plans for patients in the inpatient and outpatient settings. We perform the operations, and we guide Americans across this country to recovery. For physicians like myself, one of the most difficult conversations to have are those with patients over the phone when they are at the pharmaceutical counter.

As I sit before you, I can hear the worry, the desperation and embarrassment of my patients from the CVS and Walgreens counter saying, "Dr. Douglas, I cannot afford this medication." I remember the face of the woman with type 1 diabetes who came to our emergency department with appendicitis who was not taking the insulin

she was prescribed. When I asked her why, her answer was simple, “I cannot afford it.” Her surgery was delayed. I sat and watched her dangerously high blood sugars improve each day with angst, hoping she didn’t have a complication as we waited.

Senator Durbin, I have story after story of people balancing the cost of medications to sustain their livelihood, and the cost of their mortgages, utilities, childcare, and groceries. And they almost always choose the more pressing immediate needs over their medications.

My father, who is in the audience today, was prescribed Jardiance for his type 2 diabetes. It cost him \$660 a month to refill. He has since been switched to a more affordable but less effective medication after free samples from his physician ran out.

In an Uber ride, Carol, a middle-aged woman, drove me to the airport after asking me what I did for a living. She divulged that she had a kidney transplant a week ago. I scolded her for not being at home recovering, and her response made me feel ashamed. She said she had no choice but to drive Uber because the cost of the drugs to keep her body from rejecting her brand-new kidney were too great.

And I’d be remiss if I didn’t share this story. I spoke at a retirees’ meeting about a week ago. And a member of the audience came to tell me about his friend who was a former police officer, who developed a blood cancer and was depleting his family’s financial reserves to pay for the medication to treat his blood cancer, and stopped taking the medication to let his disease run its course in order for his family to have finances to survive.

In our State of Illinois, a survey of adults revealed that one in four people split ration, or take sips of their medications to prolong needing a refill. That means approximately 20 Americans in this room right now are not taking their medications as they are prescribed because they must delay paying to refill the prescription. As a physician, I can tell you drugs do not work like that. Medication non-adherence accounts for 25 percent of hospitalizations, and 125,000 deaths a year.

One of the significant drivers of how much our country spends on healthcare is inefficiency. The lack of prescription affordability leads Americans to visit the emergency department, or be admitted to the hospital for conditions that could be effectively controlled at home if they simply had access to the appropriate medications that is inefficient.

In 2023, according to the U.S. Department of Health and Human Services, 4,200 drug prices had price increases, and 46 percent of those increases were larger than the rate of inflation, as alluded to earlier. The average price increase was 15 percent, or about \$590 per drug. The Inflation Reduction Act was a pivotal step toward addressing the rising cost of prescription drugs for Medicare Part D patients. The Act helped to reduce the price of a drug like Xarelto, a blood thinner that I prescribe almost daily from \$517 to \$197, a 62 percent cut.

Other drug prices were cut between 38 to 79 percent. This and the annual drug spending cap for senior Americans will make medications more affordable and save lives. But in my experience, Medicare Part D enrollees are merely a fraction of the population

that is suffering from the rising costs of prescription drugs. We cannot forget about the number of other vulnerable groups as well; the young and uninsured who unexpectedly develop an illness, the middle working class who develop chronic diseases, and whose employer-based or private insurance doesn't quite relieve the cost, ethnic minorities who are disproportionately uninsured, unemployed, living in poverty, and victims of health inequities. All of these populations are suffering.

We spend hours as physicians filling out prior authorizations just to find out that even after insurance kicks in, the cost of a medication is still out of reach for some patients. We need additional intervention at the Federal level related to patent abuse, vice transparency, and PBM practices. The pharmaceutical industry threatens that regulation of drug pricing would force them to remove drugs from the market, attempting to incite fear among Americans who are desperately in need of their medications.

In reality, the pharmaceutical industry spends more on advertising in America than research and development. As a result, the citizens of these United States pay more on drug costs than any other developed country. Why should a State like Florida have to import prescription drugs made and manufactured here in the United States from Canada to lower the cost of medications for their citizens?

This price gouging must end and it must end through Federal regulation. Drugs do not work if people cannot afford them, and I cannot fulfill my duty as a physician if my patients cannot follow their doctor's orders. Thank you.

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

Chair DURBIN. Thank you, Dr. Douglas. Dr. Sandsmark.

STATEMENT OF MICHAEL A. SANDSMARK, PHARMD, DIRECTOR OF PHARMACY, IROQUOIS MEMORIAL HOSPITAL AND RESIDENT HOME, WATSEKA, IL

Dr. SANDSMARK. First of all, thank you, Chairman Durbin, for inviting me here today to discuss prescription drug prices and their effects on my patients.

As a pharmacist, I've had countless discussions with patients at the pharmacy counter about their prescription drug costs. It is never an easy task to explain to a retired teacher, a grandma, or a neighbor, that their prescription copay will be over \$600 simply because it is a new year, but that the prescription that was \$47 last month is now \$260 because they're now in the Medicare coverage gap.

For the last 5 to 10 years, I have been having these conversations with my patients all too frequently as the cost of prescription drugs have far outpaced inflation. These conversations often led to patients leaving prescriptions behind or rationing previously filled prescriptions solely due to the accessibly high cost.

At the beginning of the year, I see patients delaying medication refills because of the high Medicare Part D deductible. As the year progresses and patients begin to enter the Medicare Part D coverage gap, we often see patients stop filling their most expensive medications for the remainder of the year. These conversations just

became disheartening to our patients and who are burning out myself and my dedicated pharmacy staff.

So, we set out to try and avoid these conversations altogether. Even before the patient arrives at the pharmacy counter, my staff and I explore all ways to reduce our patient's costs and bridge these coverage gaps. We want to ensure that the patient leaves the pharmacy with the prescribed medication or a therapeutically equivalent medication in their hands.

Being a part of a critical access hospital affords my staff the time to advocate for our patients and more closely work with providers, nurses, social workers, and medical assistants to overcome these financial barriers. It often takes the entire healthcare team across multiple departments to connect patients with manufacturer samples, find a free trial coupon, enroll patients in a prescription assistance program, explore opportunities to the 340B drug savings program, and if all else fails, paying for the patient's copay out of our own pockets.

Since the passage of the Inflation Reduction Act, our patients have certainly benefited directly at the pharmacy counter. This legislation has drastically improved the financial stability of many of my elderly patients who are almost all living on a fixed income. I'm reminded of a type 1 diabetic farmer that was spending nearly \$7,500 a year solely on insulin copays prior to turning 65 in 2022. He now spends less than \$900 annually because of the \$35 month cap on copays for his NovoLog and Lantus that he has prescribed.

Another way that we have helped reduce our patient's prescription expenses is by counseling them, selecting the right Medicare Part D plan each year. Unfortunately, the open enrollment period has typically led me to explaining ever increasing prices, and patients becoming increasingly worried about their household budgets.

However, this open enrollment period has led to entirely different feelings for my patients. I'm looking forward to showing them their 2025 plan comparisons because more out-of-pocket savings will be rolled out to all patients, not just those dependent on insulin.

Last week, I counseled an 84-year-old retired home healthcare aide, suffering from heart disease and type 2 diabetes. She takes 13 medications, including Entresto, Xarelto, Victoza, Praluent, and Jardiance. She will see her out-of-pocket costs fall from over \$7,000 in 2024 to only \$2,000 in 2025. These are life-changing savings for many of my patients, and now my staff and I can focus more on clinical aspects of our profession instead of chasing them coupons and dealing with manufacturer samples.

The Inflation Reduction Act not only has helped reduce prescription drug expenses, but has also had a dramatic effect on one of the most important medications we have in our toolkit today; vaccines. At Iroquois Memorial Hospital, the pharmacy staff helps lead a vaccination program across many care areas, including long-term care residents, patients in our rural health clinics, and acute care patients.

The expansion of coverage for many recommended adult vaccinations, including shingles, RSV, and COVID-19, has undoubtedly led to increased vaccination rates among our patients. Two years ago, nearly all patients interested in receiving the two dose shin-

gles series first inquired about the cost before we ever discussed effectiveness or potential side effects. Unfortunately, a large percent of these patients would decline receiving the vaccine when they discover their out-of-pocket cost for nearly \$400 for the series.

Today, these vaccines are fully covered for Medicare beneficiaries, and the conversations I have with patients are censored around the importance of receiving the vaccines instead of the cost.

Although current legislation has led to significant reductions in the price of prescription medications to a large segment of the U.S. population, there is still more work to be done. I've seen every increasing need to legislate meaningful cost reductions for all patients in the United States, especially those working-class Americans with employer-sponsored health insurance.

As we see type 2 diabetes and heart disease diagnosed in patients in their 20's and in their 30's, it is increasingly important to ensure these patients and their families can afford to treat these diseases effectively for decades during their most productive years.

Thank you, again, Senator Durbin for the opportunity to share my experience and those of many of my patients here today.

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

Chair DURBIN. Thank you, Dr. Sandsmark. Ms. Deanna Brandt.

**STATEMENT OF DEANNA BRANDT,
MEDICARE BENEFICIARY, COUNTRYSIDE, IL**

Ms. BRANDT. Thank you, Chairman Durbin, and Members of the Committee. My name is Deanna Brandt. I live in Countryside, Illinois. I'd like to tell you a little bit about my experience in using the Part D section of Medicare. I've been on Medicare for since 2002, where about 19 of those years, I was on very few prescriptions. And for the most part, they were generic and considered tier 1 drugs, and very inexpensive. I was very healthy. So, very few problems.

In 2021, I developed Covid, although I was unaware, with no symptoms. However, I developed atrial fibrillation, or AFib, maybe from Covid. It was detected when I was sent to the hospital to be treated for the AFib. From 2021 to the present, I have had RSV, two back surgeries, a bladder tumor, and stones in my bile ducts. Needless to say, it has required more prescriptions, but happy to say I now feel very well.

Three of the medications I take are quite expensive and put me in the coverage gap. Pretty early in the year, in 2021, I was able to stay in the initial coverage section until I had to deal with AFib, and then I was pushed very quickly into the coverage gap in October. In 2022, it was May, 2023, April, and this year I got all the way to June.

My out-of-pocket costs in 2021 were \$4,533. In 22, they were \$7,019, just \$31 from the catastrophic stage. In 2023, it was \$7,528, and I did reach the catastrophic stage. To date, this year, I've spent \$5,634, but I will have at least another \$1,200 through the end of the year.

Although I have Social Security and a pension, and therefore on a fixed income, I do have to watch my spending. I live in a moderately priced condo, have a mid-price car, and I don't go on vaca-

tions. The amount I spend on drugs was more than I received from required distribution from my 401K. Instead of saving that money, I paid for drugs. I do like to assist my grandchildren with their school loan debt, but the last 3 years I was unable to assist.

For others, that \$7,000 would mean their basic needs like food, housing, or transportation. They're greatly affected. The average person spends about \$3,000 in groceries a year, and about \$1,500 a month in rent. For many, the cost of their drugs is a decision of whether they do or do not pay for their basic needs.

I also was at a pharmacy one day when a lady came to pick up her prescriptions, one prescription. They told her the price. I don't remember exactly what it was, but it was well over \$100. She stood there for a minute and then said, "I don't have that kind of money," and she walked away from the counter without her medication. My regret was that I didn't react and offer her some help.

I have a friend that's in a study for cancer. The drug she is taking would cost her \$4,000 a month if she wasn't in the study. That is more money than most people receive from Social Security. She would not have been able to afford to pay that amount. She's, thankfully, in remission at the moment. I have another friend that pays \$1,000 a month for a cream for a dermatology problem.

There's assistance for low-income people, and there is a group of people with enough disposable income to afford medications. It's the group in the middle that seemingly bear the heaviest burden in this matter. Prescriptions that are necessary for quality of life should not be beyond any senior, let alone any other age group's ability to afford it. Being healthy should not just be for people with discretionary income.

Food for thought. I sometimes question how the incessant advertising of prescription drugs on all forms of media affect the overall drug cost. Could that money spent be repurposed into lowering drug cost? I cannot decide which drugs I take. Only my doctor can.

My friends and I are very grateful for Medicare and the drug program. We certainly don't want to go backward. It just seems for the cost for drugs that are considered tiers 3, 4, and 5 are very excessive. We're all grateful that next year there'll be a cap on our medications at \$2,000. It could be the difference for many of eating or taking their medications.

Thank you for your time and your efforts to lower prescription drugs. Keep working on this to make it better for me and others.

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

Chair DURBIN. Thank you for being here. Sincerely, thank you very much. I'm sorry you don't consider this trip a vacation since you—

[Laughter.]

Ms. BRANDT [continuing]. It is kind of.

Chair DURBIN. It's kind of a vacation, a little ways, but you're telling your personal story. Thank you. Makes a difference. Really does make a difference. I'm going to ask you a few things about it in a minute. What a panel. What a great panel. Thank you all for being here.

Dr. Douglas, thanks for telling your personal story as your perspective as a physician. It really is meaningful. You mentioned that

to manage his diabetes, your father was prescribed Jardiance, which he was unable to afford.

I think we have a chart on Jardiance. As you can see from the chart, Jardiance manufacturers steadily raised the drugs price over the last 5 years from around \$450 to nearly \$600 for a 30-day supply. Your father lived through this under the Inflation Reduction Act. Medicare is finally able to negotiate the price it pays for certain drugs, including Jardiance, and the Biden/Harris Administration was able to negotiate the price for Jardiance down to \$197 a month. A 66 percent discount over the high price your dad faced.

Tell me what that price reduction, you think, will mean to your patients.

[Poster is displayed.]

Dr. DOUGLAS. Well, in short, Senator, it means saving lives. I mean, people who have access to the medications that they need because they are affordable and within reach means that their conditions such as Jardiance, which is utilized to manage diabetes as well as some other comorbidities as well means that they have their blood sugars in control. They stay out of the hospital. They don't have complications associated with diabetes like strokes, heart attacks, peripheral vascular disease. Ultimately it means that we keep people out of the hospital. We keep people from the morbidity and the mortality associated with diseases like diabetes.

Chair DURBIN. So, I'm going to ask you a question about the medical profession and vis-a-vis this issue, and maybe you'll feel comfortable answering, if you don't just say so. But it strikes me that there are a handful of drugs which we are bombarded with when it comes to advertising. You just can't watch a football game, or frankly, anything on your television without getting an ad for a new drug, or many times, a drug you know pretty well.

Dr. DOUGLAS. Yes.

Chair DURBIN. The fact that we can pronounce and even spell Xarelto at this point is proof positive that we've certainly been trained with all these ads. I'm assuming, and you tell me if I'm wrong, that the pharmaceutical companies have basically decided if we can convince the ultimate consumer to go into the doctor's office and say, I need Xarelto, I need Wegovy, or whatever it happens to be. That the doctor is going to prescribe that as opposed to questioning whether or not it's necessary, or whether there's an affordable generic. Is that true?

Dr. DOUGLAS. Yes. I mean, I certainly, I think that is the strategy. Not only do they advertise directly to physicians to encourage us to prescribe these medications, but they also encourage patients to go in the clinics and the hospitals to ask for these medications.

For example, the drug that we've all been talking about today, Ozempic. We're constantly, as physicians, being bombarded with questions about their ability to get on the Ozempic, just to find out that the patients can't afford Ozempic. That I think the list price for Ozempic is around almost \$1,000. And so, they certainly—this is certainly a strategy, I believe, from the pharmaceutical industry to encourage patients to ask for the medications that they see on the television screen.

Oftentimes, patients aren't even aware that these medications are applicable to their situations, and we as physicians have to

educate them and tell them why, you know, this medication is not appropriate for your condition.

Chair DURBIN. Let's take Ozempic, and look at some numbers. Novo Nordisk sells it for \$71 in France, \$59 in Germany. The United States, they charge patients \$969, and the price is only going up. And I can understand the demand are coming from the consumer side, anything that is reduction in weight which doesn't involve strict adherence to diet or exercise. People have been looking for that miracle care for a long, long time, and it's going to create an ethical issue for us, too, unless we bring the price down to an affordable level in terms of the fact that weight reduction in and of itself, I think, is beneficial in almost every circumstance. And so, how do you react to that?

Dr. DOUGLAS. Well, my concern is, again, for those patients who Ozempic is not appropriate for. There's certainly conditions and situations where medication is not the right answer to address weight reduction. In some cases, surgery is more appropriate for patients with high BMI scores.

And so, my concern is that those patients who come in asking for the medication, often for some of them, that medication is not applicable to them. And then for the patients who it is applicable to, most of them can't afford to even take the medication for us to prescribe it to them. So, I think that there's certainly—I think it's issues on both sides.

Chair DURBIN. Dr. Sandsmark, let me ask you a question that I raised earlier with the first panel. What's going on with Walgreens? Why is it when you go in there, you have to wait in line to get a prescription filled? I had to return a third day to get a prescription filled at Walgreens, smack-dab in the middle of Chicago. And you better pick the time of day when you're coming. If it's anytime near the end of a workday, the lines are just unbearable. And here we have a situation where they're saying, well, the answer to this from Walgreens corporate perspective is we're going to have to start closing drug stores. Closing drug stores? How does that solve a corporate financial problem? But it certainly doesn't address the basic problem of people waiting in line forever and ever to have a prescription filled. What's your take on that?

Dr. SANDSMARK. Yes, it's certainly not going to lead to better health healthcare outcomes by closing pharmacies. I think a lot of it has to do with how a lot of retail pharmacists are treated. There's a lot of burnouts with staff. Not only the pharmacists, but technicians. They're forced to administer vaccines, counsel patients, you know, fill hundreds and hundreds of drugs each day. And so, there is a lot of burnouts in there.

You know, these corporations are having trouble finding staffs, like aren't able to keep their stores open. And then, going along with the reimbursement rates from these PBMs that, yes, some of them are controlled by big pharmacy chains, but some of them are not. So, you see the pharmacies as an individual getting squeezed by the low reimbursement rates on these ever-increasing prices on these drugs.

Chair DURBIN. I'd like to invite Professor Sachs and the Attorney General, to comment on the PBM experience that I've just described and any aspect of it.

Professor SACHS. Oh, sure. So, in terms of the prices of prescription drugs, I'll defer on the question of independent pharmacies. In terms of the prices, there's clearly a role for some type of actor to negotiate for lower prices for drugs. But we've heard already about the ways in which PBMs don't seem like in many cases, they're passing on the discounts that they're getting to insurers or to patients. And so, in my view, we should think broadly about opportunities at the Federal level and even at the State level for PBM reform.

So, you might have, for example, a regulatory reform or statutory reform that acts on the PBMs themselves, but you could think about a reform that would affect another actor in the healthcare system to push back on the problems that we're seeing. And so, the Inflation Reduction Act, I think is one example of this.

So, if you look at, for example, the Federal Trade Commission regarding PBMs and their conduct in the insulin market, one of the concerns is about patients' exposure to these really high out-of-pocket costs. You could respond to that, and maybe we should respond to that by looking at the conduct of the PBMs themselves. But another way to respond to it is, as the IRA does, it caps Medicare beneficiaries' out-of-pocket costs for insulin at \$35 per month, and it has this additional out-of-pocket cap and the Medicare Part D program as a whole.

So, one option is to look at reforms that address the PBM itself, but another is to say, insurers are working with the PBMs in this way, and that relationship is subject to some of these concerns that might be harming patients. Let's look at the harm to patients more directly. So, that's maybe just one point I would make.

Chair DURBIN. Attorney General.

Mr. RAOUL. Yes, Mr. Chairman. The transparency is desperately needed. As we initiated our first investigation into a PBM that I mentioned earlier, getting the resolution was rather quick because they knew what they were doing was in inappropriate.

Chair DURBIN. Inappropriate. From an Attorney General's point of view, I might use a different word, but go ahead.

Mr. RAOUL. Yes. The stronger language that could be used on—it's unconscionable. Because as mentioned by several speakers today, the role of the PBM is the opposite of what the effect has been. It's to be able to negotiate, to drive down the costs. And the impact on end users, the patients, is that they're not using their medication or they're not using their medication appropriately, and the consequence can be fatal in some instances.

The question that we're faced with State actions to regulate PBMs is whether we're preempted by the feds. And that's why we've been trying to use both efforts to encourage and protect State efforts to control the pricing as well as to encourage Congress to be able to get some transparency, get these PBMs to furnish their pricing data to the feds as well as State payers.

Chair DURBIN. Ms. Brandt, as you described it, I'm impressed by the fact that you've been able to juggle all these numbers and how they apply to you personally. And you seem to have made it through this thicket, but you describe people who have not been able to do so. Do you think this notion of \$2,000 a year maximum out-of-pocket expense, also define maybe \$40 a week, is the most

that you can have to pay out-of-pocket? Do you think that this is a cleanup of a system that is too complicated?

Ms. BRANDT. It might be. I'm a person that charts everything. So, every year, I compare the medication programs, and I write everything to how much every one will cost me. Not everybody does that.

Chair DURBIN. I think you could be an influencer.

[Laughter.]

Ms. BRANDT. I'm yelling at people all the time. People have told me, oh, I don't look at it. I just pay the same, do the same. So, I'm kind of yelling at them. But I think it's such a wonderful addition, the \$2,000. I'm very, very happy.

Chair DURBIN. It does make a big difference.

Ms. BRANDT. Big difference.

Chair DURBIN. Dr. Sandsmark, when it comes to the role of the pharmacist, I think we ought to put a couple things on the record. What does it take to become a licensed pharmacist in the State of Illinois?

Dr. SANDSMARK. Usually, about 6 to 8 years of schooling. And then—

Chair DURBIN. Beyond college?

Dr. SANDSMARK [continuing]. That'd be total.

Chair DURBIN. Pardon me?

Dr. SANDSMARK. Yes. Beyond high school, that'd be total.

Chair DURBIN. So, it's 8 years.

Dr. SANDSMARK. Yes. Depending on which school you go to. Yes. It'd be up to it.

Chair DURBIN. Is it an expensive education?

Dr. SANDSMARK. Probably about quarter to a half a million dollars, depending on which school you choose.

Chair DURBIN. And ultimately, these pharmacists are still in high demand, right?

Dr. SANDSMARK. Very, very much so.

Chair DURBIN. And how many pharmacy schools do we have in our State, or nearby?

Dr. SANDSMARK. I think we're up to like five or six now. Used to be only a couple.

Chair DURBIN. And you work out of the hospital, the Iroquois County Hospital?

Dr. SANDSMARK. Yes.

Chair DURBIN. But you do retail?

Dr. SANDSMARK. We do everything. We might go from mixing \$100,000 chemo in the morning to filling a \$4 antibiotic from a patient in our urgent care. So, it's really all over the board.

Chair DURBIN. Professor Sachs, I can't tell you how many times I've heard on the floor about the freeze on innovation and preventing new drugs from coming to market. You teach a course on that, don't you?

Professor SACHS. I do teach classes on innovation in the pharmaceutical industry, but also on access to new medications.

Chair DURBIN. The cancer drug, Keytruda, had \$25 billion in sales last year. \$25 billion. The revenue for this single medication is on par with what MasterCard or McDonald's Corporation earns

in a year. How is it possible? How can it possibly be that a penny less in profit to Big Pharma will stifle innovation?

Professor SACHS. One of my favorite quotes on this topic is from former Health and Human Services Secretary Azar, who himself was a former pharmaceutical company executive, and he referred to this as a tired talking point, right? He said, “it’s not the case that if one penny disappears from pharma profit margins, American innovation will grind to a halt.” And yet, over time, we certainly have seen the pharmaceutical industry oppose all kinds of measures of drug pricing reform from the larger scale drug price negotiation programs to much smaller scale bills that would focus on particular patent or FDA abuses.

And so, in my view, what we really care about is the value of innovation to patients. It’s about delivering real, new clinical value for patients, and reforms that preserve and protect that value, rather than just the amount of innovation are really what matters. And here, one thing about the Inflation Reduction Act, the IRA’s drug price negotiation program, is it really centers that concept of innovation that delivers value for patients.

So, Congress specifically directed Medicare to consider as part of the negotiation process factors like; whether a drug is a therapeutic advance as compared to existing therapeutic alternatives, the drug’s comparative effectiveness, and whether the drug addresses unmet medical needs.

Those are the kinds of things where Medicare is directed to consider. Whether this drug delivers more value for patients. If so, maybe we should pay more for it, rather than if there’s a drug that’s one of these, you might use the term “me too drugs”, but doesn’t provide a new mechanism of action or a new option for patients.

Chair DURBIN. We also know that pharmaceutical companies spend more in sales and marketing than they do on research and development. In 2020, Johnson & Johnson, one of the leaders, spent nearly twice as much on sales and marketing, \$22 billion than it spent on R&D. GlaxoSmithKline was even worse. It spent \$7 billion on research and development. Less than half of the \$15 billion it spent on sales and marketing.

Dr. Douglas, you seem like you’re aware of this. Have you discussed this with people in the pharmaceutical industry?

Dr. DOUGLAS. Yes, certainly. The uneven spending in terms of on advertising and marketing versus the actual research and development, I think that a common conversation amongst my own colleagues and around the hospital is the fact that, you know, in America, we prioritize capitalism, right?

And there’s nothing wrong with turning a profit, but when that profit takes priority over people, especially in the healthcare industry, that’s when it becomes a problem. And it’s not an over exaggeration that people are dying because they can’t afford the medications that they need, and they’re spending much more time in the hospital in the emergency department.

When we look at the—you quoted the Johnson & Johnson numbers. Novartis spent \$14.6 billion in advertising and \$9.9 billion in research and development. Pfizer spent \$11.4 billion advertising and \$6.6 billion in research and development. I have a hard time

grappling why these numbers. Well, one, why would your advertising cost be significantly higher than research and development, but why they would even be close in terms of numbers. And so, I think that it is a moral hazard on the behalf of the pharmaceutical industry in order to turn over large profits.

And, you know, another point I want to make is that we talked about the evasiveness of the pharmaceutical industry and avoiding legislation to regulate these prices and industries. Like, the hospitals and some of our clinics, our larger scale clinics that get a lot of bad rep about care and affordability of care are being gouged by the pharmaceutical industry as well.

We talk about the 340B Program, which is currently under attack by the pharmaceutical industry and some other opponents of the 340B Program. But that those type of programs that make prescription drugs more affordable for hospitals and patients allow us to provide resources in strapped environments like at the University of Chicago, where we care for a large percentage of Medicaid and Medicare patients.

So, these programs that they've—the legislation that they've evaded and the regulation that they have evaded from making prescriptions more affordable, is harmful to patients, and it leads to less, and less, and poorer and poorer outcomes in terms of healthcare outcomes in our country.

Chair DURBIN. Now, the pharmaceutical industry is going to counter that they put these ads in the air for consumer education so that they can learn more about these drugs. I'm going to ask you about one of the drugs, and one of the statements that's made over and over again. The Xarelto, the warning is this, "Don't take Xarelto if you're allergic to Xarelto"

[Laughter.]

Chair DURBIN. Tell me as a doctor what you make of that.

Dr. DOUGLAS. Well, I think, oftentimes, in a lot of these advertising, you—I mean, we all see that the ads and on the television about all the warning signs and how quickly they rattle off?

Chair DURBIN. Oh, yes.

Dr. DOUGLAS [continuing]. All the potential side effects or potential hazards to taking these medications, which is important for people to know and to be aware of. But there's evidently not a priority for people to know that otherwise they wouldn't be the last 3 seconds of the commercial in these advertisements. Right? So, I think it is important, the transparency about the harm and the risk of taking these medications is important, but it's not a priority for the pharmaceutical industry.

And it's a marketing tactic. There's a science to marketing. It's like there's a science to medicine. I think in one of the previous hearings you had, one of your colleagues on the Judiciary Committee talked about that the ads are a cure for loneliness, right, and how we look at these ads and the people start off as depressed and sad because they are dealing with the disease. And then at the end, they're surrounded by family and loved ones

Chair DURBIN. Marching down the street.

[Laughter.]

Dr. DOUGLAS. Marching, yes. And that's not reality, right? It's a marketing scheme by the pharmaceutical industry to encourage

and inspire patients to go and purchase or lobby their physicians to prescribe those medications.

Chair DURBIN. Well, I kind of challenged the industry on consumer education when Senator Grassley and I introduced a bill, which said that every one of these ads had to contain a disclosure of the actual list price of the pharmaceutical drug. So, that the people who are watching this ad and thinking about maybe I can march down the street, too, having lost 35 pounds, maybe that's in my future as well.

Well, we introduced this and it turned out the pharmaceutical industry did not want to educate any American consumers on the actual list price they set for the drug itself. Do you have any idea what the number one advertised drug is on television now?

Mr. RAOUL. I'm not aware.

Chair DURBIN. Well, when you hear the name, you will be; Rinvoq. Rinvoq. Any idea, perhaps Dr. Sandsmark, you might know this. Do you know what a monthly prescription of Rinvoq cost?

Dr. SANDSMARK. I don't think I've dispensed that one before, which is probably fortunate for my patients because I'm sure the prices can be rather high.

Chair DURBIN. Six thousand one hundred dollars. Six thousand one hundred dollars. Now, if you knew, if it were flashed on the screen while you're watching this ad, you might have second thoughts about whether or not I want to recommend that to the doctor next time I go in. Now, I don't want to stop anybody from a legitimate conversation and exchange with a medical professional. I'm not suggesting that at all. But this is not designed for legitimate information to be given to consumers. It is designed to market a product, and it's very successful in that effort in what they're achieving.

I want to ask the Attorney General a question. When you join these other attorneys general on an amicus to the Ninth Circuit Court of Appeals supporting an Oregon law that requires pharmaceutical manufacturers to annually report information for certain types of prescription drugs, why is it important for the States to be able to provide more transparency?

Mr. RAOUL. Yes. As I mentioned with regards to the PBM, having everything, certain information—allows for inflated pricing, and more transparency does, you know allows for State and Federal regulators to rein in on some of these practices.

Chair DURBIN. It certainly does. And, I think, we've made that point today. Dr. Sandsmark, let me ask you about specific pharmacy near my home in Springfield. I've heard concerns from independent rural pharmacy owners like Dave Bagot, Petersburg Pharmacy in Menard County. He's highlighted the systemic underpayment by PBMs to small pharmacies, and how these middlemen steer patients to their preferred networks.

The Federal Trades Commission has also found the same thing in enforcement against the three big PBMs; CVS Caremark, Express Scripts, and Optum, for anti-competitive and unfair rebating practices. This is a complicated subject that I'd like to ask you and Dr. Professor Sachs. We need more transparency around PBMs, as the Attorney General just said. Can you help us unpack these issues?

Dr. SANDSMARK. So, first of all, you know, preferred pharmacies is a loaded term, right? So, preferred doesn't mean more affordable. It just means that they, the PBM wants you to go there. It doesn't mean you're going to save money there. So, even on the Medicare Part D website, patients can go and see that one insurer might say that a chain pharmacy is preferred, but if they were to select a small independent pharmacy, like the one you talked about, that pharmacy might not be preferred, but more affordable for the patient at the bottom line annually.

So, you have to see who's calling it preferred, right? Is it the PBM calling it preferred? That's, you know, steering you toward that. And we see the low underpayments all the time on these, you know, brand name drugs that we've been talking about all morning. You know, those are the drugs that a lot of times we're losing the most money on, right? The independents are 20 percent of our prescriptions each month, we're usually losing some amount of money to the PBMs because they're not paying us enough for what we're paying it from the wholesaler.

Chair DURBIN. So, they make the drugs available, but they charge prices which you can't recover at the counter?

Dr. SANDSMARK. Yes, exactly.

Chair DURBIN. Dr. Sachs?

Professor SACHS. So, one, I think, of the real challenges here, and we've heard a little bit about this, is the role of vertical integration, and the ways in which these PBMs are incorporated into pharmacy chains, or insurers, or other parts of the drug pricing supply chain and ecosystem, which makes transparency particularly important, but also even more complicated.

So, we heard already, for example, reference to this New York Times series about the role of PBMs. Something that comes up in that series is about the role that PBMs are now creating these GPOs, these group purchasing organizations, that they're separating out from their core PBM functions. And whether through those GPOs, they might be siphoning off additional fees or other services. And it's very difficult to know. And so, transparency or sort of other oversight in general might be helpful in getting at that information.

Another point that comes up in that news series and also in the interim staff report from the FTC from earlier this summer is this question of PBMs now introducing their own co-branded biosimilars, and in some cases, referencing them over biosimilars from other manufacturers. That's something where there also has yet to be, I think, a real sustained look at whether that's pro-competitive or anti-competitive. And so, there's a whole range of practices that have been raised in these reports that it'd be helpful to know much more about.

Chair DURBIN. It appears there's another process underway. Some of the largest pharmaceutical companies have gone further. They have launched new telehealth platforms. Now, patients seeing a drug ad on social media can, "Click here," to talk to a doctor about a company's advertised medication. These platforms link patients with hand-selected healthcare providers. The ensuing visits are often briefed with little review of health records or histories. It makes a healthcare appointment more like an Amazon shopping

experience, and the financial relationship between the drug company and the doctor raises concerns about inappropriate inducement of prescribing.

What concerns would you have about pharmaceutical companies' handpicked doctors writing prescriptions for patients who are connected via their own ads? Dr. Douglas?

Dr. DOUGLAS. Yes, I would have significant concerns. There's financial incentive for these physicians to prescribe medications that may not be the most appropriate for that patient situation. So, I'm not personally aware of any physicians who are employed or work through telehealth and are supported through prescription drug industries, but I certainly would be concerned that there's incentive for the physician to prescribe medications that won't necessarily benefit the patient or be appropriate for their situation.

Chair DURBIN. Professor Sachs?

Professor SACHS. Well, as a health law professor, something we talk about often is the independence of the medical profession, and the importance of physicians being able to make independent medical judgments based on clinical evidence about what might be best for their patients. And so, there's a whole series of different laws that are designed to make sure that physicians are exercising that independent judgment, maybe that they're not being financially induced, right, by other actors.

And so, I'd have to look more at that case study in particular, but that certainly would be something that would be potentially concerning in thinking about the role of the physician and the relationship with their patient.

Chair DURBIN. I want to thank this panel for their contributions to this hearing. This hearing is really laid out in real terms how the market failure is caused by Big Pharma's exploitation of the patent system and bombardment of TV ads have made medications unaffordable for many people.

The perspectives we heard from patients, pharmacists, providers, and legislators, are a call to action, from my point of view. We need to build upon the Inflation Reduction Act. For Ms. Brandt's observation, we've got to have affordable drugs. Your money or your life is not an acceptable outcome from this hearing. The perspectives we heard today will help us to build upon bringing down the high cost of prescription drugs.

I'm not against pharmaceutical companies making a profit, I'm for it. I wanted to incentivize them to find new cures, new approaches in medicine. What we have now in this country is just almost indescribable. Try to get somebody to describe the role of a PBM. Attorney General, there was a full-page ad in the New York Times not that long ago from the PBM industry saying, "We are not middlemen." But they were middlemen, completely lost the role that they play. We need to continue to incentivize pharmaceutical companies to develop these drugs while ensuring that they're accessible to Americans who need them at a price they can afford.

The hearing record will remain open for a week for statements to be submitted. Questions for the record may be submitted by Senators by 5 p.m. on Tuesday, November 5, a day you should remember.

Chair DURBIN. I want to thank the witnesses again for coming. This hearing stands adjourned. And this is the end of your vacation Ms. Brandt.

[Laughter.]

[Whereupon, at 11:59 a.m., the hearing was adjourned.]

[Additional material submitted for the record follows.]

U.S. Senate Committee on the Judiciary Committee Hearing
 "Reducing Prescription Drug Prices:
 How Competition Can Make Medications Affordable for Patients"
 October 29, 2024

Chair Durbin and members of the Committee. My name is Deanna Brandt and I live in Countryside, Illinois. I would like to tell you a little about my experience in using the Part D section of Medicare.

I have been on Medicare since 2002. For about 19 of those years, I was on very few prescriptions and for the most part they were generic and considered Tier One drugs and very inexpensive. I was very healthy so very few problems.

In 2021, I developed Covid, although I was unaware with no symptoms. However, I developed atrial fibrillation, or Afib, maybe from Covid. It was detected when I was sent to the hospital to be treated for the Afib. From 2021 to the present I have had RSV, 2 back surgeries, a bladder tumor and stones in my bile ducts. Needless to say, it has required more prescriptions but happy to say, I now feel very well.

Three of the medications I take are quite expensive and put me in the coverage gap pretty early in the year. In 2021, I was able to stay in the initial coverage section until I had to deal with Afib and then I was pushed very quickly into the coverage gap in October. In 2022 it was May, 2023, April and this year I got all the way to June.

My out-of-pocket costs in 2021 were \$4,533. In 2022 they were \$7,019, just \$31 from the catastrophic stage. In 2023 it was \$7,528 and I did reach the catastrophic stage. To date this year, I have spent \$5,634 but I will have at least another \$1,200 through the end of the year.

Although I have Social Security and a pension, and therefore on a fixed income, I do have to watch my spending. I live in a moderately priced condo. I have a mid-priced car. And I do not go on vacations. The amount I spent on drugs was more than I received from the required distribution from my 401K. Instead of saving that money, I paid for drugs. I do like to assist my grandchildren with their school loan debt but the last 3 years I was unable to assist. For others, that \$7,000 could mean their basic needs like food, housing or transportation are greatly affected. The average person spends about \$3,000 in groceries a year and about \$1,500 a month in rent. For many the cost of their drugs is a decision of whether they do or do not pay for their basic needs. I was at a pharmacy one day when a lady came to pick up her prescription. They told her the price. I don't remember exactly what it was but it was well over \$100. She stood there for a minute and then said, I don't have that kind of money and she walked away from the counter without her medication. My regret was that I didn't react and offer her some help.

U.S. Senate Committee on the Judiciary Committee Hearing
"Reducing Prescription Drug Prices:
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October 29, 2024

I have a friend that is in a study for cancer. The drug that she is taking would cost her \$4,000 a month if she wasn't in the study. That is more money than most people receive from Social Security. She would not have been able to afford to pay that amount. She is thankfully in remission at the moment. I have another friend that pays \$1,000 a month for a cream for a dermatology problem.

There is assistance for low income people and there is a group of people with enough disposable income to afford medications. It is the group in the middle that seemingly bear the heaviest burden in this matter. Prescriptions that are necessary for quality of life should not be beyond any senior, let alone any other age group's ability to afford it. Being healthy should not just be for the people with discretionary income.

Food for thought — I sometimes question how the incessant advertising of prescription drugs, on all forms of media, affect the overall drug cost. Could that money spent be repurposed into lowering drug costs? I cannot decide which drugs I take, only my doctor can.

My friends and I are very grateful for Medicare and the drug program. We certainly don't want to go backwards. It just seems for the cost for drugs that are considered Tiers 3, 4 and 5 are very excessive. We are all grateful that next year there will be a cap on our medications at \$2,000. It could be the difference, for many, of eating or taking their medications.

Thank you for your time and your efforts to lower prescription drugs. Keep working on this to make it better for me and others.

U.S. Senate Committee on the Judiciary Committee
“Reducing Prescription Drug Prices:
How Competition Can Make Medications Affordable for Patients”
October 29, 2024

Testimony of:

Dr. Anthony Douglas II
General Surgery Resident Physician
University of Chicago Medicine
Surgical Advocacy Fellow

Good morning, thank you Senator Durbin and members of the Judiciary Committee for the opportunity to testify today. My name is Dr. Anthony Douglas II, I am a General Surgery Resident Physician at University of Chicago Medicine with a focus on Trauma and Acute Care Surgery, and I am the founder of the Surgical Advocacy Fellowship. I'm here on the behalf of my patients and Citizen Action Illinois.

As physicians on the front lines, we have a pulse on how everyday Americans are affected by high out of pocket prescription costs. We make and carry out the plans for patients in the inpatient and outpatient settings. We perform the operations, and we guide Americans across this country to recovery.

For physicians like myself, one of the most difficult conversations to have are those with patients over the phone when they are at the pharmaceutical counter. As I sit before you, I can hear the worry, the desperation, and embarrassment of my patients from the CVS or Walgreens counter saying, “Dr. Douglas I cannot afford this medication.” I remember the face of the woman with type 1 diabetes who came to our emergency department with appendicitis, who was not taking the insulin she was prescribed. When I asked her why, her answer was simple: “I cannot afford it.” Her surgery was delayed. I sat and watched her dangerously high blood sugars improve each day with angst, hoping she didn't have a complication as we waited. Senators, I have story after story of people balancing the cost of medications to sustain their livelihood and the cost of their mortgage, utilities, childcare, and groceries. And they almost always choose the more pressing immediate needs over their medications.

My father who is in the audience, was prescribed Jardiance for his type 2 diabetes. It costs him \$660 dollars a month to refill. He has since been switched to a more affordable, but less effective medication. In an Uber ride, Carol, a middle-aged woman, drove me to the airport. After asking me what I did for a living, she divulged that she had a kidney transplant a week ago. I scolded her for not being at home, recovering, and her response made me feel ashamed. She said she had no choice but to drive Uber because the cost of the drugs to keep her body from rejecting her brand-new kidney were too great.

In my state of Illinois, a survey of adults, revealed that 1 in 4 people split, ration, or take sips of their medications to prolong needing a refill. That means X Americans in a room like this are not taking their medications as prescribed because they must delay paying to refill the prescription. As a physician, I can tell you drugs do not work like that. Medication non-adherence accounts for 25% of hospitalizations and 125,000 deaths a year. One of the significant drivers of how much our country spends on health care is inefficiency. The lack of prescription affordability leads Americans to visit the emergency department or be admitted to the hospital for conditions that could be effectively controlled at home if they simply had access to the appropriate medications. That is inefficient.

In 2023, according to the US Department of Health and Human Services, 4200 drug products had price increases. 46 percent of those increases were larger than the rate of inflation. The average price increase was 15% or about \$590 per drug. The Inflation Reduction Act was a pivotal step towards addressing the rising costs of prescription drugs for Medicare Part D patients. The Act helped to reduce the price of a drug like Xarelto, a blood thinner I prescribe almost daily, from \$517 to \$197, a 62% cut. Other drug prices were cut between 38-79%. This and the annual drug spending cap for senior Americans will make medications more affordable and save lives.

But, in my experience Medicare Part D enrollees are merely a fraction of the population that is suffering from the rising cost of prescription drugs. We cannot forget about a number of other vulnerable groups: the young and uninsured, who unexpectedly develop an illness; the middle working class who develop chronic diseases and whose employer-based or private insurance doesn't quite relieve the costs; ethnic minorities who are disproportionately uninsured, unemployed, living in poverty, and victims of health inequities. All of these populations are suffering. We spend hours as physicians filling out prior authorizations, just to find out that even after insurance kicks in, the cost of a medication is still out of reach for some patients.

We need additional intervention at the Federal level. The pharmaceutical industry threatens that regulation of drug pricing would force them to remove drugs from the market— attempting to incite fear among Americans who are desperately in need of their medications. In reality, the pharmaceutical industry spends more in advertising in America than research and development. As a result, the citizens of these United States pay more in drug costs than any other developed country. Why should a state like Florida have to import prescription drugs, made and manufactured here in the U.S., from Canada, to lower the costs of medications for their citizens? This price gouging must end, and it must end through federal regulation. Drugs do not work, if people cannot afford them. And I cannot fulfill my duty as a physician if my patients can't follow their doctor's orders. Thank you.

**Illinois Attorney General Kwame Raoul
Written Testimony for October 29, 2024
Senate Judiciary Committee Hearing on Prescription Drug Pricing**

Overview of Issue

Good morning. Thank you, Chairman Durbin, for inviting me to speak on this important issue.

As Attorney General, I take seriously my office's fundamental function to protect the health and wellness of Illinois residents. High prescription drug prices harm Illinois patients by obstructing access to treatments needed to sustain their health and wellbeing. Without access to affordable medications, medical conditions worsen, patients' overall health outcomes decline, and for some patients it can be fatal.

According to the U.S. Department of Health and Human Services, from January 2022 to January 2023, more than 4,200 drug products had price increases, of which 46% were larger than the rate of inflation. With these ever-increasing costs, patients may stop taking critical medications as prescribed or eventually abandon treatment altogether.

In addition to the direct burden on Illinois consumers, high prescription costs also impact States because they are significant payors of health care services. State dollars pay for prescription drugs used by state employees and their dependents, people housed by corrections, and Medicaid beneficiaries. In Illinois, about 3.9 million people are enrolled in Medicaid.

Pharmaceutical companies and Pharmacy Benefit Managers (PBMs) must be more transparent about their pricing and business practices. They should also be held accountable for unnecessary and overly burdensome increases in the prices of prescription drugs. The original purpose of PBMs was to negotiate on behalf of employers, government payors, and consumers to minimize overpricing by manufacturers. Instead, PBMs have made the pharmaceutical market more opaque by driving up prescription drug prices.

My office and those of other state attorneys general have worked to hold PBMs accountable. However, before expounding on the actions my office has taken, I do have to mention that the scope of what I can share and answer is limited. Due to litigation and investigations that are subject to confidentiality agreements, I am restricted from commenting on certain pending matters.

I want to emphasize that I have used multiple tools available to go after bad actors in the industry. We have used our authority under the Illinois Consumer Fraud and Deceptive Business Act, the Illinois False Claims Act, and Antitrust laws to target the prescription affordability crisis from every possible angle.

Pharmacy Benefit Managers (PBMs)

PBMs profit from fees charged to market participants and by reimbursing pharmacies less than the PBM is paid by plans for dispersing medications.

We believe PBMs have engaged in practices that drive up their own profits at the expense of patients and the State actors who have contracted with them. My office has uncovered practices that have allowed PBMs to largely overcharge State agencies through their contracts with the State, and I have been successful in bringing money back to Illinois through these investigations.

As a PBM for Illinois' Medicaid program, a Centene subsidiary, Envelope, and other subsidiaries delivered pharmacy benefits to Illinois state agencies, such as the Illinois Department of Healthcare and Family Services. We initiated an investigation that determined that Centene allegedly submitted inaccurate pharmaceutical reimbursement requests that failed to accurately disclose the cost of pharmacy services. In addition, requests for reimbursement did not disclose available pharmaceutical discounts and improperly inflated dispensing fees. On September 27, 2021, my office, on behalf of the State, executed a settlement agreement that required Centene to pay the State a total of \$56,717,652.

As recently as June 24, 2024, my office recovered \$45 million to the State through a settlement agreement with CVS after an investigation under the False Claims Act showed that CVS, as a PBM contracted with the State, improperly failed to pass rebates back to the State from April 1, 2020, through September 30, 2023.

PBMs have been largely unregulated and, as recently as earlier this year, I joined a bipartisan group of AGs calling on Congress to reform the way PBMs do business. Federal legislation is needed to curb undue price increases and to increase transparency around the way PBMs operate and set prices.

In the absence of federal regulation, states have passed their own regulations, which have been met with pushback from the industry. There is a petition pending in front of the US Supreme Court to determine whether federal laws (ERISA and Medicaid) preempt State laws that regulate PBMs. This past summer, my office joined a bipartisan coalition of states urging the Court to review a decision from the 10th Circuit, holding that federal laws preempt Oklahoma laws regulating PBMs. The coalition seeks to protect consumers by assuring that states can regulate PBMs as part of our efforts to address access and affordability of prescription drugs.

Insulin Pricing Scheme

In December 2022, my office originally filed a complaint in Cook County against PBMs and manufacturers alleging violations of the Illinois Consumer Fraud and Deceptive Business Practices Act for engaging in an insulin pricing scheme. Our case is now joined

in an MDL (Multi District Litigation), pending in the U.S. District Court for the District of New Jersey.

We alleged in the complaint that the manufacturer and PBM defendants have agreed to artificially inflate the reported prices for diabetes medications and that PBMS have given the manufacturers preferred placement, resulting in increased utilization of those products. The complaint alleges that the insulin pricing scheme has caused the costs of insulin to skyrocket. To be clear, insulin costs these manufacturers less than \$2 per unit to produce, yet prices can range from \$300 and \$700 per unit.

Antitrust Litigation

My Antitrust Bureau investigates the conduct of brand drug manufacturers who engage in illegal activities to delay the entry of generic competitors, which drives up prices for consumers. Such activities could include agreements with generic drug companies to delay entry into the market ("pay for delay"), product-hopping schemes, (where the brand manufacturer makes minor changes to the drug to secure extended patent rights while baselessly disparaging the off-patent version to limit generic competition), and exclusive contracting schemes, which prevent generic companies from accessing the components needed to manufacture the drug.

My Antitrust Bureau is working with nearly all other states on litigation against the generic drug industry for engaging in price-fixing conspiracies involving hundreds of generic drugs (in an MDL, pending in the District of Connecticut). We have filed multiple complaints against generic drug manufacturers alleging that they engaged in widespread, long-running conspiracies to artificially inflate and manipulate prices, reduce competition, and unreasonably restrain trade to numerous generic prescription drugs. The drugs span all types, including tablets, capsules, suspensions, creams, gels, ointments, and classes, including statins, ace inhibitors, beta blockers, antibiotics, anti-depressants, contraceptives, non-steroidal anti-inflammatory drugs, and treat a range of diseases and conditions from basic infections to diabetes, cancer, epilepsy, multiple sclerosis, HIV, ADHD, and more.

The state coalition has already settled with several individuals and two corporations who have agreed to provide monetary relief and substantial cooperation.

In 2023, my Bureau, in partnership with the FTC and several other state AGs, was able to secure a settlement agreement with Amgen, one of the world's largest biopharmaceutical drug companies, to address the potential competitive harm that would result from Amgen's purchase of Horizon Therapeutics.

The settlement resolved the potential anticompetitive acquisition and prevents Amgen from engaging in anticompetitive actions to disadvantage any product that would compete

with these drugs. The agreement requires Amgen to submit annual compliance reports, and a monitor is in place to oversee compliance.

Conclusion

These are examples of how my office has worked to rein in the ongoing problem of prescription drug overpricing.

I am thankful to this committee for shining a light on these challenges, and I hope that we can collectively work on behalf of patients, employers, and government payors to reduce the price of prescription drugs.

**Testimony of Rachel E. Sachs, JD, MPH
Professor of Law, Washington University in St. Louis**

Before the

**United States Senate
Committee on the Judiciary**

**Reducing Prescription Drug Prices: How Competition Can Make Medications Affordable
for Patients**

October 29, 2024

Chair Durbin, Ranking Member Graham, and members of the United States Senate Committee on the Judiciary, my name is Rachel Sachs and I am a Professor of Law at Washington University in St. Louis, where my research focuses on innovation into new healthcare technologies, primarily pharmaceuticals, and access to those same technologies. I also serve as a Faculty Scholar with Washington University's Institute for Public Health, a Faculty Fellow with Washington University's Cordell Institute for Policy in Medicine and Law, and a Non-Resident Fellow with the Center on Health Policy at the Brookings Institution. I am currently the Howard J. and Katherine W. Aibel Visiting Professor of Law at Harvard Law School. Thank you for the opportunity to testify before you today about the role of competition in making prescription drugs more affordable for patients and how this Committee might take steps toward solving these problems. All views I offer today are my own.¹

In this testimony, I will explain how existing law both keeps branded drug prices high but has also enabled the development of lower-cost generic and biosimilar competition for branded prescription drugs and biological products. This competition can be used to promote access to affordable prescription drugs, benefiting not only patients but also our public payers. However, I will also explain the ways in which existing legislative and regulatory efforts have not always succeeded in promoting competition and will offer a path forward for this Committee to examine reforms that not only encourage the approval of lower-cost products but also ensure access to such products through insurance coverage, physician prescription, and pharmacy substitution. I will also situate the recently passed Inflation Reduction Act in this discussion, as it is part of this tradition of envisioning market competition from generics and biosimilars as the primary tool to drive down prescription drug prices over time.

I. HOW THE LAW KEEPS PRESCRIPTION DRUG PRICES HIGH

Prescription drug prices in the United States are high, and too many patients have difficulty affording essential medications. Today, more than one quarter of adults report difficulty affording their prescriptions, and about 30% report not taking their medicines as prescribed — not filling a prescription, cutting pills in half, or skipping doses — because of the cost.² One recent study found that 30% of Medicare beneficiaries who did not have low-income subsidy support failed to fill a new prescription for cancer medication.³ Spending for public payers is also rising. Between 2009 and 2022, the federal government's Medicare Part B spending increased from \$15.4 billion to \$46.9 billion, increasing an average of 8.9% per year.⁴ Gross spending in Medicare Part D increased from \$121.4 billion in 2014 to \$240.5 billion in 2022, also growing at an average of 8.9% per year.⁵ Increases in the prices of drugs, not simply increases in utilization, played key

¹ From April 2023 to April 2024, I served as a Senior Advisor at the Department of Health and Human Services Office of the General Counsel, Centers for Medicare and Medicaid Services Division.

² Grace Sparks et al., *Public Opinion on Prescription Drugs and Their Prices*, KAISER FAMILY FOUND. (Oct. 4, 2024), <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>.

³ Stacie B. Dusetzina et al., *Many Medicare Beneficiaries Do Not Fill High-Price Specialty Drug Prescriptions*, 41 HEALTH AFF. 487, 487 (2022).

⁴ MEDPAC, A DATA BOOK: HEALTH CARE SPENDING AND THE MEDICARE PROGRAM 141 (July 2024), https://www.medpac.gov/wp-content/uploads/2024/07/July2024_MedPAC_DataBook_SEC.pdf.

⁵ *Id.* at 162.

roles in these spending increases.⁶ Median launch prices of new drugs have increased from \$2,115 per year in 2008 to \$180,007 per year in 2021.⁷

Existing legal structures enable pharmaceutical manufacturers to set and maintain high prices for prescription drugs in the United States over time in two main ways. First, through both patent law and Food & Drug Administration (FDA) regulations, manufacturers may obtain exclusive rights to make, use, and sell their branded products. Second, public payers are often required by law to provide reimbursement for those branded products, which limits the development of market competition and ties the hands of public payers in the negotiating process.

First, pharmaceutical companies typically obtain several patents granted by the United States Patent & Trademark Office (PTO) in the process of bringing their branded small-molecule drugs and biological products to market.⁸ Those patents entitle the manufacturers of the relevant branded drugs to exclude others (particularly would-be generic or biosimilar competitors) from making, using, and selling the patented invention while the patents are in force. Pharmaceuticals typically have effective patent lives for their products that are approximately 12 years from approval,⁹ or 14-15 years for first-in-class drugs.¹⁰

Prescription drugs are also typically entitled upon their approval to an exclusivity period overseen by FDA. Depending on the type of drug involved, pharmaceutical companies may receive either five years (for small-molecule drugs where there is no Paragraph IV filing), seven years (for products for rare diseases), or twelve years (for biological products) of exclusivity for their products.¹¹ In the case of the small-molecule and biological product exclusivity periods, during these times manufacturers seeking to bring generic or biosimilar products to market cannot rely on the clinical trial data developed by the branded drug manufacturer. As a result, these FDA-administered exclusivity periods in many ways function similarly to patents, enabling branded drug manufacturers to exclude small-molecule generic or biosimilar competition.¹²

Second, public payers have to date been structurally constrained or prohibited by statute from negotiating fair prices for these branded pharmaceutical products.¹³ Focusing on Medicare, by statute Medicare Part B must cover all prescription drugs which are “reasonable and necessary

⁶ See, e.g., *id.* at 142 (“Growth in the average price that Medicare Part B paid per drug was the largest factor contributing to increased spending” in Part B); *id.* at 162 (“Overall [in Part D], growth in price per prescription accounted for most (4.5 percentage points) of the 5.2 percent average annual growth in spending per beneficiary”).

⁷ Benjamin N. Rome, Alexander C. Egilman, & Aaron S. Kesselheim, *Trends in Prescription Drug Launch Prices, 2008-2021*, 327 J. AM. MED. ASS’N 2145, 2145 (2022). A significant portion of this trend is due to a compositional change, including the approval of more biological products (as compared to small-molecule drugs). *Id.*

⁸ Caroline Horrow et al., *Patent Portfolios Protecting 10 Top-Selling Prescription Drugs*, 184 J. AM. MED. ASS’N INTERNAL MED. 810, 813 (2024) (“At FDA approval, drugs were protected by a median (IQR) of 16 (8-22) active patents.”).

⁹ C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 336 (2012).

¹⁰ Bo Wang et al., *Variations in Time of Market Exclusivity Among Top-Selling Prescription Drugs in the United States*, 175 J. AM. MED. ASS’N INTERNAL MED. 635, 636 (2015).

¹¹ 21 U.S.C. § 355(j)(5)(F)(ii) (2012) (Hatch-Waxman Act, conferring five years of data exclusivity for small-molecule drugs); 21 U.S.C. § 360cc(a) (2012) (Orphan Drug Act, conferring seven years of market exclusivity for Orphan Drugs); 42 U.S.C. § 262(k)(7)(A) (2012) (Biologics Price Competition and Innovation Act, conferring twelve years of data exclusivity for biologics). To be sure, these different exclusivity periods differ slightly in terms of the type of exclusivity and its implementation, but in practice they often perform similarly.

¹² See Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals-Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 431 (2012).

¹³ Rachel E. Sachs, *Delinking Reimbursement*, 102 MINN. L. REV. 2307, 2308-09 (2018).

for the diagnosis or treatment of illness or injury,”¹⁴ without regard to cost, and Part B has no structural ability to create price competition even among drugs within the same class. As a result, economic experts have referred to Medicare Part B as a “price taker,”¹⁵ arguing that under its coverage and payment system, “a drug manufacturer with a new product with limited competition effectively sets its own Medicare payment rate.”¹⁶ At the same time, experts have noted the lack of brand-brand price competition in a class of cancer drugs with at least seven different entrants.¹⁷ Even where there is the potential for competition — such as where multiple drugs exist in a particular class — the regulatory structure creates market power for drug manufacturers in Part B, to which Part B cannot currently provide a counterweight.

Medicare Part D plans must cover at least two FDA-approved drugs per therapeutic class,¹⁸ and under the current statutory and regulatory structure, Part D plans must cover essentially all FDA-approved drugs in six protected classes — anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants.¹⁹ In classes where plans have a choice as to which products to cover (and assuming that multiple such products exist), plans may be able to create the conditions for brand-brand competition by offering to cover or to preference only drugs whose manufacturers offer pricing discounts. But where plans must cover essentially all drugs per class or where there are only two (or fewer) drugs per class, such price concessions are difficult to extract, and studies show that the protected class policy is associated with lower price discounts (and therefore higher prices) for products in those classes.²⁰

To be sure, these laws and regulations serve important public purposes. The drug approval process is typically lengthy,²¹ risky,²² and costly, with some estimates exceeding a billion dollars for each new drug approval.²³ When juxtaposed against the relatively inexpensive process of

¹⁴ 42 U.S.C. § 1395y(a)(1)(A) (2012).

¹⁵ See, e.g., Medicare PAYMENT ADVISORY COMMISSION, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM at 84 (June 2022) (“Under the Part B ASP-based payment system, the program is a price taker”); Craig L. Garthwaite, *Testimony Before the Senate Committee on Health, Education, Labor, and Pensions* at 23 (March 22, 2023), https://www.help.senate.gov/imo/media/doc/Senate_Testimony_HELP_Garthwaite.pdf.

¹⁶ MEDICARE PAYMENT ADVISORY COMMISSION, *supra* note 15, at 84.

¹⁷ Kyle Blankenship, *With 7 PD-(L)1s on the Market, Price Competition Hasn’t Been a Factor. Will Regeneron Be the First to Ask for Less?*, ENDPOINTS NEWS (April 23, 2021), <https://endpts.com/with-7-pd-ls-on-the-market-price-competition-hasnt-been-a-factor-will-regeneron-be-the-first-to-ask-for-less/>.

¹⁸ 42 C.F.R. § 423.120(b)(2)(i) (2012).

¹⁹ 42 U.S.C. § 1395w-104(b)(3)(G)(iv) (2012).

²⁰ Pragya Kakani et al., *Medicare Part D Protected-Class Policy Is Associated With Lower Drug Rebates*, 43 HEALTH AFF. 1420, 1426 (2024).

²¹ CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY at 14 (2021), <https://www.cbo.gov/publication/57126> (noting that “on average” it takes approximately 10.5 years to bring a new drug to market, though noting that estimates differ and timing may be lower in certain fields).

²² *Id.* at 13–14 (noting that only about 12% of products entering clinical trials are approved by the FDA).

²³ *Id.* at 14–16 (estimating the average R&D cost per new drug between \$1 and \$2 billion and discussing the evidentiary differences between existing studies providing such estimates).

bringing a small-molecule generic to market,²⁴ it is understandable that scholars,²⁵ policymakers,²⁶ and industry²⁷ agree that exclusive rights (through the patent and FDA exclusivity system) are important to encourage pharmaceutical innovation. Medicare's coverage requirements, including the Part D protected class rules, also serve important purposes, with Congress and the Centers for Medicare and Medicaid Services (CMS) aiming to prevent discrimination against beneficiaries with these conditions and ensure continuity of care.²⁸ But the combination of exclusive rights and guaranteed insurance reimbursement has allowed manufacturers to set and maintain ever-higher prescription drug prices over time.

Importantly, the Inflation Reduction Act (IRA) of 2022 begins to establish a counterweight to these types of incentives. As described below in Part II.C, the IRA is very much part of the existing approach of relying on market competition from generics and biosimilars to drive down prescription drug prices over time. But when that competition does not materialize, the IRA recognizes that these above-described market conditions and regulations may disadvantage both patients and taxpayers and creates the opportunity for Medicare to negotiate the prices it pays for prescription drugs, an authority other federal agencies already possess.

II. PROMOTING ACCESS TO AFFORDABLE MEDICINES THROUGH COMPETITION

Members of this Committee and other key legislative and regulatory stakeholders may seek to establish and support robust market competition in order to lower prescription drug prices and promote access to affordable drugs for patients. In many ways, the promotion of such competition has been the primary tool used by Congress and the executive branch to bring down prescription drug prices for the last 40 years, since the passage of the Hatch-Waxman Act²⁹ in 1984. More recently, both the Biologics Price Competition and Innovation Act (BPCIA), passed in 2009 as part of the Affordable Care Act,³⁰ and the IRA³¹ have become part of this tradition of relying on the role of competition to lower drug prices for patients. Taken as a whole, these laws seek to encourage the approval and market entry of new small-molecule generic or biosimilar versions of branded pharmaceutical products.

²⁴ See, e.g., Henry Grabowski, Genia Long, & Richard Mortimer, *Implementation of the Biosimilar Pathway: Economic and Policy Issues*, 41 SETON HALL L. REV. 511, 522 (2011) ("the cost of completing bioequivalence studies for generic drugs is estimated to be only \$1 to \$2 million"); AYLIN SERTKAYA, ANDREAS LORD, & CLARA BERGER, COST OF GENERIC DRUG DEVELOPMENT AND APPROVAL at 8 (2021), <https://aspe.hhs.gov/sites/default/files/documents/20e14b66420440b9e726c61d281cc5a5/cost-of-generic-drugs-erg.pdf> (estimating total cash outlays at \$2.6 million and providing an average expected capitalized cost of \$6.5 million).

²⁵ Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1617 (2003); see also, e.g., Rebecca S. Eisenberg, *The Problem of New Uses*, 2 YALE J. HEALTH POL'Y L. & ETHICS 717, 720–21 (2005).

²⁶ FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 3, at 14 (2003).

²⁷ See, e.g., Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255, 1286 (2009); Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 2, 12 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000), <http://www.nber.org/papers/w7552>.

²⁸ See CTRS. FOR MEDICARE & MEDICAID SERVS., DEP'T OF HEALTH & HUMAN SERVS., MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL ch. 6, § 30.2.5 (2016), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

²⁹ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (1984).

³⁰ Patient Protection and Affordable Care Act, Pub. L. No. 111–148, Title VII ("Biologics Price Competition and Innovation Act of 2009"), 124 Stat. 119, 804 (2010).

³¹ Inflation Reduction Act of 2022, Pub. L. No. 117–169, 136 Stat. 1818 (2022).

A. The Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984 is more frequently referred to as the Hatch-Waxman Act in honor of the two legislative leaders primarily responsible for its passage: Senator Orrin Hatch, then the Chair of the Senate Committee on Labor and Human Resources, and Representative Henry Waxman, then the Chair of the United States House Committee on Energy & Commerce, Subcommittee on Health and the Environment.³² But the law's full name more clearly reveals one of its core goals: to promote "drug price competition." To that end, the Hatch-Waxman Act is often described as a "compromise" between the interests of the generic manufacturers and the branded drug manufacturers.³³ The statute established a simplified pathway enabling generic versions of small-molecule drugs to enter the market by relying on the clinical trial data generated by the manufacturer of the branded reference drug.³⁴ At the same time, it also provided branded drug manufacturers with a period of patent term restoration for some of the patent term lost as the manufacturer traversed the FDA approval process,³⁵ extending patent protection on the branded drug and delaying generic entry.

The generic approval pathway created by the Hatch-Waxman Act has largely been successful in several ways. First, when generic drugs enter the market, they quickly take over more than 80% of the branded drug's market share.³⁶ Second, the market entry of multiple generic products can drive down the price for a particular drug compound by over 90%.³⁷ Third, and partially as a result, generic drugs have achieved widespread acceptance: today, 91% of all prescriptions dispensed in the United States are for generic drugs.³⁸

Importantly, The Hatch-Waxman Act is not the only legal intervention responsible for these high rates of generic prescription and substitution. The Hatch-Waxman Act creates the conditions for market entry of small-molecule generics, but not necessarily for their dispensation at the pharmacy counter. As a result, these high rates of generic drug uptake in the market stem significantly from state generic substitution laws. All states have laws that either permit or require pharmacists to substitute an FDA-approved generic for a prescribed branded drug.³⁹

To be sure, there continues to be ongoing policy focus on the ability of small-molecule generics to be approved by FDA and to enter the market, and specifically on whether branded drug

³² See, e.g., *Drug Price Competition and Patent Term Restoration Act of 1984: Hearing on S. 2748 Before the S. Comm. on Lab. & Hum. Res.*, 98th Cong. 36 (1984); *Drug Legislation: Hearings on H.R. 1554 and H.R. 3605 Before the Subcomm. on Health & the Env't of the H. Comm. on Energy & Com.*, 98th Cong. 1 (1983).

³³ See, e.g., Rachel E. Sachs, *The Accidental Innovation Policymakers*, 72 DUKE L.J. 1431, 1466–67 (2023) (describing the legislative history of the Act and the ways in which key actors described it as a compromise between these stakeholders).

³⁴ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, Title I ("Abbreviated New Drug Applications"), 98 Stat. 1585, 1585 (codified at 21 U.S.C. § 355(j)).

³⁵ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, Title II ("Patent Extension"), 98 Stat. 1585, 1598 (codified at 35 U.S.C. § 156).

³⁶ Benjamin N. Rome, et al., *Factors Associated With Generic Drug Uptake in the United States, 2012 to 2017*, 24 VALUE IN HEALTH 804, 806 (2021).

³⁷ Food & Drug Admin., *Generic Competition and Drug Prices* (Oct. 5, 2023), <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices> (demonstrating that, with a larger number of generic entrants, prices decline by over 90% relative to the brand price).

³⁸ FOOD & DRUG ADMIN., OFFICE OF GENERIC DRUGS 2022 ANNUAL REPORT, at 1 (Jan. 2023), <https://www.fda.gov/media/165435/download?attachment>.

³⁹ Chana A. Sacks et al., *Assessment of Variation In State Regulation of Generic Drug and Interchangeable Biologic Substitutions*, 181 J. AM. MED. ASS'N INTERN. MED. 16, 18 (2021) (noting that 19 states mandate generic substitution and 31 states and Washington, D.C. permit but do not require substitution).

manufacturers are engaging in different types of business strategies in an attempt to delay generic competition. For example, focusing as it relates to the jurisdiction of this committee over intellectual property law, experts have identified branded pharmaceutical companies' use of continuation patents,⁴⁰ double patenting,⁴¹ terminal disclaimers,⁴² or the time limitations on the PTO staff who review patent applications⁴³ as potential areas of interest. Additional issues, such as the listing of patents in the Orange Book⁴⁴ or "pay for delay" agreements,⁴⁵ may also play key roles in delaying generic drug approval and market entry. But in general, the Hatch-Waxman Act has been highly effective at accomplishing its core goals.

B. The Biologics Price Competition and Innovation Act

The BPCIA as enacted in the Affordable Care Act in 2010 partially replicated Hatch-Waxman's "compromise" model for more complex biological products, creating a pathway to market for biosimilar versions of biological products in exchange for an extended period of data exclusivity for branded biologic manufacturers. The type of traditional small-molecule drugs encompassed under the Hatch Waxman Act's framework — products like aspirin or a statin, for example — are produced through standard chemical synthesis technologies. But many new prescription drugs that treat cancer or autoimmune conditions like arthritis are more complex biological products "produced by living cells,"⁴⁶ now encompassed within the BPCIA's framework. As Professors Nicholson Price & Arti Rai have written, "[i]n terms of size and rough complexity, if an aspirin were a bicycle, a small biologic would be a Toyota Prius, and a large biologic would be an F-16 fighter jet."⁴⁷

To date, the BPCIA has been less successful at creating biologic-biosimilar competition than the Hatch-Waxman Act has been at creating brand-generic competition. Since the BPCIA's passage in 2010, as of this writing just 61 biosimilars for 17 distinct biological products have been approved,⁴⁸ and many of these have not yet been marketed. Even those biosimilars that have been

⁴⁰ See, e.g., S. Sean Tu et al., *Changes in the Number of Continuation Patents on Drugs Approved by the FDA*, 330 J. AM. MED. ASS'N 469, 470 (2023); Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 65 (2004).

⁴¹ Mark A. Lemley & Lisa Larrimore Ouellette, *Fixing Double Patenting* (July 5, 2024), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4888563.

⁴² S. Sean Tu, Rachel Goode, & William B. Feldman, *Biologic Patent Thickets and Terminal Disclaimers*, 331 J. AM. MED. ASS'N 355, 356–57 (2024).

⁴³ Michael D. Frakes & Melissa F. Wasserman, *Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination*, 15 AM. ECON. J.: ECON. POL'Y 151, 171 (2023) (arguing that "as examiners are allocated more time to review secondary drug-patent applications, they are notably less likely to issue invalid patents" and noting that reforms providing examiners with more time may produce benefits including "earlier generic entry").

⁴⁴ Federal Trade Comm'n, *Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book* (Sept. 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf; Jacob S. Sherkow, *Administrating Patent Litigation*, 90 WASH. L. REV. 205, 215–16 (2015).

⁴⁵ Robin C. Feldman, *The Price Tag of "Pay-for-Delay"*, 23 COLUM. SCI. & TECH. L. REV. 1 (2022).

⁴⁶ W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1026 (2016).

⁴⁷ *Id.*

⁴⁸ Food & Drug Admin., *Biosimilar Product Information* (updated Oct. 18, 2024), <https://www.fda.gov/drugs/biosimilars/biosimilar-product-information>.

approved have struggled to gain market share and have driven prices down by a smaller amount (typically between 15% and 35%) than the market entrance of small-molecule generics.⁴⁹

The relative weakness of biosimilar approval and market entry to date in the United States is traceable to a range of factors, both scientific and legal. From a legal perspective, to provide just one example, manufacturers of both potential generic and biosimilar competitors to existing branded products would benefit from being aware of the patents that cover their reference branded products. That information could be used to determine both when the primary patents covering a product's active ingredient would expire and when secondary patents covering additional uses or formulations would expire,⁵⁰ potentially enabling manufacturers of generic and biosimilar products to devise a strategy for entering the market. However, at present only small-molecule generic manufacturers (and not biosimilar manufacturers) can easily identify the patents covering the relevant branded reference product. Small-molecule drug manufacturers are required to submit all patents that reasonably cover their products to FDA,⁵¹ and the patent information is then made public in the Orange Book.⁵² Branded biologic manufacturers are not required to make such a disclosure, and there is no comprehensive public database of such biological product patents.⁵³ More generally, the statutory distinction between biosimilars that possess an "interchangeable" distinction and those that do not, when combined with comparatively weak state biosimilar substitution laws, has limited the uptake of even the biosimilars that have been approved. At the same time, the creation of a biosimilar pathway remains a significant step forward for the use of competition to lower prescription drug prices for patients.

C. The Inflation Reduction Act

The IRA and its creation of a Medicare drug price negotiation program are part of this tradition of envisioning market competition from generics and biosimilars as the primary tool to drive down prescription drug prices over time. That is, the IRA fundamentally still elevates the role of competition within the market (through small-molecule generic or biosimilar products) as being the primary or first strategy to lower prescription drug prices, and only if that competition does not emerge does the IRA then envision a role for Medicare to negotiate the prices of the drugs it purchases in its capacity as a market participant. In other words, the law recognizes that its previous compromises (both the Hatch-Waxman Act and BPCIA) have in some cases not fully succeeded in enabling market entry of generic and biosimilar versions of branded drugs. In those circumstances, the IRA establishes a role for the government to come to the table and negotiate to lower the prices of the drugs it purchases as an insurer, as a participant in the market for prescription drugs.

⁴⁹ Kimberly Feng et al., *Patient Out-of-Pocket Costs for Biologic Drugs After Biosimilar Competition*, 5 J. AM. MED. ASS'N HEALTH FORUM e235429 (2024).

⁵⁰ See, e.g., Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLoS ONE e49470 (2012), <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0049470> (describing the distinction between primary and secondary patents).

⁵¹ 21 U.S.C. § 355(b)(1)(A)(viii).

⁵² 21 U.S.C. § 355(j)(7); Food & Drug Admin., *The Listing of Patent Information in the Orange Book* at 1 (2021), <https://www.fda.gov/media/155200/download>.

⁵³ Jeanne C. Fromer, *Dynamic Patent Disclosure*, 69 VAND. L. REV. 1715, 1728 (2016) ("The Orange Book is so useful that biologics manufacturers have fought, thus far successfully, to exclude patent listings of covered biologics from the FDA's comparable Purple Book").

Perhaps most importantly, the IRA only permits a drug to qualify for negotiation after it has been FDA-approved or licensed for many years and where no generic or biosimilar competitor for the drug has been approved and marketed.⁵⁴ More specifically, the statute envisions that any prices resulting from negotiations between manufacturers and Medicare would not take effect for at least 9 years from the date of approval for small-molecule drugs, and 13 years from the date of licensure for biological products.⁵⁵ These figures represent statutory lower bounds. One of the drugs selected for the first cycle of the negotiation program, for example, was first approved in 1998 and yet lacks biosimilar competition 26 years later.⁵⁶ Once a drug has been approved for the relevant period of time, a drug that has a generic or biosimilar competitor that is approved and marketed is not eligible for selection for the negotiation program.⁵⁷ Where a drug is selected for the negotiation program, the law envisions that a drug would begin the process of being deselected from the program after such a generic or biosimilar competitor is approved and marketed.⁵⁸

The IRA's solicitude for the role of competition in driving down prescription drug prices goes even farther in the case of biosimilars. The statute contains a "special rule" that delays the selection and negotiation of a biologic drug if there is a "high likelihood" (as so defined)⁵⁹ that a biosimilar will be "licensed and marketed" in the next two years for that biologic drug. That is, a biologic drug may avoid selection for the negotiation program even where biosimilar competition is highly likely but has not yet occurred. To be sure, the IRA also specifies that the biosimilar delay rule cannot be invoked where a biologic has been approved for more than 16 years without biosimilar competition,⁶⁰ placing an outer limit on the use of such "likely" competition to delay a product's selection into the negotiation program.

Although the preceding analysis has focused on various legal reforms which are targeted at supporting the market entry of small-molecule generic and biosimilar versions of existing branded products, it is important to make clear that the approval and market entry of such products is necessary for but not sufficient to enable robust generic competition. The example of biosimilar competition as described above most vividly illustrates these dynamics. Even where biosimilars have been approved, they must be *covered* by insurance companies in order to have the ability to lower prescription drug prices. Physicians must further decide when to *prescribe* a particular drug or its competitors to their patients. Finally, pharmacists must *substitute* the relevant small-molecule generic or biosimilar for its branded reference drug. Although FDA is approving increasing numbers of biosimilars, they often struggle to gain insurance coverage, to be prescribed by physicians, or be substituted at the pharmacy counter.

Consider the example of Humira. In 2023, 20 years after Humira was first approved, nine Humira biosimilars entered the market.⁶¹ Yet a little over a year after the first Humira biosimilar

⁵⁴ 42 U.S.C. § 1320f-1(e)(1).

⁵⁵ *Id.*

⁵⁶ Food & Drug Admin., *Prescribing Label: Enbrel* (Sept. 12, 2024), https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/103795s5600lbl.pdf; Joshua P. Cohen, *Blockbuster Biologic Enbrel Will Continue As a Monopoly for Another 8 Years*, FORBES (May 22, 2021), <https://www.forbes.com/sites/joshuacohen/2021/05/22/blockbuster-biologic-enbrel-will-continue-as-a-monopoly-for-another-8-years/>.

⁵⁷ 42 U.S.C. § 1320f-1(e)(1).

⁵⁸ 42 U.S.C. § 1320f-1(c)(1).

⁵⁹ 42 U.S.C. § 1320f-1(f)(1)(A).

⁶⁰ *Id.*

⁶¹ Fraiser Kansteiner, *As Humira Biosim Sales Languish, Boehringer Ingelheim Plots Layoffs in Pivot to Hybrid Marketing Model*, FIERCE PHARMA (April 5, 2024), <https://www.fiercepharma.com/pharma/humira-biosimilar-revenues-languish-boehringer-ingelheim-plots-layoffs-pivot-hybrid-sales>.

entered the market, biosimilars had captured just 4% of the market,⁶² compared with the more than 80% which would be expected for a small-molecule drug. Insurers often failed to cover the Humira biosimilars or did not preference them. For example, a study focusing on Medicare Part D plans as of January 2024 found that just over half of all Part D plans covered any of Humira's biosimilars. In other words, nearly half of plans covered only Humira.⁶³ Physicians often prescribed Humira rather than its biosimilars.⁶⁴ And pharmacists were limited in their ability to substitute biosimilar versions at the pharmacy counter when the brand was prescribed. In the context of small-molecule generics, by contrast, additional policy efforts over the 40 years since the passage of the Hatch-Waxman Act have largely addressed these issues of insurance coverage, physician prescribing, and pharmacy substitution. To be sure, more work is needed on these fronts. But the focus of the Hatch-Waxman Act and BPCIA are fundamentally on market entry.

III. PROTECTING THE ROLE OF INNOVATION

Critics of drug pricing reform often argue that such reform will jeopardize pharmaceutical innovation in the future. For example, the trade group PhRMA memorably argued that a 2019 drug price negotiation bill would bring “nuclear winter” for innovation.⁶⁵ Because the intended result of such reform would be to pay less for existing pharmaceuticals, the argument is that prescription drug manufacturers would be less willing to maintain existing levels of research and development funding going forward, with a potential outcome being that fewer drugs are brought to market. In keeping with these arguments, the Congressional Budget Office (CBO) estimated at the time the IRA was being debated that the law would result in 2 fewer drugs brought to market in the decade after its passage, 5 over the decade after that, and 8 over the decade after that, or approximately 1% of the 1,300 drugs CBO otherwise would have expected to be approved over the next 30 years.⁶⁶ For too long, the continued apocalyptic rhetoric from industry and other stakeholders has been successful in blocking even common-sense, bipartisan drug pricing reforms, and industry and others have reacted with arguments similar in tone regardless of the size of the pricing reform, the timing in the life cycle of a product when it would take effect, and which products it would most likely impact.

⁶² Samsung Bioepis, *Biosimilar Market Dynamics*: 5th Edition, Q2 2024, at 20 (April 2024), <https://www.samsungbioepis.com/upload/attach/SB+Biosimilar+Market+Report+Q2+2024.pdf>.

⁶³ Matthew J. Klebanoff et al., *Formulary Coverage of Brand-Name Adalimumab and Biosimilars Across Medicare Part D Plans*, 332 J. AM. MED. ASS'N 74, 74 (2024) (finding that 53.4% of plans covered biosimilars).

⁶⁴ Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167 (2016); U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON OVERSIGHT AND REFORM, DRUG PRICING INVESTIGATION: ABBVIE – HUMIRA AND IMBRUVICA, at 40-42 (May 2021), <https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/Committee%20on%20Oversight%20and%20Reform%20-%20AbbVie%20Staff%20Report.pdf>.

⁶⁵ Jonathan Gardner, *House Passes Drug Pricing Bill That Pharma Warned Would Bring “Nuclear Winter,”* BIOPHARMA DIVE (Dec. 12, 2019), <https://www.biopharmadive.com/news/house-approves-hr3-drug-pricing-bill-pharma/568966/>.

⁶⁶ Cong. Budget Office, *Estimated Budgetary Effects of Subtitle I of Reconciliation Recommendations for Prescription Drug Legislation, as Posted by the Senate Committee on Finance on July 6, 2022* (July 8, 2022), https://www.cbo.gov/system/files/2022-07/senSubtitle1_Finance.pdf. CBO's final post-enactment budgetary estimate, issued after the passage of the law and after the reconciliation procedure limited some of the law's impacts, reduced these numbers, estimating that the law would result in 1 fewer drug brought to market in the decade after its passage, 5 over the decade after that, and 7 over the decade after that. Cong. Budget Office, *Summary: Estimated Budgetary Effects of Public Law 117-169* (Sept 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

One critical and often overlooked aspect of this discussion relates to not just the amount, but the value of innovation. That is, a discussion of the impact on innovation of a bill or proposed regulatory change must consider the clinical value of the relevant innovation for patients and not merely the amount of it. What matters most is innovation that delivers new clinical value for patients — for example, a drug with a novel mechanism of action or one that meets an unmet medical need.⁶⁷ Critics who point only to analyses of the number of new drugs that might or might not come to market after a law's passage but who ignore whether those new drugs would provide real clinical value to patients miss this key element.⁶⁸

One example of this dynamic stems from the creation of Medicare Part D.⁶⁹ Economists analyzing the Part D program did find that it provided a large new financial subsidy for pharmaceutical companies and encouraged them to invest more in research on products with higher market share among senior citizens.⁷⁰ In other words, Congress' decision to provide seniors with a prescription drug plan served as a demand-side policy lever that increased rewards for pharmaceutical firms developing drugs which would be expected to have high market share under the new program.⁷¹ Economists also found, however, that most of the increased investment in the decade after Part D's creation was concentrated in disease classes with multiple existing treatments.⁷² Drug pricing reforms that would impact what Medicare pays for prescription drugs that it covers, for example, might have a greater impact on the development of me-too drugs or drugs with a number of existing therapeutic alternatives, not necessarily on first-in-class products.

More generally, the baseline of this discussion matters here. Whenever Congress or the executive branch proposes an action that might lower drug prices and improve access for beneficiaries, critics claim that it will destroy innovation.⁷³ But Congress has often passed laws that *expand* markets for industry, including through the creation of Medicare Part D or the Affordable Care Act. When those laws were being debated and passed, the primary discussion in Congress was framed around providing seniors or Americans with access to insurance that would allow them to pay for and access prescription drugs or health care more generally.⁷⁴ In other words, Congress did not appear to be motivated by providing large new innovation subsidies to the pharmaceutical industry through substantially expanding their potential markets in the United States. And yet, the significant expansion of markets for prescription drugs (and increased revenues for pharmaceutical manufacturers) was one effect of the passage of those laws. There is no reason to think that our current level or type of investment in innovation — driven by current patterns of insurance coverage and pricing across programs — was even chosen intentionally, let

⁶⁷ Rachel E. Sachs, Loren Adler, & Richard Frank, *A Holistic View of Innovation Incentives and Pharmaceutical Policy Reform*, 1 HEALTH AFFAIRS SCHOLAR 1, 1 (July 2023); Rachel E. Sachs & Austin B. Frakt, *Innovation-Innovation Tradeoffs in Drug Pricing*, 165 ANNALS OF INTERNAL MEDICINE 871, 871 (2016).

⁶⁸ Sachs & Frakt, *supra* note 67, at 871.

⁶⁹ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (creating the Medicare Part D program).

⁷⁰ Margaret E. Blume-Kohout & Neeraj Sood, *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development*, 97 J. PUB. ECON. 327, 327 (2013).

⁷¹ See generally, e.g., Mark A. Lemley, Lisa Larrimore Ouellette, & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 NYU L. REV. 75 (2020); Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J. L. & TECH. 153 (2016).

⁷² David Dranove, Craig Garthwaite, & Manuel Hermosilla, *Pharmaceutical Profits and the Social Value of Innovation* 2–3, 6–7 (Nat'l Bureau of Econ. Research, Working Paper No. 20212, 2014).

⁷³ Michael A. Carrier & Genevieve Tung, *The Industry That Cries Wolf: Pharma and Innovation*, STAT (Sept. 26, 2019), <https://www.statnews.com/2019/09/26/innovation-boy-cried-wolf-pharma-industry>.

⁷⁴ See generally Sachs, *supra* note 33.

alone represents an optimal innovation strategy. Congressional appreciation of the context for these innovation-based arguments is necessary to prevent these criticisms from becoming a one-way ratchet, in which prices and spending can only rise over time and cannot be reduced in any circumstances. This is especially concerning if the savings from those reductions would have been intended to be reinvested in additional benefits for Americans or seniors more specifically, as is true of the IRA.

The IRA provides a key illustration of these dynamics. The pharmaceutical industry and other critics of the law have continued to argue that the IRA's drug price negotiation program in particular will have harmful effects on innovation. But these critics have not considered the ways in which the IRA itself centers innovation. As I have previously argued with colleagues Dr. Richard Frank and Loren Adler, the IRA preserves "innovation *as a whole*, innovation in *certain classes of products*, and innovation specifically delivering *high value for patients*."⁷⁵

To identify a few specific examples (though there are others), Congress directed Medicare to consider as part of the IRA's negotiation process a range of factors which specifically relate to innovation and clinical value for patients. In the negotiation process, Medicare must consider a drug's clinical value — whether it "represents a therapeutic advance as compared to existing therapeutic alternatives," the drug's "comparative effectiveness" relative to its therapeutic alternatives, and whether the drug "address[es] unmet medical needs."⁷⁶ In implementing Congress' directive, Medicare has chosen to use these factors to determine and adjust their starting point for determining initial offers to manufacturers.⁷⁷ The manufacturer of a drug selected for the negotiation program that delivers additional clinical value for patients relative to existing treatments, for example, may be able to negotiate a higher price for that drug with Medicare, relative to a drug selected for the negotiation program that does not deliver such additional clinical value. Congress also instructed Medicare to consider the "research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped" those costs.⁷⁸ In implementing this statutory directive, Medicare has stated that "if a Primary Manufacturer has not recouped its R&D costs, [Medicare] may consider adjusting the preliminary price upward,"⁷⁹ reflecting the agency's solicitude for innovation incentives. Taken as a whole, the IRA's negotiation process has been constructed in a way that "should maintain strong financial incentives for manufacturers to develop new drugs that represent clinical improvements and to invest in the development of evidence to demonstrate those improvements."⁸⁰

Early empirical analyses of R&D investments after the passage of the IRA support this conclusion. Given the recency of the law, several analyses have begun to look at markers of early innovation activity, including mergers and acquisitions (M&A) and venture capital funding. One analysis of M&A found "little evidence suggesting a disruption in activities and investments that will yield new pharmaceutical products in the years to come," including "for the number of M&A deals being pursued, the total dollars being spent on M&A, and importantly, the types of products

⁷⁵ Sachs, Adler, & Frank, *supra* note 67.

⁷⁶ 42 U.S.C. § 1320f-3(e)(2).

⁷⁷ Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027*, at Section 60.3 (Oct. 2, 2024), <https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>.

⁷⁸ *Id.* at § 1320f-3(e)(1).

⁷⁹ Ctrs. for Medicare & Medicaid Servs., *supra* note 77, at 259.

⁸⁰ Sachs, Adler, & Frank, *supra* note 67.

involved in M&A actions including early stage (small molecule drugs) and products that serve older adults.”⁸¹ Two analyses of venture capital investments — one by CBO and one by independent academic researchers — similarly found “no evidence of a systematic decrease in the percentage of venture capital flowing to pharmaceutical companies after August 2022 — or in the period immediately preceding the law’s enactment.”⁸² To be sure, there may be reasons why potential negative impacts of the IRA would not be observable in data like these. But it is also possible that “the IRA will not have the adverse consequences some of the discourse around it suggests or that the law’s effects will not manifest as changes in investment levels, but rather changes in investment allocation across drug development projects.”⁸³ Analyses using historical data similarly suggest that the IRA “will not likely result in large-scale defunding of research and development.”⁸⁴ It will be critical to assess the impact of the IRA on a range of innovation outcomes — for example, experts have also highlighted the potential for the law to affect the ways in which manufacturers of oncology products seek to sequence clinical trials for new indications for those products.⁸⁵ But at least at this time, the apocalyptic projections of many industry pundits do not appear to be on the horizon.

Many critics argue that innovation will be harmed no matter what the potential drug pricing reform is. Former Health and Human Services Secretary Alex Azar, himself a former pharmaceutical company executive, has referred to this as a “tired talking point.”⁸⁶ It’s just not the case, he said, that “if one penny disappears from pharma profit margins, American innovation will grind to a halt.”⁸⁷ Going forward, both this Committee and others must critically evaluate these types of claims in context.

IV. AREAS FOR LEGISLATIVE FOCUS

Congress in general — and this Committee in particular — ought to consider legislative interventions with the goal of improving prescription drug competition. To date, much of the work of this Committee has focused on the approval of both new drugs and their potential generic and biosimilar competitors, to the extent that PTO and patent law more generally play key institutional and doctrinal roles. Additional work remains to be done on this front, particularly as it relates to biosimilar approval, but necessary legislative and regulatory intervention goes beyond the context

⁸¹ Richard G. Frank & Ro W. Huang, *Early Claims and M&A Behavior Following Enactment of the Drug Provisions in the IRA*, BROOKINGS (Aug. 23, 2023), <https://www.brookings.edu/articles/early-claims-and-ma-behavior-following-enactment-of-the-drug-provisions-in-the-ira/>.

⁸² Cong. Budget Office, *Letter Re: Additional Information About Drug Price Negotiation and CBO’s Simulation Model of Drug Development*, at 4-5 (Dec. 21, 2023), <https://www.cbo.gov/system/files/2023-12/59792-Letter.pdf>; Matthew Vogel, Rena M. Conti, & Amitabh Chandra, *Biopharma Venture Capital And The Inflation Reduction Act*, HEALTH AFFAIRS FOREFRONT (March 5, 2024), <https://www.healthaffairs.org/content/forefront/biopharma-venture-capital-and-inflation-reduction-act>.

⁸³ Vogel, Conti, & Chandra, *supra*.

⁸⁴ Matthew Vogel, Pragya Kakani, Amitabh Chandra, & Rena M. Conti, *Medicare Price Negotiation and Pharmaceutical Innovation Following the Inflation Reduction Act*, 42 NATURE BIOTECH. 406, 406 (2024).

⁸⁵ Stacie B. Dusetzina & Frank S. David, *Cancer Drug Access and Innovation Under the Inflation Reduction Act—A Balancing Act*, J. AM MED. ASS’N ONCOLOGY (Oct. 24, 2024).

⁸⁶ Carolyn Y. Johnson, *Trump’s Big Campaign Promise on Drug Prices Wouldn’t Have Worked, Health and Human Services Secretary Says*, WASH. POST. (May 14, 2018), <https://www.washingtonpost.com/news/wnk/wp/2018/05/14/trumps-big-campaign-promise-on-drug-prices-wouldnt-have-worked-health-and-human-services-secretary-says/>.

⁸⁷ Alison Kodjak, *Trump Administration’s 3 Biggest Ideas For Lowering Drug Prices*, NAT’L PUB. RADIO (May 14, 2018), <https://www.npr.org/sections/health-shots/2018/05/14/611075950/trump-administrations-3-biggest-ideas-for-lowering-drug-prices>.

of approval. For example, as articulated above, biosimilars must not only be approved, but also covered by insurance companies, prescribed by physicians, and substituted by pharmacists for their branded reference drug. Legislative and regulatory intervention at each of these stages — particularly at the often-overlooked stages of coverage and prescription — are likely to be essential to more thoroughly establish robust competition in the prescription drug marketplace. Many of the below-described policy categories have elements that fall within the jurisdiction of this Committee, but some may require additional support from other Committees.

A. APPROVAL

The Hatch-Waxman Act and the BPCIA provide the foundation for approval of generic and biosimilar versions of branded prescription drugs. However, more work can be done — particularly in the context of biosimilar products — to respond to efforts by branded drug manufacturers to extend their monopoly periods and discourage generic or biosimilar entry. Much of this work would be squarely within the substantive jurisdiction of this committee. Bills including the Interagency Patent Coordination and Improvement Act of 2023,⁸⁸ Preserve Access to Affordable Generics and Biosimilars Act,⁸⁹ Stop STALLING Act,⁹⁰ and Affordable Prescriptions for Patients Act of 2023⁹¹ are all intended to help promote such market entry.

Recent actions by the Federal Trade Commission challenging over 400 patents allegedly improperly or inaccurately listed in the Orange Book would also fall into this category,⁹² as “[b]y listing patents [in the Orange Book], brand drug manufacturers may benefit from a 30-month stay of FDA approval of generic drug applications, regardless of whether a court ultimately finds the patent at issue is valid or infringed by the competing product.”⁹³ The Committee might seek to support the Commission’s activities in this area.

B. COVERAGE

Even where a generic or biosimilar competitor has been approved, insurance companies must decide both *whether* and, if so, *how* to provide coverage for that competitor. As noted above, in the context of many biosimilar products, insurers have been slow to cover lower-priced versions of branded biological products. Many of these decisions by insurers regarding which products to cover on their formularies will be mediated through insurers’ relationships with pharmacy benefit managers (PBMs). PBMs negotiate with pharmaceutical companies on insurers’ behalf and play a role in deciding which drugs will be covered by insurers, and in theory PBMs work to obtain

⁸⁸ S. 79, 118th Cong., <https://www.congress.gov/bills/118/congress/senate-bill/79>.

⁸⁹ S. 142, 118th Cong., <https://www.congress.gov/bills/118/congress/senate-bill/142>.

⁹⁰ S. 148, 118th Cong., <https://www.congress.gov/bills/118/congress/senate-bill/148>.

⁹¹ S. 150, 118th Cong., <https://www.congress.gov/bills/118/congress/senate-bill/150>.

⁹² Federal Trade Comm’n, *FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs* (April 30, 2024), <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>.

⁹³ FEDERAL TRADE COMM’N, FEDERAL TRADE COMMISSION STATEMENT CONCERNING BRAND DRUG MANUFACTURERS’ IMPROPER LISTING OF PATENTS IN THE ORANGE BOOK, at 1 (Sept. 14, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf.

pricing discounts for those insurers.⁹⁴ A PBM might, for example, negotiate a preferred formulary placement for a particular drug in exchange for the manufacturer offering a discount on that drug.⁹⁵

In practice, PBMs have been increasingly criticized for “steer[ing] patients toward pricier drugs, charg[ing] steep markups on what would otherwise be inexpensive medicines and extract[ing] billions of dollars in hidden fees.”⁹⁶ A recent Federal Trade Commission report documented the ways in which PBMs sometimes “negotiate prescription drug rebates that are expressly conditioned on limiting access to potentially lower cost generic alternatives.”⁹⁷ Both the Federal Trade Commission and several state attorneys general have now sued the nation’s largest PBMs over their conduct in the market for insulin, alleging that the PBMs’ business practices preferenced high list price products over lower list price products, and that doing so harmed both competition and patients.⁹⁸ This Committee should consider to what extent elements of PBM reform might be implemented through its jurisdiction, including through support for the Commission’s lawsuit against the PBMs.

C. PRESCRIPTION

At present, in the case of biosimilar versions of branded biological products, approval and coverage are not enough. For non-interchangeable biosimilars, physicians must also decide when to prescribe a particular drug or its competitors to their patients. This Committee might work collaboratively with other Committees to encourage the prescribing of lower-cost products where they exist, either through legislation that would influence physicians themselves or that would influence insurers’ relationships with physicians. For example, many experts have previously argued for reform of the existing payment system for prescription drugs within Medicare Part B, arguing that the existing system “can create incentives for some providers to choose higher-priced products over lower-priced products.”⁹⁹ Some physician-centered reforms to the Part B average sales price-based payment structure might move toward a flat fee reimbursement structure,¹⁰⁰

⁹⁴ Robin Feldman, *The Devil in the Tiers*, 8 J.L. & BIOSCIENCES 1, 10 (2021).

⁹⁵ *Id.* at 12.

⁹⁶ Rebecca Robbins & Reed Abelson, *The Opaque Industry Secretly Inflating Prices for Prescription Drugs*, N.Y. TIMES (June 21, 2024), <https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html>.

⁹⁷ FEDERAL TRADE COMM’N, PHARMACY BENEFIT MANAGERS: THE POWERFUL MIDDLEMEN INFLATING DRUG COSTS AND SQUEEZING MAIN STREET PHARMACIES – INTERIM STAFF REPORT at 4 (July 2024).

⁹⁸ Fed. Trade Comm’n, *FTC Sues Prescription Drug Middlemen for Artificially Inflating Insulin Drug Prices* (Sept. 20, 2024), <https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-sues-prescription-drug-middlemen-artificially-inflating-insulin-drug-prices>; Benjamin Ryan, *California Joins Other States in Suing Companies Over Insulin Prices*, N.Y. TIMES (Jan. 18, 2023), <https://www.nytimes.com/2023/01/18/health/insulin-drug-prices-california.html>; Casey Smith, *Indiana AG Todd Rokita Files Lawsuit Against Drug Companies, PBMs Over Inflated Insulin Prices*, INDIANA CAPITAL CHRON. (March 20, 2024), <https://indianacapitalchronicle.com/2024/03/20/indiana-ag-todd-rokita-files-lawsuit-against-drug-companies-pbms-over-inflated-insulin-prices/>; Emily Olsen, *Texas Sues Major PBMs, Pharma Companies Over High Insulin Prices*, HEALTHCARE DIVE (Oct. 4, 2024), <https://www.healthcaredive.com/news/texas-pharmacy-benefit-manager-pharma-company-lawsuit-insulin-prices/728937/>.

⁹⁹ See, e.g., MEDICARE PAYMENT ADVISORY COMMISSION, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM at 32 (June 2023).

¹⁰⁰ See, e.g., MEDICARE PAYMENT ADVISORY COMMISSION, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM at 62 (June 2015) (presenting “two policy options that convert part or all of the 6 percent add-on to a flat fee add-on”).

while others would pursue reforms at the level of the institution or insurer, such as Medicare's Accountable Care Organization program.¹⁰¹

D. SUBSTITUTION

Finally, increasing pharmacists' ability to substitute a small-molecule generic or biosimilar product for its branded reference drug is critical to ensuring patient access to these products. While state generic substitution laws are robust, current state laws regarding biosimilar substitution typically only permit pharmacists to substitute a biosimilar for its branded reference biologic where the biosimilar has been deemed "interchangeable" by FDA.¹⁰² To date, most of the approved biosimilars lack the interchangeable designation, limiting their ability to gain market share.¹⁰³

FDA has more recently, however, published research finding "no difference in the safety profiles" of patients who "switched" between a biologic and an approved biosimilar product,¹⁰⁴ including but not limited to those without the "interchangeable" designation.¹⁰⁵ Following from the conclusions of this research,¹⁰⁶ in June 2024 FDA issued draft guidance proposing that manufacturers may attempt to demonstrate interchangeability without requiring a fully separate switching study.¹⁰⁷ FDA has even asked Congress to "eliminate the statutory distinction between the approval standard for biosimilar and interchangeable biosimilar products and deem that approved biosimilars are interchangeable,"¹⁰⁸ though Congress has not yet done so. In light of this research and FDA's scientific findings, this Committee might support efforts to alter state biosimilar prescribing statutes to permit biosimilar substitution even where FDA has not specifically determined that a biosimilar is "interchangeable" and might support efforts by other Committees regarding the existence of the "interchangeable" designation, as FDA has argued.

V. CONCLUSION

This Committee has the ability to help promote access to affordable prescription drugs through the creation of robust competition by generic and biosimilar products, benefiting not only patients but also our public payers. In considering potential avenues for reform, this Committee should consider reforms that not only help promote the FDA approval of competitive generics and

¹⁰¹ See, e.g., Melissa Morley, Biruk Bekele, & Gabriel Sullivan, *Comparing Part B and D Treatment Patterns of ACO and Non-ACO Providers*, AVALERE (Oct. 22, 2020), <https://avalere.com/insights/comparing-part-b-and-d-treatment-patterns-of-aco-and-non-aco-providers>.

¹⁰² Sacks et al., *supra* note 39, at 17, 18.

¹⁰³ Kevin Noonan, *FDA Approves Three Interchangeable Biosimilar Drugs in 2024*, PATENT DOCS (March 11, 2024), <https://www.jdsupra.com/legalnews/fda-approves-three-interchangeable-3811961/> (noting that at the time, FDA had approved 48 biosimilars, just 10 of which were interchangeable).

¹⁰⁴ Thomas M. Herndon et al., *Safety Outcomes When Switching Between Biosimilars and Reference Biologics: A Systematic Review and Meta-Analysis*, 18 PLoS ONE 1, 1 (2023).

¹⁰⁵ *Id.* at 3.

¹⁰⁶ *Id.* at 11 ("The findings reported here support reducing the regulatory burden of switching studies as the default approach for addressing the switching standard for the interchangeable designation.").

¹⁰⁷ Food & Drug Admin., *Considerations in Demonstrating Interchangeability With a Reference Product: Update*, at 7 (June 2024), <https://www.fda.gov/media/179456/download>. The effect of this position on agency approvals of interchangeable biosimilars remains to be seen.

¹⁰⁸ Food & Drug Admin., *FY25 Legislative Proposals*, at 2 (2024), <https://www.fda.gov/media/176924/download>. As FDA notes, this standard would be "more consistent with... the approach adopted by other major regulatory jurisdictions such as the European Union." *Id.*

biosimilars, but that also ensure access to these lower-cost products through insurance coverage, physician prescription, and pharmacy substitution. Chair Durbin, Ranking Member Graham, and Members of the Committee, I am appreciative of your focus on this important issue and I thank you for the opportunity to testify before you today. I look forward to answering your questions.

Senate Judiciary Committee Testimony - October 29, 2024

As a pharmacist, I have had countless discussions with patients at the pharmacy counter about their prescription drug costs. It is never an easy task to explain to a retired teacher, a grandma, or a neighbor that their prescription copay will be over \$600 simply because it is a new year or that their prescription that was \$47.00 dollars last month is now \$260, because they are in the Medicare coverage gap.

For the last 5-10 years, I have been having these conversations with my patients all too frequently as the cost of prescription drugs have far outpaced inflation. These conversations often lead to patients leaving prescriptions behind or rationing previously filled prescriptions solely due to the excessively high costs. At the beginning of each year, I see patients delaying medication refills because of the high Medicare Part D deductible. As the year progresses and patients begin to enter the Medicare Part D coverage gap, we often see patients stop filling their most expensive prescriptions for the remainder of the year.

These conversations just became disheartening to our patients and were burning out myself and my dedicated pharmacy staff. So, we set out to try and avoid these conversations all together. Even before the patient arrives at the pharmacy counter, my staff and I explore ways to reduce our patients costs and bridge these coverage gaps. We want to ensure that the patient leaves the pharmacy with the prescribed medication or a therapeutically equivalent medication in their hands. Being a part of a critical access hospital, affords my staff the time to advocate for our patients and more closely work with providers, nurses, social workers, and medical assistants to overcome these financial barriers. It often takes the entire healthcare team, across multiple departments, to connect patients with manufacturer samples, find a free trial coupon, enroll patients in a prescription assistance program, explore opportunities through the 340B Drug Savings Program, and if all else fails paying for a patient's copay out of our own pockets.

Since the passage of the Inflation Reduction Act, our patients have certainly benefited directly at the pharmacy counter. This legislation has drastically improved the financial stability of many of my elderly patients who are almost all living on a fixed income. I am reminded of a type-1 diabetic farmer that was spending nearly \$7,500 a year solely on insulin copays prior to turning 65 in 2022. He now spends less than \$900 annually because of the \$35 per month cap on the copays for Novolog and Lantus that he is prescribed.

Another way we have helped reduce our patients' prescription expenses is by counseling them on selecting the right Medicare Part D plans each year. Unfortunately, the open enrollment period has typically led to me explaining ever increasing prescriptions costs and patients becoming increasingly worried about their household budgets. However, this open enrollment period has led to entirely different feelings for my patients. I am looking forward to showing them their 2025 plan comparisons, because more out of pocket savings will be rolled out to all patients, not just those dependent on insulin. Last week, I counseled an eighty-four year-old retired home healthcare aide suffering from heart disease and Type 2 diabetes. She takes 13 prescription medications including Entresto, Xarelto, Victoza, Praluent, and Jardiance. She will see her out of pocket costs fall from over \$7,000 in 2024 to only \$2,000 dollars in 2025. These

are life-changing savings for many of my patients and my staff and I can focus on the more clinical aspects of our profession.

The Inflation Reduction Act not only has helped reduce prescription drug expenses, but has also had a dramatic effect on one of the most important medication classes we have in our toolkit today, vaccines. At Iroquois Memorial Hospital, the pharmacy staff helps lead our vaccination program across many care areas including long-term care residents, patients of our rural health clinics, and acute care patients. The expansion of coverage for many recommended adult vaccinations including shingles, RSV, and COVID-19 has undoubtedly led to increased vaccination rates among our patients. Two years ago, nearly all patients interested in receiving the 2 dose shingles vaccine series first inquired about the cost, before we ever discussed the effectiveness or potential side effects. Unfortunately, a large percentage of patients would decline receiving the vaccine when they discovered their out of pocket costs were nearly \$400 for the series. Today, these vaccines are fully covered for Medicare beneficiaries and the conversations I have with patients are centered around the importance of receiving the vaccines, instead of the cost.

Although current legislation has led to significant reductions in the price of prescription medications to a large segment of the US population, there is still more work to be done. I see an ever increasing need to legislate meaningful cost reductions for all patients in the United States, especially those working class Americans with employer sponsored health insurance. As we see type 2 diabetes and heart disease diagnosed in patients in their 20s and 30s, it is increasingly important to ensure these patients and their families can afford to treat these diseases effectively for decades and during their most productive years.

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A P P E N D I X

The following submissions are available at:

<https://www.govinfo.gov/content/pkg/CHRG-118shrg61373/pdf/CHRG-118shrg61373-add1.pdf>

Submitted by Chair Durbin:

Patients For Affordable Drugs NOW, letter	2
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